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Gonzenbach, Derek L. ***Setup Time Reduction of Medical Device Assembly Process and the application of single minute exchange of dies (SMED) concepts***

Abstract

The purpose of this field research project was to examine the current state of the complete changeover process between a 0.15 mg and 0.3 mg product configuration for both identical manufacturing lines A and B, implement SMED tool, and develop a new changeover system to allow for future reduction of the overall setup time by 50%. Reduction of time between changeovers increased the ability of Phillips Medical to be more efficient, flexible, and adaptive to future customer demand.

In order complete this study, an examination of the current state of changeovers on line A and line B was conducted. Upon examination of the current state, the changeover operations conducted at each station was identified as internal and external setup operations. The examination allowed for an understanding of which operations could be performed when the assembly line is manufacturing assemblies or when the individual stations are idle between assembly lots. Once the setup operations were identified each individual operation was optimized or eliminated through streamlining and standardization methods. The future state changeover process includes new standardized instructions for all operators and technicians to reference during each changeover process. The training and instructions ensure equal instruction and transfer of training for the future state changeover assessment.

According to the results of the former/previous assessments of changeovers, the new changeover system and SMED implementations indicate the potential of an overall reduction of 73% for a 0.15mg Generic to a 0.3mg Generic configuration changeover and a reduction of 75% in overall changeover time for 0.15mg Generic to a 0.3mg Generic configuration.

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Table of Contents

List of Tables

Chapter I: Introduction

The progressive medical device manufacturing industry is constantly changing as the needs of patients and technological advancements transform on a daily basis. High quality expectations from customer and governmental agencies add to the already complex and extremely competitive market (Duggan, 2007; Kuntz, 2007). It is common for companies to implement continuous improvement projects to ensure their company's prosperity and future. Continuous improvement efforts, otherwise referred to as kaizen events, focus on the common objective of increasing the overall efficiency and effectiveness of a process (Santos, Torres, & Wysk, 2006).

In order for manufacturing facilities to remain profitable they must meet their customer's ever changing needs. The principles of lean manufacturing allow for increased flexibility regarding order sizes and quantities. When quantifying the time spent on individual process steps on an annual basis the reduction of setup time can substantially impact the ability to serve the customer and optimize resource utilization. Lean practices such as the elimination of unneeded processes, actions, and activities are applicable to processes business wide. In order to prove the effectiveness of a process an evaluation is necessary. The evaluation of the current state of a process shows where improvements and opportunities exist regarding reducing setup time and waste (Rubrich & Watson, 2004).

Within the past year, Phillips Medical has undergone a full validation of an additional identical assembly line, multiple new product configurations, and a nearly doubled demand for 2011. In accordance with Phillips Medical validation procedures the additional assembly line, a new product platform launch, and customer demand increase involves new setup, documentation, and process requirements. According to the current assembly processing data from Phillips

Medical located in Menomonie, Wisconsin a complete changeover takes 3 to 4 hours. The current assembly line throughput is 350 finished assemblies per hour, which equates to a potential output of 1,050 – 1,400 assemblies that are lost during 3 to 4 hours of down time during a changeover. This study examined the current state of the complete changeover process which indicated areas where tools and implementations can be introduced to reduce overall setup time.

Statement of the Problem

The former state of a complete changeover in an assembly process between the 0.15 mg and 0.3 mg product configuration was very time consuming taking anywhere from 3 to 4 hours. Manufacturing line A and line B, which are examined in this study, produce a completed assembly that contains a pharmaceutical product. The assembled drug product is shelf life sensitive; therefore timely batch turns and setup time optimization is critical in regards to the overall finished product delivery to the customer.

Purpose of the Study

The purpose of this study was to examine the current state of the complete changeover process between a 0.15 mg and 0.3 mg product configuration for both identical Manufacturing lines A and line B and implement process improvements to reduce setup time, referred as SMED tools and develop a new changeover system to allow for future reduction of the overall setup time by 50%. Reducing the overall setup time by 50% would equate to roughly $4000 of additional assemblies shipped per month. It would increase the ability of Phillips Medical to be more efficient, flexible, and adaptive to future customer demand.

Assumptions of the Study

1. All of the assembly operators of Phillips Medical are aware of the study and we will be willing to participate in the study.

2. The setup reduction time tools will be in compliance to Title 21 CFR 210 and 211 regulations and requirements. Title 21 is The Code of Federal Regulations for Food and Drugs. Parts 210 and 211 regard the cGMP (Current Good Manufacturing Practice Regulations) in manufacturing, processing, packing, or holding of Drugs and finished pharmaceuticals (FDA, 2005).
3. Participants of the study will not deviate from normal setup practices during the study.
4. Management and employees will be supportive of the purpose of the study and will cooperate to the best of their ability and provide accurate data for this examination.
5. The changeover tools will contribute to error reduction as operators will be trained and the changeover process will be more standardized and controlled.

Definition of Terms

Baseline. An understanding of a facility's knowledge, understanding, and capability regarding any training or improvement activity (Rubrich & Watson, 2004).

Benchmarking. Developing an understanding of a facilities knowledge, understanding, and capability regarding any training or improvement activity (Rubrich & Watson, 2004).

cGMP. Current Good Manufacturing Practices (FDA, 2005).

CFR- Code of Federal Regulations (FDA, 2005).

Continuous improvement. The relentless challenge of the status quo with the regard to the elimination of waste and customer satisfaction, which is also known as Kaizen process (Rubrich & Watson, 2004).

Defects. Irregular products that interfere with productivity, stopping the flow of high quality products (Santos, Torres, & Wysk, 2006).

External setup operations. Setup operations that can be performed while the machine or process is still running, such as transporting materials or parts (Shingo, 1981/1989).

ICS. Phillips Medical acronym which stands for Inventory Control Specialist

Inactivities. Machines with idle time or operators with idle time. (Santos, Torres, & Wysk, 2006).

Internal setup operations. Setup operations that can be performed only when a machine or process is stopped, such as removing dies (Shingo, 1981/1989).

Inventory. Material stored as raw material, work-in-progress (WIP), and final products (Santos, Torres, & Wysk, 2006).

Just in time manufacturing (JIT). The manufacturing philosophy of producing only what a customer needs and only when they need it. (Rubrich & Watson, 2004).

Kaizen. A Japanese word that means to change for the good (Rubrich & Watson, 2004).

Kaizen tools. Continuous improvement tools (Santos, Torres, & Wysk, 2006).

KPI. A "key performance indicator" is a measurement that strongly supports and facilitates achieving a critical goal of the organization (Vorne, 2007).

Lead time. A productivity metric that consists of the period of time between the start of any process of production and the completion of a process. (Santos, Torres, & Wysk, 2006).

Lean manufacturing. The systematic elimination of waste (Santos, Torres, & Wysk, 2006).

Operations. The discrete stage at which a worker may work on different products, that is, a human temporal and spatial flow that consistently centers around the worker (Robinson, 1990).

Overproduction. Producing unnecessary products when they are not needed and in greater quantities than required (Santos, Torres, & Wysk, 2006).

Parallel operations. The strategy of dividing setup operations between two setup operators to reduce the overall amount of time to complete each setup operation (Santos, Torres, & Wysk, 2006).

Phillips Medical. Medical Molding and Assembly Operation Facility owned by Phillips Plastics Corporation located in Menomonie, WI.

Poka Yoke. A Japanese word that means art of error-proofing operations (Robinson, 1990)

Processes. Tasks accepted as necessary to complete production process (Santos, Torres, & Wysk, 2006).

PST/PSS. Phillips Medical acronym which stands for production support technician

QT. Phillips Medical acronym which stands for quality technician

Setup reduction. Techniques which reduce the elapsed time required to changeover a machine from manufacturing part "A" to part "B" (Rubrich & Watson, 2004).

SMED. "Single minute exchange of dies." A comprehensive methodology that has often reduced setup times which took hours to less than ten minutes (Robinson, 1990).

Spaghetti diagram. The visual examination and mapping of the distance traveled and the number of stops during a process (Carreira, 2005).

Takt time. The available production time divided by the rate of the customer demand (Womack & Jones, 1996).

TPS. Toyota production system (Santos, Torres, & Wysk, 2006).

Transportation. Material handling between internal sections (Santos, Torres, & Wysk, 2006).

Value stream mapping. The methodology of examining and creating a picture of all the contributing processes that occur in a company beginning with a customer order to when the customer receives the product (Rubrich & Watson, 2004).

Waste. Anything other than the minimum amount of people, time, equipment, material, part, and space required to add value to the product (Rubrich & Watson, 2004).

WIP. Work in progress (Rubrich & Watson, 2004).

5S. Keys to workplace organization and housekeeping (Rubrich & Watson, 2004).

Limitations of the Study

1. This study is limited to Phillips Medical white room assembly processes.
2. The study is focused on only setup time reduction.
3. The participants would have completed the PST (production support technician) or QT (quality technician) training within the past year

Methodology

In the evaluation of the current state of the changeover process at Phillips Medical on assembly line A and line B, the single minute exchange of dies (SMED) methodology was applied with the objective to streamline the setup process and reduce the overall time that is required to conduct a complete changeover in the future. The study will consisted of six main steps which are derived from SMED methodology (Shingo, 1983/1985). The first step was the evaluation of the current state of a complete changeover on manufacturing line A and line B. The evaluation included identifying all the individual setup activities and performing a time study to evaluate the total length of time it takes for each corresponding activity. The second

step consisted of the determination of the internal and external setup processes. This consisted of classifying each individual task from step one and categorizing them into internal and external processes. Step three consisted of trying to convert internal and external processes. The conversion of internal and external processes consisted of reexamining operations and determining ways to convert internal processes to external processes. Step four consisted of streamlining both external and internal processes at each individual assembly station. Step five consisted of standardization of both internal and external processes. Lastly, step six is testing of all of the implementations. Similarly to step one, the future testing would include a time study that will evaluate the total length it takes for a complete change over after streamlining and standardization.

Summary

With the recent validation of an additional identical assembly line and a nearly doubled demand for 2011, the six steps of the SMED methodology were applied to the current state of the changeover process to reduce the overall time of complete changeover in an assembly process in the white room at Phillips Medical. The objective of implementing the SMED tools and implementations is to implement SMED concepts to allow for a future reduction in the overall setup time by 50%. This reduction in overall setup time will allow Phillips Medical to be more efficient, flexible, and adaptive to future customer demand.

Chapter II: Literature Review

The development of continuous improvement and lean manufacturing strategies in manufacturing became prominent in the United States manufacturing industry during the revolution of modern industrial techniques in the early twentieth century (Santos, Torres, & Wysk, 2006). Lean concepts were applied even as far back as the early mass production times of Ford. Lean manufacturing is defined as the application and identification of most efficient manufacturing practices that will eliminate waste and process variation (Ford, 1926; Herron, 2007; Ohno, 1978/1988; Womack & Jones, 1996). This literature review will cover topics such as the history of lean thinking, synergy of lean manufacturing and single minute exchange of dies (SMED) principles, lean manufacturing and waste elimination, waste elimination and setup reduction with SMED implementation, SMED application in industry, identification of internal and external setup operations, the standardization from SMED implementation, the transfer and training of SMED implementation, and organizational improvements and customer focus with SMED Implementation.

Lean Manufacturing and SMED Principles

As the manufacturing markets became more competitive and the success of firms became more transparent in the early 1900's businesses around the globe were in pursuit of manufacturing excellence and waste elimination, or later known as lean thinking. According to Womack & Jones (1996):

> Lean thinking can be summarized in five principles: precisely specify value by specific product, identify the value stream for each product, make value flow without interruptions, let customer pull value from the producer, and pursue perfection. (p. 10)

Continuous improvement or the consistent change in processes for overall process improvement was adopted by Taiichi Ohno post World War II. While at Toyoda Gosei, Ohno benchmarked the original and successful improvement efforts of Henry Ford's manufacturing strategies. Henry Ford, a sponsor of mass production, focused on waste elimination in mass production in the early 1900's in the US (Ford, 1926; Ohno, 1978/1988; Rubrich & Watson, 2004). According to Shingo (1987/1988) "The Ford System seems to be an improvement of processes and not merely of operations" (p. 386). The Japanese collaborative focus on waste elimination and continuous improvement efforts lead to the development of the Toyota production system and just-in-time production strategy. Through years of improvements and implementation the pioneering managers at Toyota, such as Ohno and Shingo, substantially improved upon the methods with the intent to be better than the global competition (Rubrich & Watson, 2004; Womack & Jones, 1996). Ohno updated the original methods benchmarked from Ford, yet additionally he focused on excess capacity. The reduction in waste in existing capacity allows for less hesitation in new costs associated with business development and increased competition (Ohno, 1978/1988).

The implicit operating rules of the Toyota Production System (TPS) and its methodologies lead to lean tools such as just in time (JIT), SMED (single minute exchange of die), and Kaizen events (Herron, 2007; Ohno, 1978/1988). The primary objective of lean tools was to increase operational efficiency and facilitate smooth production flow; however that could only be achieved if machine changeovers were drastically reduced (Goddart, 1986; Rubrich & Watson, 2004; Womack & Jones, 1996).

In the early 1950's Toyota recognized the need for rapid changeovers of their large dies. With the motivation from Ohno and the TPS principles, Shigeo Shingo introduced the single

minute exchange of dies methodology, which focused on the examination and optimization of overall setup operations. The single minute exchange of dies methodology refined and developed over a period of nineteen years. SMED implementations allows for reduction in changeover activities that would normally take hours to single digit minutes (King, 2009; Ohno, 1978/1988, Shingo, 1983/1985).

Waste Elimination and Setup Time Reduction with SMED Implementation

The utilization of lean tools allows for the elimination of non-value added activities or waste with the objective of making companies more profitable and efficient (Ford, 1926; Herron, 2007; Ohno, 1978/1988). Hiroyuko Hirano defined waste as "everything that is not absolutely essential" (Santos, Torres, & Wysk, 2006). Shigeo Shingo, a leading expert in Toyota production system (TPS), identified seven common wastes in manufacturing operations which include: overproduction, inventory, transportation, defects, processes, operations, and inactivites (Santos, Torres, & Wysk, 2006; Shingo, 1987/1988). In agreement with the previously mentioned seven common wastes, Rubrich and Watson (2004) also include underutilized human resources as the eighth waste in a manufacturing operation. There is high emphasis on equipment and hardware assets, however people as a resource are rarely included as an eighth common waste.

The waste of overproduction occurs when the quantity of goods produced is more than the quantity of goods which are actually sold. This form of waste can be greatly reduced by efforts that reduce lead time. Reducing lead time increases the overall capacity for future orders and customer demand (Goddart, 1986; Robinson, 1990; Shingo, 1983/1985). Waiting or delay in the setup process ultimately affects the customer as they must wait longer for the end product. An examination, such as a time and motion study, allows for the understanding of where

improvement is needed in a setup process. The elimination of unneeded waiting time will allow for more throughput and opportunity to be more competitive to meet the customer's needs in a timely matter (Birmingham & Jelinek, 2007; Goddart, 1986; Shingo, 1983/1985). Idle time and waiting is another common form of waste. Idle time can be caused by waiting for material deliveries, inspection, waiting for information, and waiting for equipment cycle time (Carreira, 2005; Shingo, 1987/1988).

Transportation is also a common waste in the manufacturing value stream. Transportation consists of moving material by hand, truck, or conveying equipment (Ford, 1926; Rubrich & Watson, 2004; Shingo, 1987/1988). According to Ohno (1978/1988) "Regardless of how much workers move, it does not mean work has been done" (p.125). Transportation wastes can be examined through time and motion studies to determine improvement areas and best practices to complete tasks regarding movement (Ford, 1922; Robinson, 1990). A common time and motion tool is a spaghetti diagram. A spaghetti diagram is the visual examination and mapping of the distance traveled and the number of stops during a process (Carreira, 2005; Womack & Jones, 1996).

Correspondingly, waste can be in the form of defective products or processes. In the instance when defects are produced, a company will experience loss of time to correct the problem, which directly affects the throughput to the customer and leads to less profitability (Robinson, 1990, Shingo, 1987/1988). According to Juran and Godfrey (1999), "An important element of manufacturing planning is the concept of designing the process to be error free through error proofing" (p. 22.24). Understanding the potential for errors and defects and ensuring that the defect will never occur again can be achieved by means of error proofing or poka-yoke. Such methods are commonly used in manufacturing (Robinson, 1990).

Rubrich and Watson (2004) indicate that underutilized human resources are also a common form of waste. This waste occurs when there is a lack of involvement and participation in value added activities. Human resources have a direct affect on the overall profitability of the company; therefore human personnel should be trained and utilized to their potential to add value to the process, company, and customer (Rubrich & Watson, 2004). A creative method to increase employee utilization is to allow for employees to conduct parallel operations which will significantly reduce the amount of time to complete an entire operation such as a changeover (Birmingham & Jelinek, 2007; Shingo, 1987/1988).

Manufacturing wastes also exist in the form of unneeded or unnecessary processes or operations. Although processes may appear to be necessary or value added it can be found that some processes can be eliminated, combined, or transformed after a formal evaluation of the entire operation due to the fact that they do not add value (Santos, Torres, & Wysk, 2006; Shingo, 1987/1988).

Lastly, another common waste found in manufacturing is inventory. Inventory wastes are found in many forms such as raw materials, WIP, finished goods, or even office supplies. Excess inventories can be detrimental to businesses as they hide unseen problems in the manufacturing value stream (Rubrich & Watson, 2004; Shingo, 1987/1988).

Value stream mapping is an effective lean tool that identifies excessive wastes of the value stream of manufacturing by examining both value added and non-value added processes required to produce and ship a product. Value stream mapping examines each element of a process with the focus of waste elimination and efficiency. The examination of the entire flow allows for excess and unnecessary inventory to be more transparent for overall improvement efforts and elimination of redundant and wasteful activities (Rubrich & Watson, 2004; Womack

& Jones, 1996). King (2009) indicated that "value stream mapping provides insight into where SMED can have the biggest benefit" (p. 32). Similarly, according to Ohno, "Eliminating manufacturing waste is not the problem, identifying it is" (Rubrich & Watson, 2004). Of all of the forms of waste inventory is considered to have to most impact on organizations due to the frequently overlooked inventory carrying costs (Santos, Torres, & Wysk, 2006; Shingo, 1987/1988). Similar to value stream mapping, process flow charting identifies each individual process step and the associated tasks and categorizes them into value added and non-value added activities. The primary difference between value stream mapping and process flow charting is that value stream mapping also includes the flow of information (Rubrich & Watson, 2004).

A key methodology derived from the Toyota production system is the reduction of setup and change over times by means of elimination of process wastes. Shingo helped develop the SMED or single minute exchange of dies which is also referred to as a quick setup or changeover (Birmingham & Jelinek, 2007; Rubrich & Watson, 2004; Shingo, 1983/1985). Although setup procedures vary between processes and businesses there are four fundamental steps of each setup process. The first step is a preparation step, which includes after process adjustment and checking of materials. The second step consists of mounting or moving of tools or parts. The third step consists of measurement, setting, or calibration. The last step in a setup process consists of a trial run or final adjustments. Each of the four foundational setup steps are examined and improved by the use of SMED implementations (Rubrich & Watson, 2004; Shingo, 1983/1985).

SMED Application in Industry

In a continuous flow production environment raw materials are converted through operations into the finished product. These individual operations directly impact the overall time

it takes to complete a finished assembly and fill a customer order (Shingo, 1983/1985). The adoption and implementation of single minute exchange of dies (SMED) concept is a commonly used method to improve the overall setup process (Goddart, 1986; Shingo, 1983/1985). SMED implementations allow for increased production capacity without adding additional equipment (Birmingham & Jelinek, 2007; Shingo, 1983/1985). In large lot size environments there are reduced number of changeovers, therefore the impact on overall throughput is less transparent. However, the reduction in setup time in industries with discrete lot sizes allows for increase in overall throughput (Goddart, 1986; Shingo, 1983/1985). According to Goddart (1986), "If you can get setup times to approach zero time, order quantities can approach one" (p. 19). The Toyota production system concentrated on the ability to produce small lot sizes with quick setups (Ohno, 1978/1988).

SMED implementations can be compared to a racing pit crew conducting a pit stop. Manufacturers strive to change product configurations much like a pit crew strives to change out the tires or fill the gasoline on a car. Both the manufacturer and the pit crew try to accomplish the necessary tasks with the least amount of down time possible. Eliminating downtime during each phase of changeovers increases profitability, job security, stability, and growth (Birmingham & Jelinek, 2007; Shingo, 1983/1985). The understanding and categorization of each individual step within a process along with the variable time and motion data associated with each step allows for a baseline or current state as the first conceptual phase of SMED application (Rubrich & Watson, 2004; Shingo, 1983/1985).

As previously mentioned an entire process can be broken into tasks and categorized into both value added and non-value added activities. Similarly, during a setup or changeover process these individual tasks can be categorized into two main categories; internal and external

setup operations. The second conceptual phase of a SMED application is separating the external setup operations from the internal operations. Understanding and strategizing the tasks that can be done while the machine is running as well as determining which tasks require the machine or line to be down can reduce the overall setup process 30 to 50% without any substantial capital investment (Shingo, 1981/1989).

Identification of Internal and External Setup Operations

The third phase of SMED application is converting the internal and external setup operations. The process of converting either of the setup operations requires a reevaluation of the internal operations to ensure that they were appropriately categorized as an internal operation or vice versa. Similarly, the exploration of potential alternatives for each internal operation could allow for a portion of the internal processes to be completed simultaneously while the line is running, which would reduce the overall downtime during an internal operation (Santos, Torres, & Wysk, 2006; Shingo, 1983/1985). According to Santos, Torres, & Wysk (2006, p. 130) "Development of this stage can achieve, in some cases, setup process times nearing single minutes (< 10 minutes)."

Streamlining Internal and External Setup Processes

The fourth conceptual phase of SMED application is streamlining both the internal and external setup processes. Streamlining internal setup operations can be achieved by the implementation of parallel operations, use of quick removal attachments, elimination of adjustments, and use of mechanization (Shingo, 1983/1985). Parallel operations allow for setup time of a process to be reduced in half due to the division of movements for each process by utilizing multiple employees to complete a task. Even an unskilled worker can conduct parallel operations effectively and offer improvement to the changeover process. In order to ensure

maximum results it is recommended that workers signal when parallel operations are completed to eliminate confusion or double work (Shingo, 1983/1985; Shingo, 1987/1988). Rubrich and Watson (2004) said "Technology alone does not insure success, teamwork, using and supporting technology to focus on the customer's requirements, does ensure success" (p. 11).

Another method of streamlining is the implementation of quick removal attachments and fasteners. Streamlined quick removal attachments can be achieved by replacing multiple fasteners with a clamping mechanism. Likewise, the elimination of adjustments can be achieved by reducing that amount of adjustable machine parameters by introducing calibrated machined gauge blocks or fixturing. The introduction of mechanization should only be considered a last resort in efforts to reduce adjustment as it offers only a temporary diversion of the faults in the setup process design (Shingo, 1983/1985).

Similar to internal operations, external operations can be streamlined by improving the storage or organization of parts, documentation, and essential tools used in external tasks (Shingo, 1983/1985). Placing tools in the same place on carts or shadow boards allows for a significant reduction in external setup operations. To ensure maximum efficiency of external setup activities tool carts should not be stored in separate areas (Birmingham & Jelinek, 2007). One critical aspect of streamlining both the internal and external operations is achieving balance amongst internal and external setup operations (Carreira, 2005).

Standardization of Internal and External Setup Processes

The next conceptual phase of SMED application is standardization. According to Masaaki (1986) standards are "a set of policies, rules, directives, and procedures established by management for all major operations, which serves as guidelines that enable all employees to perform their job successfully" (p. xxiv). There are two main standardization types: shape

standardization and function standardization. An example of shape standardization is by making all of the bolts or fasteners the same size and fastener head type. However, function standardization concentrates on only parts that are necessary for the setup operations. Standardization by function can be achieved by analyzing each function and assembly station to understand where it can be implemented (Shingo, 1983/1985). Standardized work was defined by Toyota as the optimized combination of materials, machines, and workers (Masaaki, 1986). Implementations such as visible arrangement storage can be implemented to standardize and define locations for change over tools and components (Rubrich & Watson, 2004). Other methods such as one touch implementations using wedges or clamping apparatuses can reduce setup operations significantly (Shingo, 1981/1989). It is sometimes necessary to create a new feature or add new functionalities when standardizing. The development of regulations and restrictions for future specifications moving forward in a setup reduction can offer benefits of this phase of SMED (Santos, Torres, & Wysk, 2006; Shingo, 1987/1988).

The final phase of a SMED application to a change over process is testing or reviewing the progress from the previous SMED phase implementations. Conducting a time study identical to the method used in the initial determination of the baseline will allow for an equal comparison to post implementation state of the setup process. Once the improvements are known to the team most companies forget the most important aspect of this phase is emphasis on continuous improvement efforts (Rubrich & Watson, 2004). If the goals were met the team should be congratulated and be allowed to communicate to other employees or staff. Next, they should move on to the next setup challenge. If the initial changeover goal is not met then the problem should be reviewed and new eyes such as consultants or new team members should be added to the project team with the objective to eliminate project complacency. The conclusion of a setup

reduction project should allow for a detailed representation of the amount of time saved and various kinds of wastes reduced (Rubrich & Watson, 2004; Shingo 1983/1985).

Transfer and Training of SMED Implementation

One of the most critical aspects to SMED implementation and transfer into production is operator training. A business strategy such as a setup reduction project and the organizational culture must correctly align with scope of the training implementation in order for business performance improvements to occur. There are five qualities organizations must possess in order for training to succeed. The five qualities include alignment, anticipation, alliance, application, and accountability (Gill, 2008). The first quality, alignment, must create a link connecting the performance objectives and each of the individual employee expectations. In regards to anticipation organizations should promote a want to learn atmosphere prior to training implementation (Gill, 2008; Shingo 1983/1985). It is equally important to clearly identify what the training information will accomplish for the employees as well as the organization. Similarly, management and executives are essential in culture of training and information retention. It is important that leaders support and genuinely promote the training which is described as total acceptance (Gill, 2008; Rubrich & Watson, 2004). The project sponsor and leaders should provide opportunities to use what employees learned and provide for them means of application. The last quality an organization must possess for successful training implementation is accountability. All who underwent training need to question the results of the training and as well as application of knowledge in order to continuously improve. The answers to such questions will give them direction for further improvement efforts. A continuously improving culture that fosters learning and development is needed for business performance improvements to occur and be sustained (Gill, 2008; Hayes & Wheelwright 1984). As

previously mentioned the early successes from the Toyota production system were witnessed in the automotive industry and did not develop as early in other industry applications such as medical device manufacturing. One of the primary constraints in the development of lean in medical devices organizations is the lack of development of a lean thinking culture. Although the intentions are there in the form of lean tool implementations such as value stream mapping, SMED, and kaizen, the lean way of thinking is what is lacking. In order to make a difference in the bottom line the company must adopt a lean thinking culture in order to reach operation excellence (Duggan, 2007; Gill, 2008; Womack & Jones, 1996).

Communication is also a key element in the overall success in an improvement effort as it improves the ability to anticipate an upcoming change. One example regarding a SMED changeover implementation would be a visual indicator that would communicates when and where the next changeover would be in the area where the changeover will occur such as a visual board. This will help employees anticipate and prepare individual stations accordingly. With management support and open communication SMED implementations performance objectives can be attained (Gill, 2008).

Organizational Improvements and Customer Focus with SMED Implementation

The intention of conducting a lean implementation such as setup reduction project is to improve the organization and make it more flexible to the customer's needs. Setup reduction projects, such as SMED implementations, are commonly adopted by various manufacturing businesses because they are easily implemented, low in overall cost, and provide instantaneous results (Rubrich & Watson, 2004). SMED implementations offer a multitude of organizational improvements and benefits (Shingo, 1983/1985).

1. Increased machine utilization and production capacity.

2. Elimination of setup errors through standardization.
3. Quality improvements as regulatory events can occur in advance or externally.
4. Improved operational safety due to simplicity of setups.
5. Cleaner and more organized work environment.
6. Ability to produce smaller lot sizes and increased flexibility for customer.
7. Reduction in down time for changeover processes
8. Lower overall operating expenses

One of the key principles of operations management is determining the order variety and order size. In some cases lengthy change over activities dictate order campaigns; however setup reduction implementations derived from basic SMED principles significantly reduce the amount of lost capacity incurred during smaller lot sizes and configuration changes. The ability to be more flexible and process smaller orders can also reduce the risk of loss in circumstances where rejects or defects are found. The objective of any manufacturing operation is to be profitable. SMED techniques have a history of success regarding the reduction in change over time. The reduction in change over time increases the business's overall ability to successfully meet the customer's ever-changing needs and reach operational excellence (Duggan, 2007; King, 2009).

Whether it is a lean implementation or strategic corporate goal, organizations implement metrics or key performance indicators to measure success. When KPI's (key performance indicators) align with the corporate objectives the success of the lean implementation and its associated success can be measured. For example, during SMED implementation if a corporation would like to reduce overall down time the key performance indicator would be the overall changeover time for that process. Similarly, if an organization would like to improve quality the key performance indicator relating directly to SMED implementation would be

startup rejects (Rubrich & Watson, 2004; Vorne, 2007). Furthermore, if a company's goal is to increase its ability to meet its customer's demand the key performance indicator of a SMED implementation would be estimated time of completion of a finished part or lot. In regards to overall productivity of an organization, the pieces per hour would be a KPI affected by SMED implementation. Similar to the principles of lean, key performance indicators provide a company and its employees with a forward looking metric with the intention of overall improvement of the company (Lubben, 1988; Vorne, 2007).

The ultimate goal of any lean implementation is to meet the customers' expectations and achieve a higher level of customer satisfaction. As stated by Ford, who was a well known lean manufacturing supporter, "It's not the employer who pays the wages, employers only handle the money. It's the customer who pays the wages" (Rubrich & Watson, 2004). The evolution of a more competitive manufacturing marketplace and evolving technology caused the need for process optimization and lean manufacturing. The fundamentals of the Toyota Production System and SMED implementations are based of organizational improvement to better serve the customer's needs (Herron, 2007; Womack & Jones, 1996).

Summary

The objective of lean thinking was simply stated by Hirano as "eliminating everything that is not essential" or commonly known as waste (Santos, Torres, & Wysk, 2006; Shingo, 1987/1988). The elimination of waste allows for increased operational efficiency and facilitates smooth production flow; however that could only be achieved if machine changeovers were drastically reduced (Goddart, 1986; Rubrich & Watson, 2004; Womack & Jones, 1996). The traditional approaches to setup activities were very time consuming and inefficient.

After nearly 30 years of being refined SMED implementations have been commonly adopted because they are easily implemented and have low implications regarding costs (Robinson, 1990). Although each business has their individual improvement needs, SMED concepts can be applied to a wide variety of processes to increase machine utilization and capacity at little to no capital cost. The basic determination of what can or cannot be carried out in advance to an actual changeover activity the second foundational element of SMED. Once the identification of internal and external setup processes have been achieved and streamlined, setup processes can achieve single minutes (Santos, Torres, & Wysk, 2006). Significant time savings and change-over reductions of 30-50 percent can be achieved from SMED implementations without significant capital investment (Robinson, 1990; Shingo, 1981/1989). SMED implementations also offer increased employee involvement during changeover activities. SMED implementations increase accountability on all levels of employees to reach corporate goals and ensure continued improvement, thus improving the corporate culture through employee empowerment. The combination of reduction in lead time, increased asset utilization, and improved corporate culture will allow for future success in meeting the needs of the customers. The utilization of lean tools allows for the elimination of non-value added activities or waste with the objective of making companies more profitable and efficient (Ford, 1926; Herron, 2007; Ohno, 1978/1988). Although businesses around the globe differ in the products they make and the customers they serve SMED is a universal lean tool that offers transparent success at a very low cost (Shingo 1981/1989).

Chapter III: Methodology

In order for operational excellence there must be a goal or an objective. Once a corporate objective has been determined the appropriate lean application and associated methodologies can be applied. If the corporate objective is to reduce overall down time, such as the goal of this research project, the key performance indicator would be the overall changeover time for the setup process (Vorne, 2007). The implementation of single minute exchange of dies (SMED) concepts allows for the reduction of downtime during changeovers (Birmingham & Jelinek, 2007).

At Phillips Medical the previous state of a complete assembly line change over process between the 0.15 mg and 0.3 mg product configuration was very time consuming and took anywhere from 3-4 hours. The assembled drug product is shelf life sensitive; therefore timely batch turns and setup time optimization is critical in regards to the overall finished product delivery to the customer.\

Improvement Procedures

In the evaluation of the current state of the changeover process at Phillips Medical on assembly line A and line B, the SMED methodologies and tools were applied with the objective to streamline and standardize the current changeover process and develop a new changeover system. The SMED implementations and new changeover system implementation carried out in this thesis can be applied to achieve future reduction of the overall time that is required to conduct a complete changeover. The study consisted of six main steps which were derived from SMED methodology (Shingo, 1983/1985).

Step 1: Evaluation of Current State of Changeover Process.

The first step was to evaluate the current state of a complete changeover on manufacturing line A and line B. The evaluation included identifying all the individual setup activities and performing a time study to evaluate the total length of time it takes for each corresponding activity. A common challenge in traditional setup operations is that the internal and external setup activities are often confused. A production analysis allows for the differentiation of the internal and external setup activities. The analysis of each setup process allows for elimination of unnecessary downtime during a setup process (Robinson, 1990). This study utilized a continuous process analysis which was performed with a stopwatch. The stopwatch provided a detailed time measurement of each individual setup element at each assembly station. The time to complete each setup element was recorded in chronological order in a current state setup observation chart. In addition, each movement by the operator to complete each of the individual tasks was also tracked and mapped on a spaghetti diagram utilizing current state floor layout.

Step 2: Determination of Internal and External Setup Processes.

The second step consisted of determining the internal and external setup processes. This consisted of classifying each individual task from step one and categorizing them into internal and external processes. In the current state, all internal setup elements included operations which were performed while the line was in an idle status. Internal setup elements included machine setup operations, line clearance activities, and vision inspection challenges. Contrarily, the external elements included operations that were performed while the line was assembling parts.

Step 3: Conversion of Internal and External Setup Processes.

Step three consisted of trying to convert the internal and external processes where possible. Converting the internal and external processes consisted of reexamining operations and determining ways to convert internal processes to external processes. Understanding and strategizing the operations that can be done while the machine is running as well as determining which tasks require the machine or line to be down can reduce the overall setup process 30 to 50 percent and ultimately allow for setup process times to achieve single minutes (Robinson, 1990; Santos, Torres, & Wysk, 2006; Shingo, 1981/1989). Once the internal and external setup elements were identified the next step in the SMED implementation was to convert as many internal setup elements to external elements. It is important to understand that during the conversion of an internal to external setup element the actual setup operation will not be changed. The current state analysis of complete changeovers between the 0.15 mg and 0.3 mg product configurations on line A and line B indicated that internal and external activities were already being conducted appropriately. All of the internal operations recorded on the changeover element charts included in Appendix A and Appendix B were evaluated for potential conversion from internal to external.

Step 4: Streamlining Internal and External Setup Processes

Step four consisted of streamlining both internal and external processes at each individual assembly station. Streamlining internal setup operations can be achieved by the implementation of parallel operations, use of quick removal attachments, elimination of adjustments, and the use of mechanization (Shingo, 1983/1985). Although the internal processes could not be converted to external processes as indicated in project step 3, it was found during this study that there were many ways to streamline the current state internal and external operations to reduce the overall

changeover process. As shown in this study a complete current state changeover takes anywhere from three to five hours from last completed part to first assembly produced on the next lot. The first element of streamlining included the implementing the assistance of additional operators at each station to help assist in changeovers and eliminating individual tasks and adjustments of technicians. In addition, standardized operator changeover documents where created for use at each individual process step. These documents are part of the new changeover process and will incorporate parallel operations conducted by operators at each process step. The implementation of a changeover system of parallel operations will allow for an overall time reduction in changeover process due to the separation of technical and non-technical setup operations, which does not exist in the current state.

In addition to conducting parallel operations another method of streamlining is the implementation of quick removal attachments and fasteners. At the adjustment screw setting stations (Assembly Process Step 3) the dose blocks must be removed and replaced during changeovers as they are dose specific to each configuration. The dose blocks are calibrated gauge blocks that set the first dose of each drug cartridge. Normally, these blocks are removed and fastened by the PST, however the new streamlined process allows for the operators to remove the dose blocks. As noted above in Table 1 the removal of the 0.3mg Dose Block on AS-41 took 15 minutes. Normally, this task takes less than a minute, however according to the current state examination the PST could not locate the wrench to remove the Dose Block which resulted in an internal delay of 15 minutes. According to Birmingham & Jelinek (2007) placing tools in the same place on carts or shadow boards allows for a significant reduction in external setup operations. The improved future state change over procedure consists of the removal of the dose blocks by loosening and removing two torque screws with a point of use wrench which

is located at the station on a shadow board. After the dose block is removed the dose block and the two torque screws are placed in a dedicated spot for removal to the changeover cart. The point of use implementation will eliminate any future need to have to look for wrenches. In addition, the shadow board will also offer a visual indication if the wrench is missing from the point of use location at the assembly station.

The reduction of process waste is another fundamental objective to increase the efficiency of a process. During the assessment of the current state changeover a time and motion studies of each setup element was conducted. Spaghetti diagrams were created to map out the travel and transportation activities required to complete each setup operation. The spaghetti diagram offered a visual representation of where wasted and redundant motion occurs. The diagram justified the need for SMED tools such as dedicated changeover carts and point of use tools.

Step 5: Standardization of Internal and External Setup Processes

Step five consisted of standardization of both internal and external processes. Similar to streamlining the internal and external processes the next step of SMED implementation in changeovers is the standardization of internal and external processes. Due to the complexity of having multiple assembly stations with specific changeover operations and three separate assembly shifts standardized changeover documents specific to each process step were written and controlled. These documents include step by step instructions of setup operations and line clearance activities specific to the individual assembly station. Each changeover document includes reference and instructional pictures specific to each station. In addition, there were separate changeover documents created for both the quality technician and production support technician. These documents provide specific instructions for the technicians to follow for each

changeover and will increase overall consistency between all shifts regarding the technical internal setup requirements. Appendix E includes all of the controlled changeover documents that will be used on future state change overs. Similarly, Appendix F is the future state changeover list for each changeover. These lists include numbers steps of the required internal operations that must be conducted while the assembly line is down.

In addition to the creation of the changeover documents all of the shifts were formally trained. A standard training presentation was given to each shift. To ensure a consistent transfer of training anyone that was absent during these training sessions were trained by means of Phillips Plastics internal training procedure which allows them to review and sign post formal training session. After the formal training sessions each employee will conduct a review of each document and sign off on training rosters. Following the final document control the controlled master copy of each changeover document and applicable training roster will be posted at each assembly station for reference and use during each future state changeover.

The future state changeover carts were also scrutinized to standardization. A total of six individual changeover carts were constructed for each dose configuration. Each changeover cart has color-coded cart labels specific for each dose configuration/platform applied to each cart. The carts have individually labeled rack locations for each dose specific component and material required for manufacturing. The standard locations of components and materials, which are identical across all changeover carts, will increase consistency and operator recognition.

As noted by King (2008) communication is a key element in the overall success in an improvement effort as it improves the ability to anticipate an upcoming change. Standardized methods of communication were implemented by using visual indicators at each station as well as added an additional changeover section on the production tracking visual board. The

production tracking board includes color coded indicator which indicates current build configuration as well as the next lot configuration. This implementation allows improved communication and anticipation for the upcoming changeover. In addition, each station now has a dedicated fixture/location where the operator will post a "station complete" green indicator circle. Once the changeover tasks are complete at an individual station the operator will affix the green indicator circle. The posted circle provides visual communication to the technician that the station is ready for final line clearance verification and sign off. The last picture page of each changeover document included in Appendix E illustrates the green indicator circles and station location for the visual communication implementation.

Step 6: Testing SMED Implementations

Lastly, step six included the testing of the individual implementations. Similarly to step one, testing included a time study that will evaluate the total length it takes for a complete change over after streamlining and standardization. Unfortunately, due to multiple supplier constraints and unplanned downtime the manufacturing line A and line B were inactive during the implementation and testing phase of the project; therefore a complete changeover process could not be conducted or tested with the new implementations. Due to these circumstances only the individual operations where new tools were implemented could be simulated with trained technicians at individual assembly station.

Subject Selection and Description

The complete changeover in an assembly process between the 0.15 mg and 0.3 mg product configuration was evaluated in this field study. The study includes observing all setup activities of the production support technician and quality technician. The setup activities

observed in this study include individual setup steps such as assembly station sub-processes, movement to complete setup tasks, and total completion time.

Data Collection Procedures

The method to collect data in this study was conducted by recording the total time from the last off product to the first off product and assessing the individual internal and external setup processes time. This also included visible assessment of the entire changeover process from start to finish. The study also included recording and measuring the distances traveled by the operators conducting the changeover activities, and timing each individual setup activity.

Limitations

The application of tools and techniques of SMED methodologies will allow for time savings and increased asset utilization during assembly changeover processes. This study was applied to a high volume medical device assembly line which is subjected to continuous improvement initiatives and optimization. With the needs of the customer constantly changing, there may be a requirement in the future for additional product configurations or new automation outside of the scope of this research project. The first limitation of this study is that it includes the current manufacturing cells and processes. If the assembly line becomes more automated in the future the study is limited to the current assembly line processes.

The second limitation is that this study is limited to the currently controlled assembly configurations which include only the 0.15mg and 0.3mg product configurations. If new product configurations are added and will be built on the current assembly line processes/equipment, a separate study and applicable training will need to be conducted to ensure that the SMED methodologies are applied and the individuals involved have been adequately trained.

Summary

The objective of SMED implementation was to streamline and standardize the current changeover process and develop a new changeover system. The study consisted of six main steps which were derived from SMED methodology. The first step evaluated the current state of a complete changeover on manufacturing line A and line B by analyzing the continuous process which was performed with a stopwatch. The time to complete each setup element was recorded in chronological order in a current state setup observation chart and motion was charted on a spaghetti diagram. The second step consisted of determining the internal and external setup processes by classifying each individual task from step one and categorizing them into internal and external processes. Step three consisted of the analysis of the setup elements and trying to convert internal and external processes where possible. Step four consisted of streamlining both external and internal processes at each individual assembly station by implementing additional operator support through parallel operations, quick removal and point of use tools, and construction of dedicated changeover carts. Step five consisted of standardization of both internal and external processes by methods of the creation of implementing changeover documents for each station, standardized training, standardized changeover carts, and visual communication implementations. Lastly, step six included the testing of the individual SMED implementations. Although the entire changeover process utilizing the new changeover system and implementations could not be analyzed, the research could only simulate individual operations where new point of use tools with trained technicians at individual assembly station. The future state implementation parallel operations and improved changeover process could not be completely simulated, however through analysis and time savings assessment realized from for the analysis of the former state the researcher can speculate with confidence that the SMED

implementations and new changeover system implementation can be applied to achieve future reduction of the overall time that is required to conduct a complete changeover.

Chapter IV: Results

The purpose of this study was to reduce the overall setup time of a complete changeover process between a 0.15 mg and 0.3 mg product configuration for manufacturing lines A and B located at Phillips Medical, at Menomonie, WI. The single minute exchange of dies (SMED) methodology was applied to analyze and optimize the current state to achieve the objective of overall setup time reduction on assembly line A and line B. The setup reduction project consisted of six main implementation steps derived from the SMED methodology. The first step evaluated the current state of a complete changeover on manufacturing line A and line B. The evaluation included identifying all the individual setup activities and a time study conducted to evaluate the total length of time it takes for each corresponding activity. The second step consisted of determining the internal and external setup processes. This consisted of the classifying each individual task from step one and categorization of them into internal and external processes. Step three consisted of the conversion of the internal and external processes. The internal and external processes were converted through reexamination of the assembly station operations and analysis of the individual station requirements. Step four consisted of streamlining both external and internal processes at each individual assembly station. Step five consisted of standardization of both internal and external processes. Lastly, step six included testing of the implementations. Similarly to step one, testing only included the individual implementations due to the line not being active. This study did not include an overall time study that will evaluate the total length it takes for a complete change over after streamlining and standardization.

Project Step 1: Evaluation of Current State of Changeover Process.

The analysis of the 0.3mg to a 0.15mg changeover indicated that it takes 2 hours 46 minutes and 32 seconds for internal setup elements and 2 hours 20 minutes and 22 seconds for external setup elements. The maximum time of an individual internal setup element was 20 minutes and 25 seconds which was the labeler type chase setup. The type chase setup consisted of a thermal transfer printing system which required an operator to remove the type chase printer stamp and manually change the individual print characters. The maximum time of an individual external setup element was 32 minutes 20 seconds which was the preparation of materials in the warehouse. In total, 5 hours 6 minutes and 54 seconds was required for a complete changeover from the last good assembly of the previous lot and first good assembly of the next run for a 0.3mg to a 0.15mg changeover.

The analysis of the 0.15mg to 0.3mg changeover indicated that it takes 1 hour 38 minutes and 29 seconds for internal setup elements and 1 hour 56 minutes and 45 seconds for external setup elements. The maximum time of an individual internal setup element was 33 minutes and 57 seconds which was the labeler type chase setup. The maximum time of an individual external setup element was 20 minutes 50 seconds which was the preparation of the labels from inventory and line clearance by quality technicians. In total, 3 hours 33 minutes and 14 seconds was required for a complete changeover from the last good assembly of the previous lot and first good assembly of the next run for a 0.15mg to 0.3mg changeover).

Further analysis and comparison of the two changeovers times and motion studies indicated that there is a lack of consistency between the internal and external setup elements which supports the need of standardized changeover procedure which is one of the primary objectives of this project.

Project Step 2: Determination of Internal and External Setup Processes.

During the analysis of each changeover each setup operation was identified and recorded as either an internal or external setup operation. Appendix A shows each individual setup operations labeled as either internal or external with the setup times of each for the current state 0.3mg to 0.15mg configuration changeover. Similarly, Appendix B indicates the individual internal and external setup times and the applicable process elements of each for the current state 0.15mg to 0.3mg configuration changeover.

Project Step 3: Conversion of Internal and External Setup Processes.

Upon examination none of current state internal processes could be converted from internal to external. It was found that all of the internal operations were required to be conducted after the last good part was produced at each applicable assembly station. The results from the analysis indicated that there were three main required internal setup elements which included: vision challenge, jig/fixture setup, and line clearance activities. The first internal process was conducting the vision challenge, which included testing our vision inspection systems with known reject samples. The second internal process was the jig/fixture setup which included the removal of all dose specific assembly fixtures, nests, and jigs. The third internal process was the line clearance, which included a complete inspection of all stations for dose specific components, labeling, and paperwork from previous manufacturing lot. The vision challenges cannot be conducted until the last finished assembly has been fully inspected. Similarly, the line clearance, which is a good manufacturing practice (GMP) requirement, cannot be completed until the current manufactured lot has been completed. Similarly, all other internal processes are fixture/station setup requirements which are specific to the dosage application. The dose specific

setup requirements such as dose blocks and assembly fixtures could not be completed until the last finished good was finished at each station.

Project Step 4: Streamlining Internal and External Setup Processes.

The analysis showed that the total time of all internal elements in a 0.3mg Generic -to- 0.15mg Branded changeover takes 2 hours 46 minutes and 32 seconds, whereas a 0.15mg Generic -to- 0.30mg Generic changeover takes 1 hour 38 minutes and 29 seconds. The implementation of additional support from an operator at each process step, individual standard operator instructions, and parallel operations will offer significant time savings. Tables 1 and 2 below show the potential time savings of the new streamlined changeover process in both the internal and external setup operations in the future state of Generic to Branded and Generic to Generic changeover procedures.

Table 1

Future State – Time Savings from Parallel Operations Implementation (0.3mg Generic-to-0.15mg Branded)

	Internal Operations - (Conducted in Parallel by Operators)	**Time**	**Unit**
1	Remove 0.3mg Drive Rods & Applicable label	0:14:35	Min.
2	Conduct Station Line Clearance / Signoff	0:14:31	Min.
3	Remove 0.3mg Dose Block AS-41 line A	0:15:00	Min.
4	Remove 0.3mg Dose Block As-58 line B	0:01:18	Min.
5	AS-40 Caser Generic Fixture Removal	0:01:07	Min.
6	AS-40 Caser Branded Fixture Installation	0:02:00	Min.
7	AS-46 Caser Generic Fixture Removal	0:01:48	Min.
8	AS-46 Caser Branded Fixture Installation	0:01:00	Min.
	Savings From Parallel Operations Implementation:	**0:51:19**	Min.
	Total Internal Setup Time (Appendix A):	**2:46:32**	Min.
	Percent Reduction:	**30.81%**	
	External Operations - (Conducted in Parallel by Operators)	**Time**	**Unit**
1	Remove 0.3mg Stop Collars & Applicable label	0:02:30	Min.
2	Remove 0.3mg Bushings & Applicable label	0:02:35	Min.
3	Remove Generic Nose Caps (smooth)	0:02:30	Min.
4	Remove Generic Sheath Removers	0:02:35	Min.

5	Remove Generic Firing Assemblies (Gray Safety Caps)	0:03:15	Min.
6	Remove Foam Pads (0.5")	0:02:30	Min.
7	Remove Generic Case Bottoms	0:03:15	Min.
8	Remove Generic Case Tops	0:03:04	Min.
9	Issue 0.15mg Stop Collars & Applicable label	0:02:30	Min.
10	Issue 0.15mg Drive Rods & Applicable label	0:02:14	Min.
11	Issue 0.15mg Bushings & Applicable label	0:02:05	Min.
12	Issue Branded Nose Caps (Knurled)	0:02:10	Min.
13	Issue Branded Sheath Removers (Green)	0:01:49	Min.
14	Issue Firing Assemblies (Green)	0:02:05	Min.
15	Add Foam Pads (0.25")	0:03:54	Min.
16	Issue Branded Case Tops	0:03:15	Min.
17	Issue Branded Case Bottoms / Load into AM-43 Hopper	0:23:00	Min.
	Savings From Parallel Operations Implementation:	**1:05:16**	Hour/Min.
	Total External Setup Time (Appendix A):	**2:20:22**	Hour/Min.
	Percent Reduction:	**46.50%**	

Table 2

Future State – Time Savings from Parallel Operations Implementation (0.15mg Generic-to-0.30mg Generic)

Internal Operations - (Conducted in Parallel by Operators)		**Time**	**Unit**
1	Remove 0.15mg & Install 0.3mg Dose Block AS-41 Line A	0:00:25	Min.
2	Remove 0.15mg Install 0.3mg Dose Block AS-58 Line B	0:00:56	Min.
3	Remove 0.15mg Drive Rods out of AS-52	0.02:55	Min.
4	Cleaned out Drive Rods out of AS-72	0:01:35	Min.
5	Conduct Station Line Clearance and Signoff	0:10:30	Min.
6	Install 0.3mg Dose Block AS-41 Line A	0.00:32	Min.
	Savings From Parallel Operations Implementation:	**0:13:26**	Min.
	Total Internal Setup Time (Appendix B):	**1:38:29**	Hour/Min.
	Percent Reduction:	**13.64%**	
External Operations - (Conducted in Parallel by Operators)		**Time**	**Unit**
1	Clearing Finished Cased Parts	0:01:15	Min.
2	Remove 0.15mg Case Bottoms from the Line to change over cart	0:02:12	Min.
3	Remove 0.15mg Stop Collars & Applicable label	0:04:00	Min.
4	Remove 0.15mg Bushings & Applicable label	0:04:30	Min.
5	Finished cleaning out Build Lines and disposition components	0:02:25	Min.
6	Remove 0.15mg Drive Rods from AS-52	0:02:47	Min.

7	Remove 0.15mg Drive Rods from AS-72	0:02:39	Min.
8	Stop Collars issued to the Build Lines	0:02:05	Min.
9	Issue the 0.3mg Drive Rods to the Build Lines	0:01:58	Min.
10	Issue 0.3mg Bushings to the Build Lines	0:01:05	Min.
11	Disposition cart/containers	0:01:05	Min.
12	Verify Work Instructions	0:05:05	Min.
13	Obtain 0.3mg Dose Block Kits	0:01:19	Min.
14	Load Case Bottoms into Hopper	0:01:35	Min.
	Savings From Parallel Operations Implementation:	**0:34:00**	Min.
	Total External Setup Time (Appendix B):	**1:56:45**	Hour/Min.
	Percent Reduction:	**29.12%**	

It was also noted in the study that there was definite pattern of repetitive and wasted motion regarding line clearance, component issuance, and disposition operations. Appendices C and D illustrate both the line clearance and component issuance transportation activities of the current state changeovers. Line clearance activity is a (GMP) requirement that consists of ensuring that all components, labeling, and configuration specific materials are removed prior to commencing manufacturing of the next batch. Component issuance transportation activities consist of current practice of adding and removing components to the manufacturing line. The future state process will utilize changeover carts which will greatly reduce the length of travel and number of trips from the assembly area. The changeover carts will be fully prepared in advance with all of the necessary documentation, labeling, components, fixtures and testing equipment specific to the next configuration of changeover. The changeover cart and all other necessary components such as Nose Cap Assemblies, Firing Assemblies, and Adjustment Screws will be located at a maximum of five feet from the assembly line. This point of use strategy will reduce the overall length of travel and the amount of trips by more than 50% as majority of the required movements will not have to exceed the distance of five feet from manufacturing line A and line B.

The application of SMED methodologies will allow for a for a more streamlined changeover process between a 0.15 mg and 0.3 mg product configuration for lines A and line B. The implementation of parallel operations will significantly reduce the amount of time and labor of the technicians. The new streamlined implementation will allow for the PST or QT to dedicate their time and complete the technical internal setup operations, which will alone reduce the overall internal setup time by 30.8% Generic to Branded and 13.6% Generic to Branded and will help improve the balance of future state setup operations.

Project Step 5: Standardization of Internal and External Setup Processes.

In efforts to design a more standardized change over system, standardized changeover documents were controlled with Phillips Medical document control systems which are specific to each process step. Appendix E includes all of the controlled changeover documents that will be used by all operators across all shifts on future state change overs. Similarly, Appendix F is the future state changeover lists, which includes separate lists for each changeover and the required internal operations that must be conducted while the assembly line is down for both changeover.

In addition, a total of six individual changeover carts were constructed for each dose configuration. Each changeover cart has color-coded cart labels specific for each dose configuration/platform. The carts have individually labeled rack locations for each dose specific component and material required for manufacturing. The standard locations of components and materials, which are identical across all changeover carts, will increase consistency and operator recognition. Effective communication is a key to future changeover success. In the future state changeover process standardized methods of communication by using visual indicators at each station as well as added an additional changeover section on the production tracking visual board. This implementation allows improved communication and anticipation for future

changeovers. In addition, each work station has a dedicated fixture/location where the operator will post a "station complete" green indicator circle. The last picture page of each changeover document included in Appendix E illustrates the green indicator circles and station location for the visual communication implementation. All shifts were trained and a controlled master copy of each changeover document and applicable training roster were posted at each assembly station for reference and use during the future state changeovers and the life of the posted document revision.

Project Step 6: Testing of the SMED implementations.

Due to multiple supplier constraints and unplanned downtime the manufacturing line A and line B were inactive during the implementation phase of the project; therefore a complete changeover could not be conducted or tested with the new implementations. Due to these circumstances this study simulated only the individual operations where new tools were implemented with trained technicians. The first SMED implementation tested was the implementation of the point-of-use tool and changeover cart used for dose block removal operation. As noted in Appendix A, the removal of 0.3mg dose blocks on the adjustment screw setting device (AS-41) took 15 minutes and the installation of the 0.15mg dose block took 5 minutes 50 seconds to install. Upon testing the implementation of the point-of-use tool and the close proximity of the new changeover cart contributed to a total time savings of 19 minutes and 2 seconds or 92.7% reduction in an individual internal setup operation.

The implementation of the changeover carts will also allow for reduction of redundant movements from the warehouse to assembly line. The standardized movement of presenting fully stocked changeover carts in and out only when changeovers occur will allow for a reduction in wasted motion of over 50% of during each changeover.

Although the complete future state implementations could not be fully tested, it can be assumed through assessment of the former state of changeovers that the incorporation of parallel operator support at each station allows for reduction of overall internal time of 51 minutes and 19 seconds per Generic to Branded changeover and 13 minutes 26 seconds or per Generic to Generic changeover. Similarly, the implementations also allow for a reduction in external setup operation of 1 hour and 5 minutes per Generic to Branded changeover and 34 minutes per Generic to Generic changeover. The original changeover method consisted of the technicians conducting all of the internal and external tasks. The savings from implementing changeover carts will help improve the balance of setup operations.

After the initial identification of the internal and external setup operations, standardizing, and streamlining the current state changeover a comprehensive list was created that includes only the required internal setup requirements. The future state changeover list do not include the additional external setup operations or internal operations conducted in parallel by operators as these will be assumed SMED implementation improvements. Being that the entire changeover process could not be tested, the total times remaining will be based off former state internal operation times required. The times may be subject to even further reductions as a result of the point of use changeover cart implementation and standardization of changeover tasks.

Summary

The application of SMED concepts on an assembly line changeover can offer improvements from the current state (0.3mg Generic to a 0.15mg Branded) changeover, which takes 5 hours 6 minutes and 54 seconds, to a future state time of 1 hour 17 min 39 seconds or less. Similarly, improvements from the current state (0.15mg Generic to a 0.3mg Generic) changeover, which takes 3 hours 33 minutes and 14 seconds, to a future state time of 57 minutes and 47 seconds or less. In either case, implementing the foundational principles of SMED can allow for future overall setup time reductions of 75% for (0.3mg Generic to a 0.15mg Branded) and 73% (0.15mg Generic to a 0.3mg Generic) changeovers.

Chapter V: Discussion

The SMED implementations and new changeover system implementation carried out in this thesis can be applied to achieve future reduction of the overall time that is required to conduct a complete changeover. The current state of a complete changeover in the assembly process between the 0.15 mg and 0.3 mg product configuration is very time consuming taking on average of 3-4 hours on Manufacturing line A and line B. This field project was conducted with the objective to examine the current state changeover process between a 0.15 mg and 0.3 mg product configuration for both identical manufacturing lines A and line B and implement SMED tools and develop a new changeover system to allow for future reduction of the overall setup time to reduce overall setup time to increase utilization of both human resources and machines to maximum overall output. In order to achieve improvements SMED methodologies were applied to the current state changeover process. There were six primary process steps applied which were derived from SMED. The first step observed the current state of a complete changeover on manufacturing line A and line B. The evaluation included identifying all the individual setup activities and a time study was performed to evaluate the total length of time it took for each corresponding activity. The second step consisted of determining the internal and external setup processes. This consisted of the classification of each individual task from step one and the categorization into internal and external processes. Step three consisted of the conversion of the internal to external processes. Step four consisted of streamlining both external and internal processes at each individual assembly station. Step five consisted of standardization of both internal and external processes. Lastly, step six tested the SMED implementations of the future state changeover process. Similarly to step one, testing included a time study and analysis that

evaluated the total length it takes for a complete changeover tasks or process after streamlining and standardization.

Limitations

Applying the tools and techniques of SMED methodologies allows for time savings and increased asset utilization during assembly changeover processes such as medical device assembly lines which is applied in this research project. With the needs of the customer constantly changing, there may be a requirement in the future for additional product configurations or new automation outside of the scope of this research project. The first limitation of this study is that it includes the current manufacturing cells and processes. A new automated labeler (AM-47) was added to the assembly line after the initial assessment of the current state of the changeovers. Therefore, any internal or external setup operations regarding the decommissioned labelers (AS-65, AM-20 & AM-30) could not be included in this study. Any time associated with the old labelers or ancillary equipment was not included in the final testing or analysis.

The second limitation is that this study is limited to the currently controlled assembly configurations which include only the 0.15mg and 0.3mg product configurations. If new product configurations are added and will be built on the current assembly line processes/equipment, a separate study, applicable training, and changeover implementations will need to be conducted to ensure that the SMED methodologies are applied and the individuals involved have been adequately trained.

The final limitation of this study was the constraint of the manufacturing line being inactive during the implementation phase of the project. The line was inactive due to supplied component constraints external of Phillips Plastics. Therefore, the complete future state

changeover could not be tested and only individual simulations with a trained technician could occur and be measured. Due to the fact that the complete future state changeover could not be measured it is probable that the new required internal setup requirements determined in this study will be the minimum time it will take for a changeover to occur in the future state.

Conclusions

Although SMED was first developed in dies and presses, the methodologies can be applied industry wide. After studying the application of SMED concepts on a complete medical device manufacturing line A and line B, it is concluded that SMED is an effective tool to provide structure and methods resulting in overall setup time reduction, increased asset utilization, and improved capacity of a complete assembly line.

The basic determination of what can or cannot be carried out in advance to an actual changeover activity is a key element of SMED. Once the identification of internal and external setup processes have been achieved and streamlined, setup processes can achieve single minutes (Santos, Torres, & Wysk, 2006). It was found in the study that there was preexisting separation of internal and external elements. However, it was immediately noted that there was a lack of standardization and limited support to conduct the setup activities required for an entire assembly line in the current state changeover process. Once the internal and external process steps were determined in project step two, the setup process was streamlined and standardized. Due supplier constraints and line down situations the complete future state implementations could not be fully tested. It is probable through analysis and assessment of the former state of changeovers that the incorporation of SMED tools will allow for the overall potential reduction of 75% in 0.3mg Generic to a 0.15mg Branded and 73% reduction of 0.15mg Generic to a 0.3mg Generic changeovers. According to Shingo and other leading experts indicate that successful SMED

implementations can result in overall setup reductions of 50-70%, which directly correlated with the results in this field study (Shingo, 1981/1989).

Recommendations

SMED implementations are an effective way to reduce waste and offer standardization to changeover processes of an entire assembly process. Due to having multiple assembly stations with individual setup requirements for each station there is an increased need for a robust and standardized changeover process. The results of this field study indicate that substantial time savings can be realized in custom assembly processes. In order to understand the impact of implementation of the SMED tools the researcher recommends additional engineering follow up and assessment of the complete changeover process. The future state assessment can be carried out by repeating process step 1. The future engineer tasked with implementing the procedures developed should conduct a continuous process analysis with a stopwatch. The stopwatch can provide a detailed time measurement of each individual setup element at each assembly station. The time to complete each setup element should be recorded in chronological order in a future state setup observation chart. A direct comparison of former and future state should be conducted to realize the overall time reduction resultant of the tools implemented in this study.

It is recommended that the ideas of the operators and technicians, who actually carry out the changeovers and utilize the tools, should be considered and implemented if deemed feasible by engineering and management. As the medical sector continues to be more competitive, the application of SMED on other assembly processes will allow for Phillips Plastics to better serve our customer and increase overall capacity for future business growth.

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Appendix A: Current State Setup Observation Chart (0.3mg Generic-to-0.15mg Branded).

Changeover Configuration: 0.3 mg Generic-to-0.15mg Branded (Non-Like-for-Like) Date: 4/5/2010

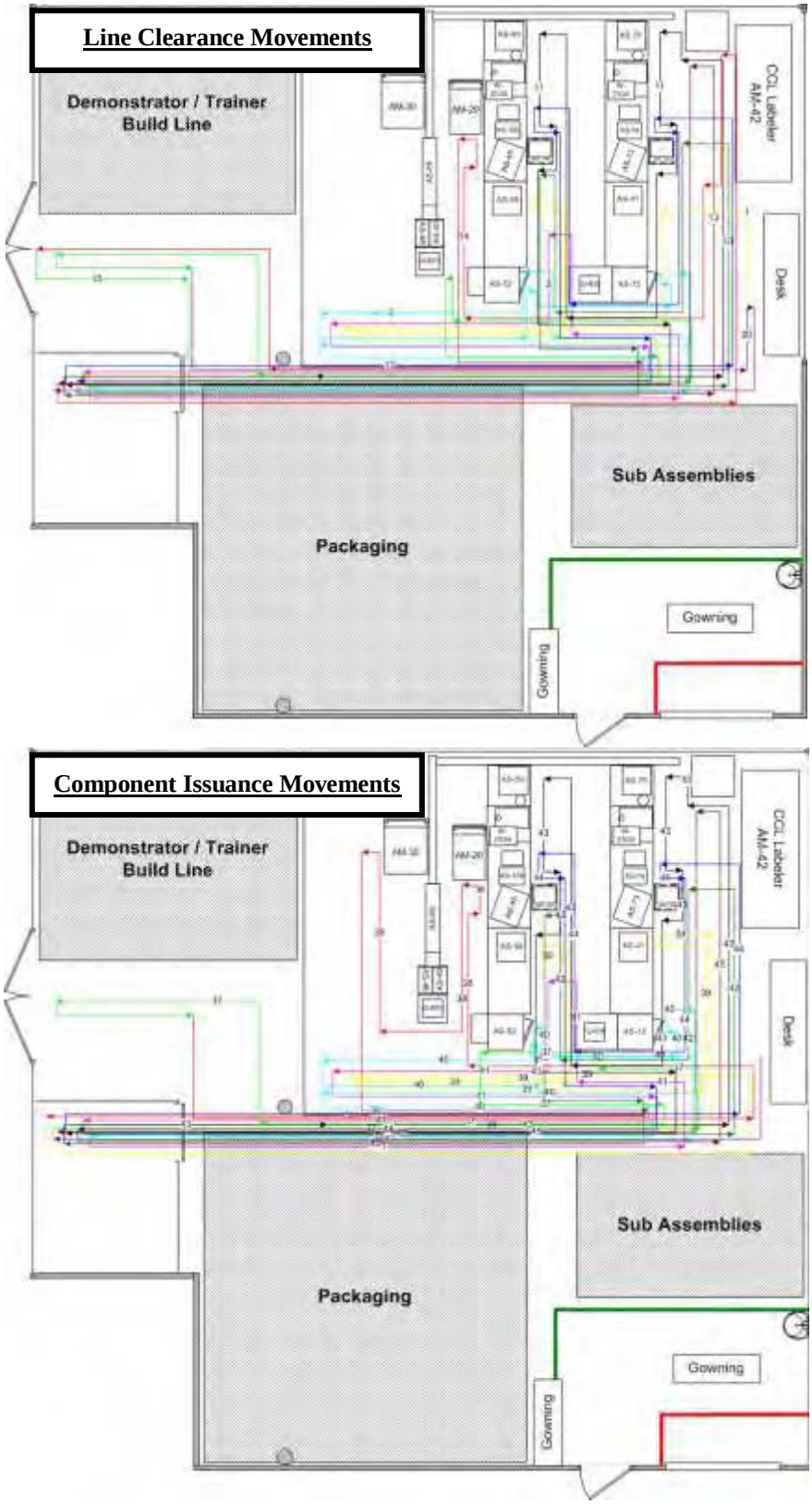
Step#	Set-up Element	Internal	External	Total Time (hh:mm:ss)	Countermeasure/improvement Ideas
				21:00:00	
1	Remove 0.3mg Stop Collars & Applicable label		0:02:30		
2	Remove 0.3mg Drive Rods & Applicable label	0:14:35			Control amount near end of run to eliminate longer unloading time, remove escapement tube and divert tube into parts bin to allow for other tasks to be conducted
3	Remove 0.3mg Bushings & Applicable label		0:02:35		Operator assistance
4	AS-73 Generic Syringe Vision Challenge (Closeout) Line A	0:06:41			
5	AS-75 Generic Final Vision Challenge (Closeout) Line A	0:04:09			
6	AS-45 Generic Syringe Vision Challenge (Closeout) Line B	0:05:30			
7	AS-50 Generic Final Vision Challenge (Closeout) Line B	0:03:50			
8	AS-73 BrandedSyringe Vision Challenge (Startup) Line A	0:06:30			
9	AS-75 BrandedFinal Vision Challenge (Startup) Line A	0:04:20			Consider Order of Testing (Combining Close out Startup)
10	Remove Generic Nose Caps (smooth)		0:02:20		Operator Assistance
11	Remove Generic Sheath Removers		0:02:35		Operator Assistance
12	Remove SDASI Firing Assemblies (Grey Safety Caps)		0:03:15		Operator Assistance
13	Remove Foam Pads (0.5")		0:02:30		Operator Assistance
14	Remove Generic Case Bottoms		0:03:15		Operator Assistance
15	Remove Generic Case Tops		0:03:04		Operator Assistance
16	AS-45 BrandedSyringe Vision Challenge (Startup) Line B	0:06:00			
17	AS-50 BrandedFinal Vision Challenge (Startup) Line B	0:05:05			Consider Order of Testing (Combining Close out Startup)
18	AM-30 Tear Down / Remove Labels / Remove Typechase	0:02:30			Consider a preheater for Typechase
19	AM-20 Tear Down / Remove Labels / Remove Typechase	0:02:45			Consider a preheater for Typechase
20	Bring Golden Samples (Vision) Back To Locked Cage		0:01:20		Point Of Use / Change over Cart location
21	Conduct Visual Line Clearance / Signoff	0:14:21			Operators can do individual station line clearance (speed up PSTIQT verification)
22	Obtain Parts List / BOM For New Material Issuance		0:05:00		Try to stage / carry out in advance
23	Obtain Dose Block Kits For AS-45/AS-73 From Locked Cage		0:02:04		Point Of Use / Change over Cart location
24	Remove 0.3mg Dose Block AS-45 Line A	0:15:00			Allen Wrench or Kit Didn't Fit, Had Trouble Finding Right Dose Blocks - Point of use tool / operator unscrew
25	Install 0.15mg Dose Block AS-45 Line A	0:05:58			
26	Remove 0.3mg Dose Block As-50 Line B	0:01:18			
27	Install 0.15mg Dose Block AS-50 Line B	0:01:08			
28	Obtain New Parts from Warehouse for 0.15 BrandedStart-up		0:22:20		Try to stage / carry out in advance
29	AS-41 Setup / CPU-Interface Settings	0:02:52			
30	AS-41 Vision Challenge (No Dose)	0:01:38			
31	AS-58 Setup / CPU-Interface Settings	0:01:08			
32	AS-58 Vision Challenge (No Dose)	0:02:05			
33	AS-40 Case Generic Fixture Removal	0:01:07			Operators Unscrew Fixtures after closeout/material/advance
34	AS-40 Case BrandedFixture Installation	0:02:00			
35	AS-40 Case Generic Fixture Removal	0:01:48			Operators Unscrew Fixtures after closeout/material/advance
36	AS-40 Case BrandedFixture Installation	0:01:00			
37	Issue CPJT's to the Line A and Line B		0:02:00		
38	Issue Wrap Labels / Case Bottom Labels		0:03:30		
39	Issue 0.15mg Stop Collars & Applicable label		0:02:30		
40	Issue 0.15mg Drive Rods & Applicable label		0:02:14		
41	Issue 0.15mg Bushings & Applicable label		0:02:05		
42	Issue BrandedNose Caps (Nutted)		0:02:10		
43	Issue BrandedSheath Removers (Green)		0:04:40		
44	Issue Firing Assemblies (Green)		0:02:05		
45	Add Foam Pads (0.25")		0:03:54		
46	Issue Branded Case Tops		0:03:15		
47	Issue Branded Case Bottoms / Load into AM-43 Hopper		0:23:00		Operators physically issue after parts are verified/signed BOM
48	BOM Material Verification / Startup BOM Verification		0:10:43		Procedure/sign Material Issuance in Advance
49	AS-72 Glue Bead Startup Checks / Settings Verification	0:01:43			
50	AS-52 Glue Bead Startup Checks / Settings Verification	0:01:40			
51	AM-30 Setup / Label Installation	0:03:15			
52	AM-42 Setup / Label Installation / Type Chase Warm Up	0:10:29			Stamp type chase in BR immediately after BR brought out
53	AS-65 Startup Vision Check	0:02:14			
54	Am-30 Pull Type Chase out list scan to Stamp in BR	0:15:25			
55	AM-30 Install Type Chase & Allow for Warm up	0:20:25			Stamp type chase in BR immediately after BR brought out
56	Complete all start up tasks/ documentation in BR		0:00:00		
	Total Internal Time	2:46:32		5:06:54	
	Total External Time		2:20:22		

Appendix B: Current State Setup Observation Chart (0.15mg Generic-to-0.30mg Generic).

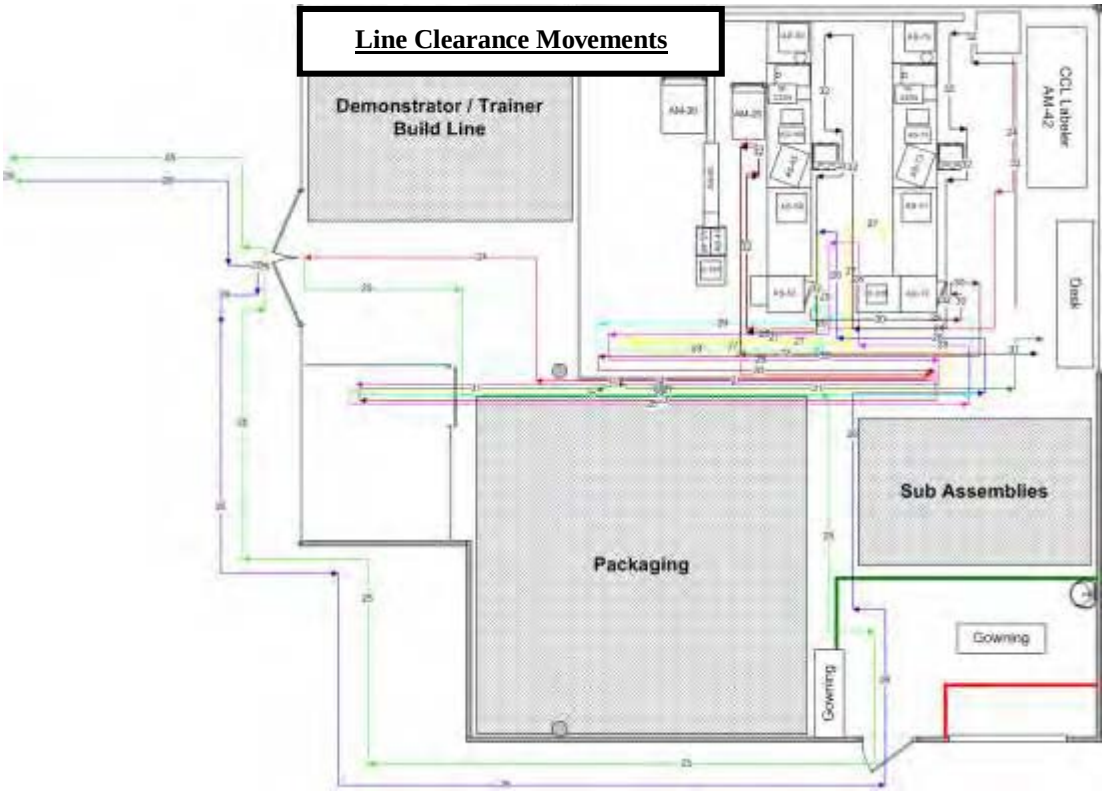
Changeover Configuration: 0.15mg Generic-to-0.30mg Generic (Like-for-Like) Date: 4/16/2010

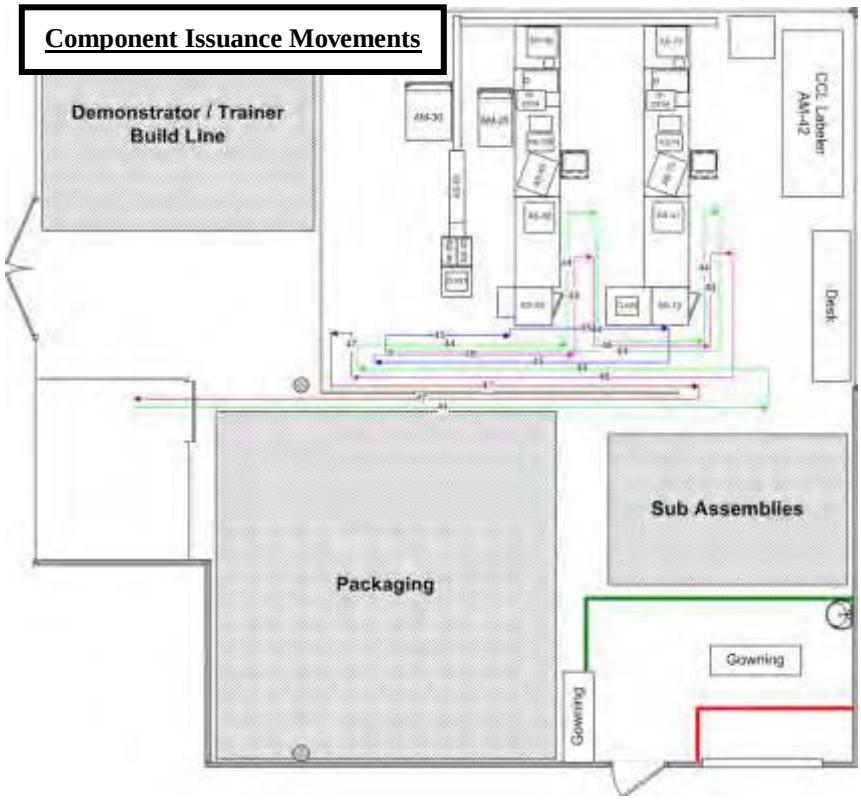
Step#	Set-up Element	Internal	External	Total Time (hh:mm:ss)	Comments/Improvement Ideas
				21:00:00	
1	Grooming Reject Sheets for BR Closeout		0:02:10		Operators could collect reject sheets and prep for PST
2	Batch Record Closeout (Reject Sheets / Reconciliation)		0:05:25		Control amount near end of run to eliminate longer unloading time
3	Batch Record Closeout (Yield Calculation)		0:03:35		
4	CPJT Yield/ Final Exit of Lot Closeout		0:05:12		PST must complete prior to leaving his/her shift
5	AM-30 Tear Down / Remove Labels / Remove Type Chase	0:00:30			
6	AM-20 Tear Down / Remove Labels	0:05:14			Tensioner Bar was cracked (could not easily get off/back) redesign improvement idea
7	Obtain Golden Samples (For Closeout)		0:01:04		
8	AS-45 Blended/Syringe Vision Challenge (Closeout) Line B	0:05:52			
9	AS-50 Generic Final Vision Challenge (Closeout) Line B	0:04:00			
10	AS-50 Generic Final Vision Challenge (Startup) Line B	0:04:04			
11	AS-75 Generic Final Vision Challenge (Closeout) Line A	0:04:00			
12	AS-75 Generic Final Vision Challenge (Startup) Line A	0:04:01			
13	AS-73 Syringe Vision Challenge (Closeout) Line A	0:05:31			
14	AS-73 Syringe Vision Challenge (Startup) Line A	0:08:26			
15	AS-45 Syringe Vision Challenge (Startup) Line B	0:08:01			
16	Obtain 0.3mg Dose Block Kits	0:01:10			
17	AS-41 Vision Challenge (No Dose) 0.15 Closeout	0:00:10			
18	Remove 0.15mg Install 0.3mg Dose Block AS-41 Line A	0:00:58			
19	AS-41 Vision Challenge (No Dose) 0.30 Startup	0:00:10			
20	AS-58 Vision Challenge (No Dose) 0.15 Closeout	0:00:10			
21	Remove 0.15mg Install 0.3mg Dose Block AS-58 Line B	0:00:58			Number of Screws on Dose Blocks Differ. (Can we eliminate screw on other)
22	AS-58 Vision Challenge (No Dose) 0.30 Startup	0:00:16			
23	Clearing Cased Parts		0:01:15		
24	Move Case Bottoms from the Line into the Warehouse		0:02:12		
25	Place Case Bottoms into totes and scan to the warehouse location		0:01:23		
26	Located Case Bottoms for the new Work Order, placed them into the container, and moved to White Room doors		0:04:25		
27	Collected Stop Collars on the Build Lines and changed labels to the new Work Order		0:04:00		
28	Collected Bushings on the Build Lines and changed labels to the new Work Order		0:04:30		
29	Cleaned out Drive Rods out of AS-52	0:02:55			
30	Cleaned out Drive Rods out of AS-72	0:01:33			
31	Finished cleaning out Build Lines and put parts from the old Work Order back in the cage		0:02:25		
32	Conduct Line Clearance	0:10:30			
33	Start BOM. Verify the part numbers are correct for the new Work Order and write down lot number for each		0:04:55		
34	Verify the part numbers are correct for the new Work Order and write down lot number for Stop Collars		0:05:45		
35	Verify the part numbers are correct for the new Work Order and write down lot number for CPJTs		0:01:00		
36	Forgot to remove some Stop Collars on the Line from the old Work Order		0:02:36		
37	Verified the part numbers are correct for the new Work Order and write down lot number for Stop Collars, Drive Rods, and Bushings		0:01:10		
38	Verified the part numbers are correct for the new Work Order and write down lot number for Case Bottoms		0:03:45		
39	Verified the part numbers are correct for the new Work Order and write down lot number for glue		0:01:25		
40	Verified the part numbers are correct for the new Work Order and write down lot number for Firing Assemblies		0:00:50		
41	Wait for Labels and quality approval of Line Clearance		0:20:50		
42	Forgot to remove Drive Rods from Hose in Drive Rod Gluing Device AS-52		0:02:47		
43	Forgot to remove Drive Rods from Hose in Drive Rod Gluing Device AS-72		0:02:30		
44	Stop Collars issued to the Build Lines		0:02:05		
45	3 Drive Rods issued to the Build Lines		0:01:50		
46	3 Bushings issued to the Build Lines		0:01:05		
47	Dispersion cardcontainers		0:01:05		
48	Verify Work Instructions		0:05:05		
49	AM-20 Setup/ Install Labels	0:02:50			
50	AM-30 Setup/ Install Labels / Install Typechase	0:33:57			Gluing (Type Chase at BR at start of pack) Allow for adequate typechase warm-up, possible preheater implementation
51	Load Case Bottoms into Hopper		0:01:35		
52	Issuing New Restock Sheets to the Line		0:02:47		
53	AS-72 Glue Bead Startup Checks / Settings Verification		0:02:20		
54	AS-52 Glue Bead Startup Checks / Settings Verification		0:02:14		
55	Overall Line Setup Checks		0:17:35		
	Total Internal Time	1:38:29		3:35:14	
	Total External Time		1:56:45		

Appendix C: Current State Spaghetti Diagrams (0.3mg Generic-to-0.15mg Branded).



Appendix D: Current State Spaghetti Diagrams (0.15mg Generic-to-0.30mg Generic).





Appendix E: Standard Changeover Documents (Process Steps 1-8, QT & PST).

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5054	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#1	**MACHINE ID(S):**	N/A

1. **Purpose**

1.1. The purpose of this document is to provide instruction for operators to conduct change-over/line clearance activities specific to each assembly station/process step.

2. **Definitions**

2.1. **Like-for-Like- Changeover**- includes the following change-over:

2.1.1. SDEAI to SDEAI (Generic to Generic)

2.1.2. TJ to TJ (Branded to Branded)

2.2. **Non-Like-for-Like - Changeover**- includes the following change-over:

2.2.1. SDEAI to TJ (Generic to Branded)

2.2.2. TJ to SDEAI (Branded to Generic)

3. **Change Over / Line Clearance Operator Instruction [PROCESS STEP 1]**

3.1. After the last good part has been produced for the current lot being manufactured at (Process Step #1) **THE OPERATORS ARE TO CONDUCT THE FOLLOWING ACTIVITIES TO ASSIST IN THE CHANGE-OVER PROCESS:**

3.2. Determine the platform configuration of next lot scheduled (SDEAI or TJ) (contact PSS or QT).

3.3. After ensuring the last produce has been processed follow change over steps listed in the table column below for **either** "Like for Like" or "Non-Like for Like" changeover.

3.4. After ensuring the last assembly has been processed follow the change over steps along with the dedicated change over columns below:

Process Step 1 - Change Over - Operator Process Steps
1) Verify all station **documentation (ie. Forms) have been completed** (*if applicable*)
2) Ensure all **unused drug product and applicable boxes, labels, clamshells** have been removed by QT and stored in **locked** storage.
3) Verify that there are no loose components/CPJT's **under all reject & component bins.**
4) Verify that there are no loose components/CPJT's **under the table** or **on the floor** of pre-inspection station.
5) Verify that there are no loose components/CPJT's **under or on weight scale**.
6) Verify that there are no components/CPJT's **under or on CPJT ramp.**
7) Verify the **lot numbers are affixed/legible** on both Shock Absorber Modifier & Shock Absorber bins and verify both component bins are filled for next lot.
8) Obtain and affix/hang the Green Indicator Circle "THIS LINE HAS BEEN CLEARED BY OPERATOR"

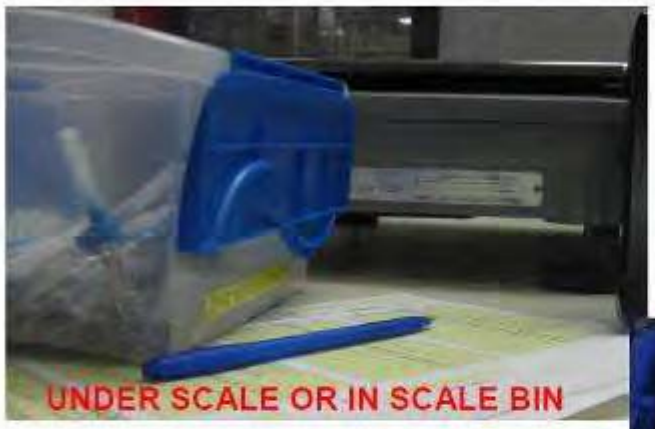
"Reject any loose or unidentified components/"strangers"

3.5. Reference the pictures on the following page/pages for **areas of emphasis** where "stranger components" can be found and ensure these spots have been inspected.

3.6. Verify all activities in the steps above have been completed and that the "THIS LINE HAS BEEN CLEARED BY OPERATOR" Green Circle is affixed on station indicating the station is ready for final line clearance verification and start-up of upcoming lot.

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5054	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#1	**MACHINE ID(S):**	N/A

Process Step 1 Areas of Emphasis



Phillips	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5054	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#1	**MACHINE ID(S):**	N/A

Verify all activities in the steps above have been completed and that the **"THIS LINE HAS BEEN CLEARED BY OPERATOR"** Green Circle is affixed on station indicating the station is ready for final line clearance verification and start-up of upcoming lot.

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5055	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#2	**MACHINE ID(S):**	AS-72 (Line A) / AS-52 (Line B)

1. Purpose

1.1. The purpose of this document is to provide instruction for operators to conduct change-over/line clearance activities specific to Process Step 2- (Line A/Line B) White Room Assembly.

2. Definitions

2.1. **Like-for-Like Changeover**- includes the following change-over:
- 2.1.1. 0.15mg SDEAI to 0.15mg SDEAI
- 2.1.2. 0.15mg TJ to 0.15mg TJ
- 2.1.3. 0.3mg SDEAI to 0.3mg SDEAI
- 2.1.4. 0.3mg TJ to 0.3mg TJ

2.2. **Non-Like-for-Like Changeover**- includes the following configuration change-over:
- 2.2.1. 0.15mg SDEAI to 0.3mg SDEAI (*or*) 0.3mg SDEAI to 0.15mg SDEAI
- 2.2.2. 0.15mg TJ to 0.3mg TJ (*or*) 0.3mg TJ to 0.15mg TJ
- 2.2.3. 0.15mg SDEAI to 0.15mg TJ (*or*) 0.15mg TJ to 0.3mg SDEAI

3. Change Over / Line Clearance Operator Instruction [PROCESS STEP 2]

3.1. After the last good part has been produced for the current lot being manufactured at (Process Step 2)

THE OPERATORS ARE TO CONDUCT THE FOLLOWING ACTIVITIES TO ASSIST IN THE CHANGE-OVER PROCESS:

3.1.1. Determine the dose/platform configuration of next work order scheduled (ask PSS or QT).

3.1.2. After ensuring the last assembly has been processed follow change over steps listed in the table below, "Like-for-Like" changeovers (*ie. 0.15mg to 0.15mg or 0.3mg to 0.3mg*)

3.1.3. After ensuring the last assembly has been processed follow the change over steps listed in the table below for Non-"Like-for-Like" changeovers (*ie. 0.15mg to 0.3mg or 0.3mg to 0.15mg*)

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5055	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#2	**MACHINE ID(S):**	AS-72 (Line A) / AS-52 (Line B)

Process Step 2 (Line A/ Line B)Change Over - Operator Process Steps

1) Verify all station specific **documentation (ie. Forms) have been completed** (*if applicable*)
2) Verify that there are no loose components/CPJT's **under all reject & component bins.**
3) Verify that there are no loose components/CPJT's **under the table** or **on the floor** of Drive Rod Gluing Station.
4) Reference the pictures on the following page/pages for areas of emphasis where "stranger components" can be found and ensure all of these spots have been inspected.

"Like for Like" Change Over	**"Non-"Like-for-Like" Change Over**
1) Verify the **lot numbers are affixed/legible** on Drive Rod, Bushing, and Adjustment Screw bins/compartments- These components can remain on the line for next "Like for Like lot."	1) Verify all areas of emphasis have been inspected and the **bowl feeder, closed loop tubing, loading blocks** of Drive Rod Gluing Machine(s) have been completely emptied and prepare all drive remaining drive rods to be issued back to the same lot number as listed as listed on component bin by PSS.
2) Verify that a TAPPI chart is present for the PST for point of use at start-up glue bead diameter checks. Verify calibration sticker is present and calibration due date is within calibration on TAPPI Chart.	2) Verify that all areas of emphasis have been inspected and the **Bushing bins have been completely emptied** and prepare all drive remaining Bushings to be issued back to the same lot number as listed on component bin by the PSS.
	3) Verify that a TAPPI chart is present for the PST for point of use at start-up glue bead diameter checks. Verify calibration sticker is present and calibration due date is within calibration on TAPPI Chart.

Verify all activities in the steps above have been completed and that the **"This Line Has Been Cleared By Operator"** Green Indicator Circle is affixed on station indicating the station is ready for final line clearance verification and start-up of upcoming lot.

CONTACT PSS AND INDICATE THAT THE STATION IS READY FOR LINE CLEARANCE VERIFICATION

PSS & QT –VERIFY THE STATION HAS BEEN CLEARED, GREEN INDICATOR STICKER IS REMOVED, WHITEROOM ASSEMBLY OPERATOR LINCE CLEARANCE FORM **F7.5334 (PSS), F7.5335 (QT), AND BRF-0011 (PSS/QT)** HAVE BEEN COMPLETED. ONCE COMPLETE THE "OLD" CHANGE OVER CART WITH BATCH RECORD CAN BE REMOVED FROM WHITE ROOM OR LOCKED IN CAGE.

QT—PRIOR TO CLOSEOUT - ENSURE ALL CORRECT CONFIGURATION COMPONENTS ARE PRESENT IN CAGE BEFORE ALLOWING OPERATOR ISSUANCE STEPS 4-6 BELOW. ONCE CART IS STOCKED AND VERIFICATION IS COMPLETE PSS/QT IS AUTHORIZED TO BRING IN NEW CHANGE-OVER CART. AND ENSURE F7.5335 IS PUT IN NEW BATCH RECORD.

	4) Verify the newly staged **Drive Rods** are the correct configuration (ref. new BOM in Batch Record). Once the PSS has recorded the lot numbers on the work order, Obtain the new Drive Rods from change-over cart and issue to the station (AS-52 or AS-72). Verify that the lot number is recorded on identification card affixed on AS-52/72.
"Like for Like" Change Over Activities Are Complete	5) Verify the newly staged **Bushings** are the correct configuration (ref. new BOM in Batch Record). Once the PSS has recorded the lot numbers on the work order, Obtain the new Bushings from change-over cart and issue to component bins at station. Verify that the lot number is recorded on the component bin the lot number on component bin. (Record the lot number on I.D. card if applicable)
	6) Verify the **Adjustment Screw** component bin has the lot number affixed and is legible.
	"Non- Like for Like" Change Over Activities Are Complete

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5055	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#2	**MACHINE ID(S):**	AS-72 (Line A) / AS-52 (Line B)

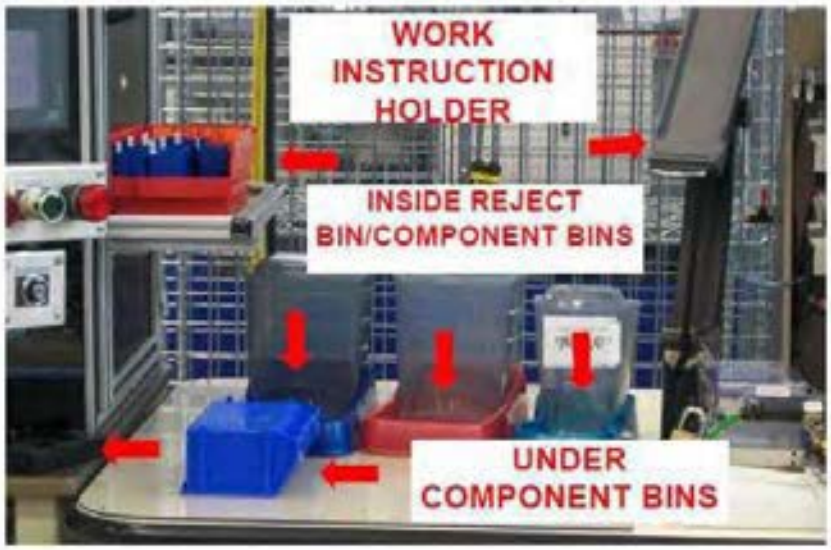
Process Step 2 Areas of Emphasis

Phillips	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5055	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#2	**MACHINE ID(S):**	AS-72 (Line A) / AS-52 (Line B)

Step 2
Continued

C-AS-XXX, Rev.

Phillips	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7 5055	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#2	**MACHINE ID(S):**	AS-72 (Line A) / AS-52 (Line B)



Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5055	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#2	**MACHINE ID(S):**	AS-72 (Line A) / AS-52 (Line B)

Verify all activities in the steps above have been completed and that the **"THIS LINE HAS BEEN CLEARED BY OPERATOR"** Green Circle is affixed on station indicating the station is ready for final line clearance verification and start-up of upcoming lot.

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5056	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#3	**MACHINE ID(S):**	AS-41 (Line A) / AS-58 (Line B)

1. **Purpose**

   1.1. The purpose of this document is to provide instruction for operators to conduct change-over/line clearance activities specific to Process Step 3- (Line A/Line B) White Room Assembly.

2. **Definitions**

   2.1. **Like-for-Like Changeover**- includes the following change-over:
   - 2.1.1. 0.15mg SDEAI to 0.15mg SDEAI
   - 2.1.2. 0.15mg TJ to 0.15mg TJ
   - 2.1.3. 0.3mg SDEAI to 0.3mg SDEAI
   - 2.1.4. 0.3mg TJ to 0.3mg TJ

   2.2. **Non-Like-for-Like Changeover**- includes the following configuration change-over:
   - 2.2.1. 0.15mg SDEAI to 0.3mg SDEAI (*or*) 0.3mg SDEAI to 0.15mg SDEAI
   - 2.2.2. 0.15mg TJ to 0.3mg TJ (*or*) 0.3mg TJ to 0.15mg TJ
   - 2.2.3. 0.15mg SDEAI to 0.15mg TJ (*or*) 0.15mg TJ to 0.3mg SDEAI

3. **Change Over / Line Clearance Operator Instruction [PROCESS STEP 3]**

   3.1. After the last good part has been produced for the current lot being manufactured at (Process Step 3)

   THE OPERATORS ARE TO CONDUCT THE FOLLOWING ACTIVITIES TO ASSIST IN THE CHANGE-OVER PROCESS:

   3.2. Determine the dose/platform configuration of next work order scheduled (ask PSS or QT).

   3.3. After ensuring the last assembly has been processed follow change over steps listed in the table below, "Like-for-Like" changeovers (*ie. 0.15mg to 0.15mg or 0.3mg to 0.3mg*)

   3.4. After ensuring the last assembly has been processed follow the change over steps listed in the table below for Non-"Like-for-Like" changeovers (*ie. 0.15mg to 0.3mg or 0.3mg to 0.15mg*)

Phillips	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5056	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#3	**MACHINE ID(S):**	AS-41 (Line A) / AS-58 (Line B)

Process Step 3 (Line A/ Line B) Change Over - Operator Process Steps
1) Verify all station specific **documentation (ie. Forms) have been completed** (*if applicable*)
2) Verify that there are no loose components/CPJT's **under all reject & component bins.**
3) Verify that there are no loose components/CPJT's **under the table** or **on the floor** of Adj. Screw Setting Station.
4) Reference the pictures on the following page/pages for areas of emphasis where "stranger components" can be found and ensure all of these spots have been inspected.

"Like for Like" Change Over	**"Non-"Like-for-Like" Change Over**
1) Verify the **lot numbers are affixed / legible** on the Stop Collar bins/compartments- These components can remain on the line for next "Like for Like lot."	1) Verify that all **Stop Collar bins have been completely emptied** and all remaining Stop Collars in the bin are prepared to be issued back to the same lot number as listed as listed on component bin by PSS.
2) Verify the Dose Blocks are securely fastened for the next manufacturing lot and verify the point of use Allen Wrench is present on shadow board (reference picture page)	2) Verify all syringe assemblies have been processed, and obtain the Allen Wrench from point of use shadow board and **loosen** the bolts and remove the Dose Block on AS-58 or AS-41 for PSS. (Reference picture page for visual instruction)

Verify all activities in the steps above have been completed and that the "**This Line Has Been Cleared By Operator**" **Green Indicator Circle** is affixed on station indicating the station is ready for final line clearance verification and start-up of upcoming lot.

CONTACT PSS AND INDICATE THAT THE STATION IS READY FOR LINE CLEARANCE VERIFICATION

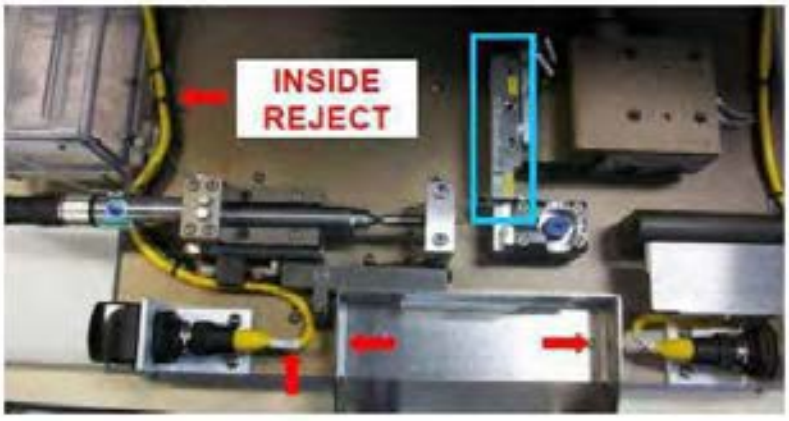
PSS & QT – VERIFY THE STATION HAS BEEN CLEARED, GREEN INDICATOR STICKER IS REMOVED, WHITEROOM ASSEMBLY OPERATOR LINCE CLEARANCE FORM **F7.5334 (PSS)** and **F7.5335 (QT)** HAVE BEEN COMPLETED. ONCE COMPLETE THE "OLD" CHANGE OVER CART WITH BATCH RECORD CAN BE REMOVED FROM WHITE ROOM OR LOCKED IN CAGE.

QT—PRIOR TO CLOSEOUT - ENSURE ALL CORRECT CONFIGURATION COMPONENTS ARE PRESENT IN CAGE BEFORE ALLOWING OPERATOR ISSUANCE STEPS 3-4 BELOW. ONCE CART IS STOCKED AND VERIFICATION IS COMPLETE PSS/QT IS AUTHORIZED TO BRING IN NEW CHANGE-OVER CART AND ENSURE F7.5335 IS PUT IN NEW BATCH RECORD.

PROCESS STEP 3 ***"Like for Like" Change Over Activities Are Complete"***	3) Verify the Stop Collars in the Change Over cage are the correct configuration (ref. new BOM in Batch Record). Once the PSS has recorded the lot numbers on the work order, Obtain the new Stop Collars from change-over cart and issue to component bins at station. Verify that the lot number is recorded on the component bin the lot number on component bin of AS-58/AS-41. (Record the lot number on I.D. card if applicable)
	4) Obtain the new Dose Block ID# from changeover cart and place near AS-58/AS-41 Station for PSS installation. Verify both the torque fasteners and point of use wrench is present for installation by PSS.
	PROCESS STEP 3 ***"Non- Like for Like" Change Over Activities Are Complete"***

Phillips	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5056	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#3	**MACHINE ID(S):**	AS-41 (Line A) / AS-58 (Line B)

Process Step 3 Areas of Emphasis



Phillips	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5656	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#3	**MACHINE ID(S):**	AS-41 (Line A) / AS-58 (Line B)

Phillips	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5056	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#3	**MACHINE ID(S):**	AS-41 (Line A) / AS-58 (Line B)

Verify all syringe assemblies have been processed, and obtain the Allen Wrench from *point of use shadow board* and **loosen** the bolts and remove the Dose Block on AS-58 or AS-41 and place the two fasteners and Dose Block in EMPTY Stop Collar Tray for PSS.

Utilize *Point of Use* Allen Wrench for loosening Dose Block Fasteners. Ensure the wrench is put back upon completion.

Verify all activities in the steps above have been completed and that the **"THIS LINE HAS BEEN CLEARED BY OPERATOR"** Green Circle is affixed on station indicating the station is ready for final line clearance verification and start-up of upcoming lot.

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5057	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#4	**MACHINE ID(S):**	AS-73 (Line A) / AS-106 (Line B)

1. **Purpose**

   1.1. The purpose of this document is to provide instruction for operators to conduct change-over/line clearance activities specific to Process Step 4- (Line A/Line B) White Room Assembly.

2. **Definitions**

   2.1. **Like-for-Like Changeover**- includes the following change-over:
   - 2.1.1. 0.15mg SDEAI to 0.15mg SDEAI
   - 2.1.2. 0.15mg TJ to 0.15mg TJ
   - 2.1.3. 0.3mg SDEAI to 0.3mg SDEAI
   - 2.1.4. 0.3mg TJ to 0.3mg TJ

   2.2. **Non-Like-for-Like Changeover**- includes the following configuration change-over:
   - 2.2.1. 0.15mg SDEAI to 0.3mg SDEAI (*or*) 0.3mg SDEAI to 0.15mg SDEAI
   - 2.2.2. 0.15mg TJ to 0.3mg TJ (*or*) 0.3mg TJ to 0.15mg TJ
   - 2.2.3. 0.15mg SDEAI to 0.15mg TJ (*or*) 0.15mg TJ to 0.3mg SDEAI

3. **Change Over / Line Clearance Operator Instruction [PROCESS STEP 4]**

   3.1. After the last good part has been produced for the current lot being manufactured at (Process Step 4)

   THE OPERATORS ARE TO CONDUCT THE FOLLOWING ACTIVITIES TO ASSIST IN THE CHANGE-OVER PROCESS:

   3.2. Determine the dose/platform configuration of next work order scheduled (ask PSS or QT).

   3.3. After ensuring the last assembly has been processed follow change over steps listed in the table below, "Like-for-Like" changeovers (*ie. 0.15mg to 0.15mg or 0.3mg to 0.3mg*)

   3.4. After ensuring the last assembly has been processed follow the change over steps listed in the table below for Non-"Like-for-Like" changeovers (*ie. 0.15mg to 0.3mg or 0.3mg to 0.15mg*)

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5057	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#4	**MACHINE ID(S):**	AS-73 (Line A) / AS-106 (Line B)

Process Step 4 (Line A/ Line B) Change Over - Operator Process Steps

1) Verify all station specific **documentation (ie. Forms) have been completed** (*if applicable*)
2) Verify that there are no loose components **under all reject & component bins.**
3) Verify that there are no loose components **under the table** or **on the floor** of Final Assembly (Nose Cap Seating) Station.
4) Reference the pictures on the following page/pages for areas of emphasis where "stranger components" can be found and ensure all of these spots have been inspected.

"Like for Like" Change Over	"Non-"Like-for-Like" Change Over
1) Verify the **lot numbers are affixed / legible** on both the Nose Cap & Firing Assembly Trays- These components can remain on the line for next "Like for Like lot."	1) Verify that all **reject bins have been completely emptied** and all remaining **Nose Cap Assembly Trays** are removed from the line and are prepared to be issued back to stock with the same part/lot number by PSS. Note: The "knurled" Nose Cap Assemblies are for Branded only and the "smooth" Nose Cap Assemblies are for SDEAI only.
2) Verify all reject bins have been emptied and locks are locked/present on reject (poka-yoke) bins.	2) Verify that all **reject bins have been completely emptied** and all remaining **Firing Assembly Trays** are removed from line and are prepared to be issued back to stock with the same part/lot number by PSS. Note: The "Green" Firing Assemblies are for Branded only and the "Gray" Firing Assemblies are for SDEAI only.
Verify all activities in the steps above have been completed and that the **"This Line Has Been Cleared By Operator"** Green Indicator Circle is affixed on station indicating the station is ready for final line clearance verification and start-up of upcoming lot. **CONTACT PSS AND INDICATE THAT THE STATION IS READY FOR LINE CLEARANCE VERIFICATION**	
PSS & QT – VERIFY THE STATION HAS BEEN CLEARED, GREEN INDICATOR STICKER IS REMOVED, WHITEROOM ASSEMBLY OPERATOR LINCE CLEARANCE FORM **F7.5334 (PSS)** and **F7.5335 (QT)** HAVE BEEN COMPLETED. ONCE COMPLETE THE "OLD" CHANGE OVER CART WITH BATCH RECORD CAN BE REMOVED FROM WHITE ROOM OR LOCKED IN CAGE. QT—PRIOR TO CLOSEOUT - ENSURE ALL CORRECT CONFIGURATION COMPONENTS ARE PRESENT IN CAGE BEFORE ALLOWING OPERATOR ISSUANCE STEP 4 BELOW. ONCE CART IS STOCKED AND VERIFICATION IS COMPLETE PSS/QT IS AUTHORIZED TO BRING IN NEW CHANGE-OVER CART AND ENSURE F7.5335 IS PUT IN NEW BATCH RECORD.	
PROCESS STEP 4 ***"Like for Like" Change Over Activities Are Complete"***	4) Verify the newly staged Nose Cap Assemblies & Firing Assemblies are the correct configuration (ref. new BOM in Batch Record). **Nose Cap Assembly**-(Knurled – Branded) or (Smooth – SDEAI) **Firing Assembly**- (Green – Branded) or (Gray- SDEAI) Obtain and issue the new Nose Cap & Firing Assemblies to the station. Verify the **lot numbers are affixed / legible** on the new Nose Cap Assembly Tray. ***PROCESS STEP 4*** ***"Non- Like for Like" Change Over Activities Are Complete"***

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5057	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#4	**MACHINE ID(S):**	AS-73 (Line A) / AS-106 (Line B)

STATION 4 - Area's of Emphasis/Reference Pictures:

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5058	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#5	**MACHINE ID(S):**	W-23 (Line A) / W-24 (Line B) [Welders] AS-75 (Line A) / AS-50 (Line B) [Final Vision]

1. **Purpose**

   1.1. The purpose of this document is to provide instruction for operators to conduct change-over/line clearance activities specific to Process Step 5- (Line A/Line B) White Room Assembly.

2. **Definitions**

   2.1. **Like-for-Like Changeover**- includes the following change-over:
   - 2.1.1. 0.15mg SDEAI to 0.15mg SDEAI
   - 2.1.2. 0.15mg TJ to 0.15mg TJ
   - 2.1.3. 0.3mg SDEAI to 0.3mg SDEAI
   - 2.1.4. 0.3mg TJ to 0.3mg TJ

   2.2. **Non-Like-for-Like Changeover**- includes the following configuration change-over:
   - 2.2.1. 0.15mg SDEAI to 0.3mg SDEAI (*or*) 0.3mg SDEAI to 0.15mg SDEAI
   - 2.2.2. 0.15mg TJ to 0.3mg TJ (*or*) 0.3mg TJ to 0.15mg TJ
   - 2.2.3. 0.15mg SDEAI to 0.15mg TJ (*or*) 0.15mg TJ to 0.3mg SDEAI

3. **Change Over / Line Clearance Operator Instruction [PROCESS STEP 5]**

   3.1. After the last good part has been produced / inspected for the current lot being manufactured at (Process Step 5)

   THE OPERATORS ARE TO CONDUCT THE FOLLOWING ACTIVITIES TO ASSIST IN THE CHANGE-OVER PROCESS:

   3.2. Determine the dose/platform configuration of next work order scheduled (ask PSS or QT).

   3.3. After ensuring the last assembly has been processed follow change over steps listed in the table below, "Like-for-Like" changeovers (*ie. 0.15mg to 0.15mg or 0.3mg to 0.3mg*)

   3.4. After ensuring the last assembly has been processed follow the change over steps listed in the table below for Non-"Like-for-Like" changeovers (*ie. 0.15mg to 0.3mg or 0.3mg to 0.15mg*)

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5058	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#5	**MACHINE ID(S):**	W-23 (Line A) / W-24 (Line B) [Welders] AS-75 (Line A) / AS-50 (Line B) [Final Vision]

Process Step 5 (Line A/ Line B) Change Over - Operator Process Steps

1) Verify all station specific **documentation (ie. Forms) have been completed** (*if applicable*)
2) Verify that there are no loose components **under all reject & component bins.**
3) Verify that there are no loose components **under the table** or **on the floor** of Sonic Welder & Final Assembly Vision Station
4) Reference the pictures on the following page/pages for areas of emphasis where "stranger components" can be found and ensure all of these spots have been inspected.

"Like for Like" Change Over	**"Non-"Like-for-Like" Change Over**
1) Verify that there are no Final Assemblies on the Final Assembly Conveyor	1) Verify that there are no Final Assemblies on the Final Assembly Conveyor
2) If the change-over is (Branded to Branded or SDEAI to SDEAI) **then the Sheath Removers may remain in component bin.** Note: The "Green" Sheath Removers are for Branded only and the "Gray" Sheath Removers are for SDEAI only	2) Verify that all **reject bins have been completely emptied and the lot number has been removed from component bin**. If the change-over is Branded to SDEAI or SDEAI to Branded that **all remaining Sheath Removers should be removed from line and are prepared to be issued back to stock with the same part/lot number by PSS.** Note: The "Green" Sheath Removers are for Branded only and the "Gray" Sheath Removers are for SDEAI only.
3) Verify all reject bins have been emptied and locks are locked/present on reject (poka-yoke) bins.	3) Verify that all Welding Rejects (SDEAI lots only) and Final Assembly Vision Rejects have been removed from the line for reconciliation.
	4) Remove the posted BRWI's (Work Instructions) and place in change over cart for the next lot **(only if change over is from SDEAI to Branded or Branded to SDEAI)**

Verify all activities in the steps above have been completed and that the **"This Line Has Been Cleared By Operator"** Green Indicator Circle is affixed on station indicating the station is ready for final line clearance verification and start-up of upcoming lot.

CONTACT PSS AND INDICATE THAT THE STATION IS READY FOR LINE CLEARANCE VERIFICATION

PSS & QT – VERIFY THE STATION HAS BEEN CLEARED, GREEN INDICATOR STICKER IS REMOVED, WHITEROOM ASSEMBLY OPERATOR LINCE CLEARANCE FORM **F7.5334 (PSS)** and **F7.5335 (QT)** HAVE BEEN COMPLETED. ONCE COMPLETE THE "OLD" CHANGE OVER CART WITH BATCH RECORD CAN BE REMOVED FROM WHITE ROOM OR LOCKED IN CAGE.

QT—PRIOR TO CLOSEOUT - ENSURE ALL CORRECT CONFIGURATION COMPONENTS ARE PRESENT IN CAGE BEFORE ALLOWING OPERATOR ISSUANCE STEP 5-7 BELOW. ONCE CART IS STOCKED AND VERIFICATION IS COMPLETE PSS/QT IS AUTHORIZED TO BRING IN NEW CHANGE-OVER CART AND ENSURE F7.5335 IS PUT IN NEW BATCH RECORD

PROCESS STEP 5 *"Like for Like" Change Over Activities Are Complete"*	5) Verify the newly staged **Sheath Removers** are the correct configuration (ref. new BOM in Batch Record) **Sheath Removers**- (Green – Branded) or (Gray - SDEAI) Once the PSS has recorded the lot numbers on the work order, Obtain the new Sheath Removers from change-over cart and issue to component bins at station. Verify that the lot number is recorded on the component bin the lot number on component bin. (Record the lot number on I.D. card if applicable)
	6) Verify the Final Vision Golden Samples are staged at Line A Final Vision Station (AS-75) for PST to conduct start-up checks for next lot. Note: There are separate golden samples for Branded and SDEAI lots.
	7) Obtain the new BRWI's (Work Instructions) from the change-over cart in accordance to the new Batch Record and issue to the station.
	PROCESS STEP 5 *"Non- Like for Like" Change Over Activities Are Complete"*

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5058	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#5	**MACHINE ID(S):**	W-23 (Line A) / W-24 (Line B) [Welders] AS-75 (Line A) / AS-50 (Line B) [Final Vision]

Process Step 5 Areas of Emphasis

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5058	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#5	**MACHINE ID(S):**	W-23 (Line A) / W-24 (Line B) [Welders] AS-75 (Line A) / AS-50 (Line B) [Final Vision]

ON ANY OF THE CONVEYORS

BETWEEN THE BUILD LINE AND THE LABELER

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5059	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#7	**MACHINE ID(S):**	**AM-47** [High Speed Labeler]

1. **Purpose**

   1.1. The purpose of this document is to provide instruction for operators to conduct change-over/line clearance activities specific to Process Step 7 - White Room Assembly.

2. **Definitions**

   2.1. **Like-for-Like Changeover**- includes the following change-over:
   - 2.1.1. 0.15mg SDEAI to 0.15mg SDEAI
   - 2.1.2. 0.15mg TJ to 0.15mg TJ
   - 2.1.3. 0.3mg SDEAI to 0.3mg SDEAI
   - 2.1.4. 0.3mg TJ to 0.3mg TJ

   2.2. **Non-Like-for-Like Changeover**- includes the following configuration change-over:
   - 2.2.1. 0.15mg SDEAI to 0.3mg SDEAI (*or*) 0.3mg SDEAI to 0.15mg SDEAI
   - 2.2.2. 0.15mg TJ to 0.3mg TJ (*or*) 0.3mg TJ to 0.15mg TJ
   - 2.2.3. 0.15mg SDEAI to 0.15mg TJ (*or*) 0.15mg TJ to 0.3mg SDEAI

3. **Change Over / Line Clearance Operator Instruction [PROCESS STEP 7]**

   3.1. After the last good part has been produced/inspected for the current lot being manufactured at (Process Step 7)

   THE OPERATORS ARE TO CONDUCT THE FOLLOWING ACTIVITIES TO ASSIST IN THE CHANGE-OVER PROCESS:

   3.2. Determine the dose/platform configuration of next work order scheduled (ask PSS or QT).

   3.3. After ensuring the last assembly has been processed follow change over steps listed in the table below, "Like-for-Like" changeovers (*ie. 0.15mg to 0.15mg or 0.3mg to 0.3mg*)

   3.4. After ensuring the last assembly has been processed follow the change over steps listed in the table below for Non-"Like-for-Like" changeovers (*ie. 0.15mg to 0.3mg or 0.3mg to 0.15mg*)

Process Step Change Over – Operator Process Steps
1) Verify all station specific **documentation (ie. Forms) have been completed** (*if applicable*)
2) Verify that there are no loose components **under all reject & component bins.**
3) Verify that there are no loose components **under the table** or **on the floor** near AM-47 High Speed Labeler and Ancillary Equipment (ie. Bowl Feeders, Component Bins, Labeler Exit Chute, Hoppers, etc)
4) Reference the pictures on the following page/pages for areas of emphasis where "stranger components" can be found and ensure all of these spots have been inspected.

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5059	REVISION DATE:	XX/XX/XX
	PROCESS STEP#7	MACHINE ID(S):	AM-47 [High Speed Labeler]

"Like for Like" Change Over	"Non-"Like-for-Like" Change Over
1) Verify that there are no Final Assemblies / Labels on the Final Assembly Conveyor, Labeler Rollers, and Out Feeder Chutes/Bins (Reference picture pages)	1) Verify that there are no Final Assemblies / Labels on the Final Assembly Conveyor, Labeler Rollers, and Out Feeder Chutes/Bins (Reference picture pages)
2) Verify the **lot numbers are affixed / legible** on the Case Bottom bins/compartments- These components can remain on the line for next "Like for Like lot." Note: The following colors of Case Bottom are representative of the platform/dosage lots as follows: "Green-0.15mg Branded," or "Blue-0.3mg Branded," "Black- 0.3mg SDEAL," or "Purple- 0.15mg SDEAL."	2) Verify that all **Case Bottom bins have been completely emptied** and all remaining unlabeled Case Bottoms in the bin, in-feed, and labeler queue are issued back to the same lot number as listed on component bin by the PSS. Note: The following colors of Case Bottom are representative of the platform/dosage lots as follows: "Green-0.15mg Branded," or "Blue-0.3mg Branded," "Black 0.3mg SDEAL," or "Purple- 0.15mg SDEAL." **Ensure that these colors are not mixed when during issuance.**
3) Verify all reject bins have been emptied and locks are locked/present on reject (poka-yoke) bins.	3) Verify all **Foam Pads** have been completely removed from the bowl feeders, hopper, and labeler and prepare all remaining Foam Pads to be issued back to the same lot number as listed as listed on component bin by PSS.
	4) Verify that all **Labeling (both Wrap and Case Bottom Labels)** have been removed from AM-47 by PSS and that there are no labels on reject plate, labeler exit, or under labeler (reference picture pages for areas of emphasis).
	5) Verify all reject label reject books and reject bins have been removed and locks are present/locked (as applicable)
Verify all activities in the steps above have been completed and that the **"This Line Has Been Cleared By Operator"** Green Indicator Circle is affixed on station indicating the station is ready for final line clearance verification and start-up of upcoming lot. **CONTACT PSS AND INDICATE THAT THE STATION IS READY FOR LINE CLEARANCE VERIFICATION**	
PSS & QT –VERIFY THE STATION HAS BEEN CLEARED, GREEN INDICATOR STICKER IS REMOVED, WHITEROOM ASSEMBLY OPERATOR LINCE CLEARANCE FORM **F7.5334 (PSS), F7.5335 (QT), AND BRF-0011 (PSS/QT)** HAVE BEEN COMPLETED. ONCE COMPLETE THE "OLD" CHANGE OVER CART WITH BATCH RECORD CAN BE REMOVED FROM WHITE ROOM OR LOCKED IN CAGE. QT—PRIOR TO CLOSEOUT - ENSURE ALL CORRECT CONFIGURATION COMPONENTS ARE PRESENT IN CAGE BEFORE ALLOWING OPERATOR ISSUANCE STEPS 6-8 BELOW. ONCE CART IS STOCKED AND VERIFICATION IS COMPLETE PSS/QT IS AUTHORIZED TO BRING IN NEW CHANGE-OVER CART. AND ENSURE F7.5335 IS PUT IN NEW BATCH RECORD.	
	6) Verify the newly staged **Case Bottoms** are the correct configuration & color (ref. new BOM in Batch Record). Once the PSS has recorded the lot numbers on the work order, Obtain the new Case Bottoms from change-over cart and issue to component bins at station. Verify the **lot numbers are affixed / legible** on the Case Bottom bin.
	7) Verify the newly staged **Foam Pads** are the correct configuration & size (ref. new BOM in Batch Record). Once the PSS has recorded the lot numbers on the work order, Obtain the new Case Bottoms from change-over cart and issue to component bins at station. Verify the **lot numbers are affixed / legible** on the Foam Pad hopper.
PROCESS STEP 7 *"Like for Like" Change Over Activities Are Complete"*	8) Verify that all **Labeling (both Wrap and Case Bottom Labels)** are the correct configuration (ref. new BOM in Batch Record)
	PROCESS STEP 7 *"Non- Like for Like" Change Over Activities Are Complete"*

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	CUSTOMER: Customer name confidential	PART NAME:	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5059	REVISION DATE:	XX/XX/XX
	PROCESS STEP#7	MACHINE ID(S):	AM-47 [High Speed Labeler]

Process Step 7 - Area's of Emphasis/ Reference Pictures:

CLOSE UP OF CASE
BOTTOM FEEDER
TRACK

 This document is electronically controlle

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	DOC#: DOC7.5059	REVISION DATE:	XX/XX/XX
	PROCESS STEP#7	MACHINE ID(S):	AM-47 [High Speed Labeler]

INSIDE FOAM HOPPER, BOWL FEEDER, AND TRACK

UNDER THE HOPPER AND BOWL FEEDER

LOOK AROUND CORNERS AND BETWEEN WIRES

This

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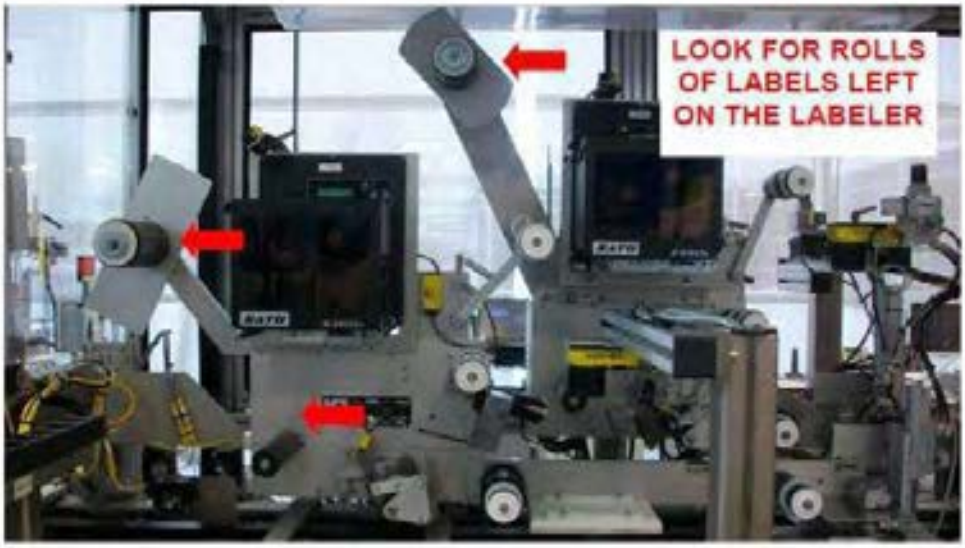
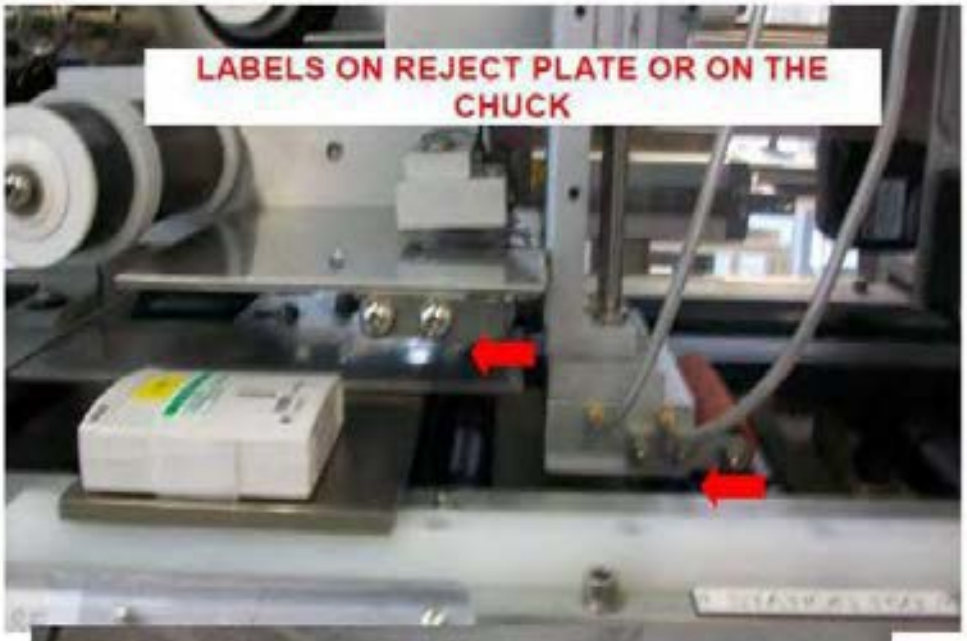
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5059	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#7	**MACHINE ID(S):**	**AM-47** [High Speed Labeler]



Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	PART NAME:	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5059	REVISION DATE:	XX/XX/XX
	PROCESS STEP#7	MACHINE ID(S):	AM-47 [High Speed Labeler]



Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5059	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#7	**MACHINE ID(S):**	**AM-47** [High Speed Labeler]

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Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5059	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#7	**MACHINE ID(S):**	**AM-47** (High Speed Labeler)

Phillips PHILLIPS PLASTICS CORPORATION™	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5060	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#8	**MACHINE ID(S):**	AS-40 (Caser) / AS-46 (Caser)

1. **Purpose**

   1.1. The purpose of this document is to provide instruction for operators to conduct change-over/line clearance activities specific to Process Step 8 - White Room Assembly.

2. **Definitions**

   2.1. **Like-for-Like Changeover**- includes the following change-over:
   - 2.1.1. 0.15mg SDEAI to 0.15mg SDEAI
   - 2.1.2. 0.15mg TJ to 0.15mg TJ
   - 2.1.3. 0.3mg SDEAI to 0.3mg SDEAI
   - 2.1.4. 0.3mg TJ to 0.3mg TJ

   2.2. **Non-Like-for-Like Changeover**- includes the following configuration change-over:
   - 2.2.1. 0.15mg SDEAI to 0.3mg SDEAI (*or*) 0.3mg SDEAI to 0.15mg SDEAI
   - 2.2.2. 0.15mg TJ to 0.3mg TJ (*or*) 0.3mg TJ to 0.15mg TJ
   - 2.2.3. 0.15mg SDEAI to 0.15mg TJ (*or*) 0.15mg TJ to 0.3mg SDEAI

3. **Change Over / Line Clearance Operator Instruction [PROCESS STEP 8]**

   3.1. After the last good part has been produced / inspected for the current lot being manufactured at (Process Step 8)

   THE OPERATORS ARE TO CONDUCT THE FOLLOWING ACTIVITIES TO ASSIST IN THE CHANGE-OVER PROCESS:

   3.2. Determine the dose/platform configuration of next work order scheduled (ask PSS or QT).

   3.3. After ensuring the last assembly has been processed follow change over steps listed in the table below, "Like-for-Like" changeovers (*ie. 0.15mg to 0.15mg or 0.3mg to 0.3mg*)

   3.4. After ensuring the last assembly has been processed follow the change over steps listed in the table below for Non-"Like-for-Like" changeovers (*ie. 0.15mg to 0.3mg or 0.3mg to 0.15mg*)

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5060	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#8	**MACHINE ID(S):**	AS-40 (Caser) / AS-46 (Caser)

Process Step 8 Change Over - Operator Process Steps	
1) Verify all station specific **documentation (ie. Forms) have been completed** (*if applicable*)	
2) Verify that there are no loose components **under all reject & component bins.**	
3) Verify that there are no loose components **under the table** or **on the floor** near Casing Equipment.	
4) Reference the pictures on the following page/pages for areas of emphasis where "stranger components" can be found and ensure all of these spots have been inspected.	
"Like for Like" Change Over	**"Non-"Like-for-Like" Change Over**
1) Verify that there are no Final Assemblies under the Casing Equipment, on Conveyor, under Scale, Reject Bins or tote. (Reference picture pages)	
2) Verify the Caser Fixtures are secured and not loose for next lot if the change-over is (Brandedto Brandedor SDEAI to SDEAI). Note: These Casing Fixtures are designed to accommodate each platform either Brandedor SDEAI.	2) Remove the Caser Fixture by loosening the bolts (reference picture page). Replace with new Caser Fixtures (Blue-TJ and Yellow-SDEAI)
3) Verify all reject bins have been emptied and locks are locked/present on reject (poka-yoke) bins.	
Verify all activities in the steps above have been completed and that the **"This Line Has Been Cleared By Operator"** Green Indicator Circle is affixed on station indicating the station is ready for final line clearance verification and start-up of upcoming lot. **CONTACT PSS AND INDICATE THAT THE STATION IS READY FOR LINE CLEARANCE VERIFICATION**	
PSS & QT –VERIFY THE STATION HAS BEEN CLEARED, GREEN INDICATOR STICKER IS REMOVED, WHITEROOM ASSEMBLY OPERATOR LINCE CLEARANCE FORM **F7.5334 (PSS), F7.5335 (QT), AND BRF-0011 (PSS/QT)** HAVE BEEN COMPLETED. ONCE COMPLETE THE "OLD" CHANGE OVER CART WITH BATCH RECORD CAN BE REMOVED FROM WHITE ROOM OR LOCKED IN CAGE. QT—PRIOR TO CLOSEOUT - ENSURE ALL CORRECT CONFIGURATION COMPONENTS ARE PRESENT IN CAGE BEFORE ALLOWING OPERATOR ISSUANCE STEP 6 BELOW. ONCE CART IS STOCKED AND VERIFICATION IS COMPLETE PSS/QT IS AUTHORIZED TO BRING IN NEW CHANGE-OVER CART. ENSURE F7.5335 IS PUT IN NEW BATCH RECORD.	
	6) Obtain and Verify the newly staged Caser Fixtures are the correct size & color for new lot configuration. (Blue-TJ and Yellow-SDEAI)
PROCESS STEP 8 ***"Like for Like" Change Over Activities Are Complete"***	***PROCESS STEP 8*** ***"Non- Like for Like" Change Over Activities Are Complete"***

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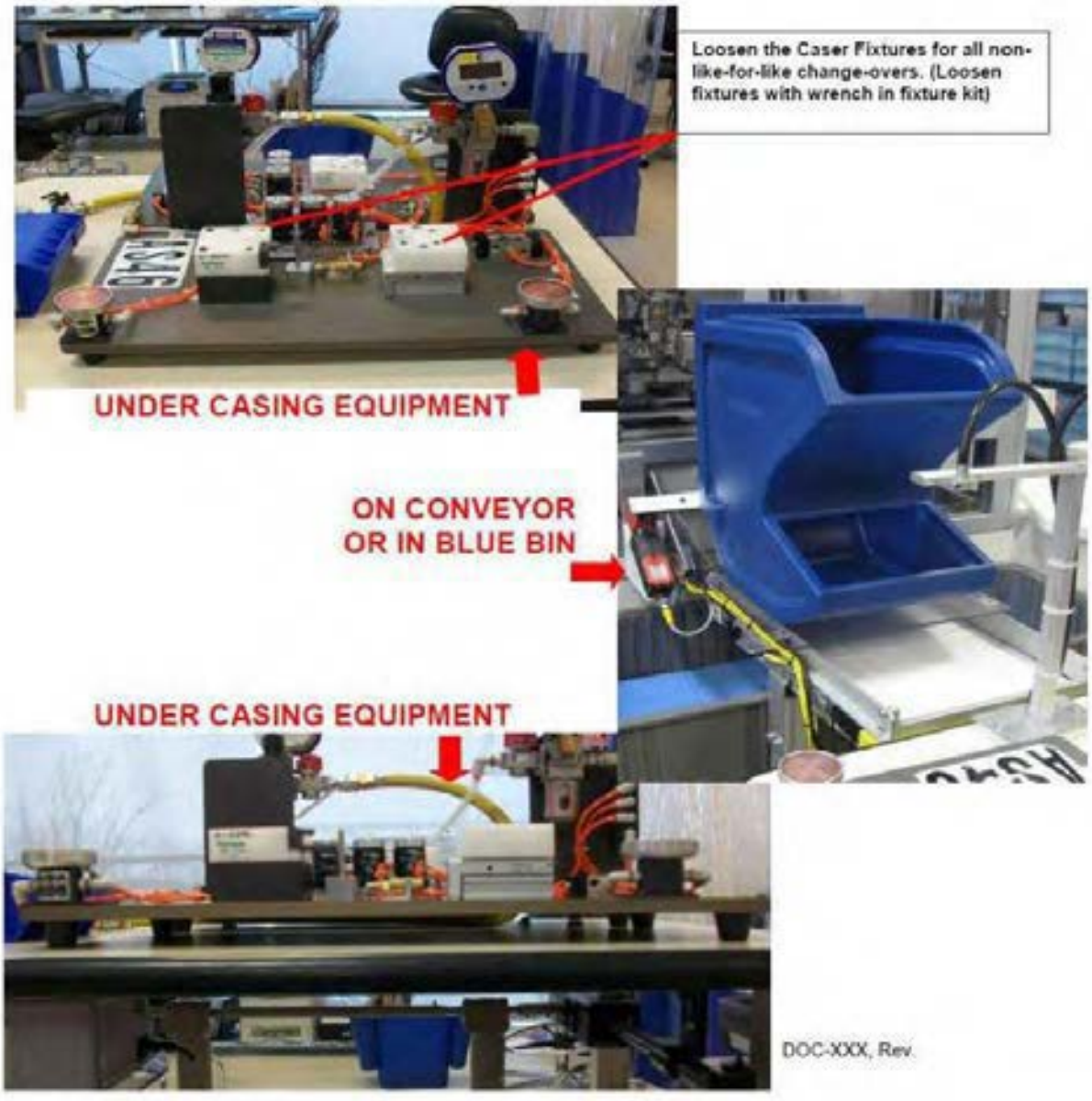
	CUSTOMER: Customer name confidential	PART NAME:	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5060	REVISION DATE:	XX/XX/XX
	PROCESS STEP#8	MACHINE ID(S):	AS-40 (Caser) / AS-46 (Caser)

PROCESS STEP 8 – AREAS OF EMPHASIS



Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7 5060	**REVISION DATE:**	XX/XX/XX
	PROCESS STEP#8	**MACHINE ID(S):**	AS-40 (Caser) / AS-46 (Caser)

UNDER SCALE

UNDER TABLE

IN REJECT BIN OR TOTE

Phillips	CHANGE-OVER / LINE CLEARANCE OPERATOR INSTRUCTION DOCUMENT		
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	DOC#: DOC7.5060	REVISION DATE:	XX/XX/XX
	PROCESS STEP#S	MACHINE ID(S):	AS-40 (Caser) / AS-46 (Caser)

INSIDE REJECT BINS
(LOOK BETWEEN BLUE BINS)

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE PRODUCTION SUPPORT SPECIALIST INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	PART NAME:	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5062	REVISION DATE:	XX/XX/XX
	PROCESS FLOW	MACHINE ID(S):	N/A

CHANGE OVER PROCESS FLOW PRODUCTION SUPPORT SPECIALIST– WHITE ROOM ASSEMBLY

1. Purpose

Change Over – PSS Process Steps
1) Before end of lot prepare change over cage with necessary components, verify with QT, and record lot numbers in BOM/forms accordingly.
2) At end of lot reconcile all CPJTs and Labels.
3) Complete batch yield calculation.
4) Enter rejects into IQMS and remove from assembly line.
5) Make sure components are off the line and put in changeover cage.
6) Move cased units from finished lot out of build area.
7) Run end of lot checks and record in form (ie. BRF-0011)
8) Remove dose blocks and casing device blocks (if applicable).
9) Clear information off from HMI displays (lot specific).
10) Remove work instructions (if applicable).
11) Complete end of lot paperwork for lot that is ending.
12) Remove change over cage.
13) Perform line clearance assessment and complete F7.5334. Verify all stations have been cleared, and that each station has green indicator circles posted.
14) Call quality to verify line clearance and ensure all line clearance circles have been removed from the line.
15) Bring in new change over cage.
16) Issue components to the build line and verify lot numbers have been recorded in BOM (allow operator assistance with PSS guidance).
17) Issue the appropriate work instructions (if applicable).
18) Install appropriate dose block and casing device blocks.
19) Run beginning of lot checks.
20) Set up HMI screens (CPJT lot number and expiry date). Verify the correct programs are loaded (as applicable).
21) Set up labeler (set up HMI screen and make adjustments if needed).
22) Get label signed off in batch record.
23) Move lot into first position in IQMS.
24) Verify the appropriate forms have been issued on the build line.
25) Bring empty cage to build area for finished goods and give it a color coded tag and pallet label from IQMS.
26) Verify all startup lot entries have been made in batch record and that the line is ready to start.

Phillips	CHANGE-OVER / LINE CLEARANCE PRODUCTION SUPPORT SPECIALIST INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name confidential	PART NAME:	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5062	REVISION DATE:	XX/XX/XX
	PROCESS FLOW	MACHINE ID(S):	N/A

The purpose of this document is to provide instruction for Production Support Specialist/Technician to conduct change-over/line clearance activities specific to the (Line A/Line B) White Room Assembly.

Change-Over Cart/Cage (For Reference)

The Work Instructions and Batch Record can be found in the applicable Change-Over Cart/Cage

Install appropriate dose block and casing device blocks.

Phillips PHILLIPS PLASTICS CORPORATION	CHANGE-OVER / LINE CLEARANCE QUALITY TECHNICIAN INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5061	**REVISION DATE:**	XX/XX/XX
	PROCESS FLOW	**MACHINE ID(S):**	N/A

CHANGE OVER PROCESS FLOW QUALITY TECHNICIAN – WHITE ROOM ASSEMBLY

1. Purpose

The purpose of this document is to provide instruction for Quality Technicians to conduct change-over/line clearance activities specific to the (Line A/Line B) White Room Assembly.

2. Definitions

2.1. **Like-for-Like Changeover**- includes the following change-over:

- 2.1.1. 0.15mg SDEAI to 0.15mg SDEAI
- 2.1.2. 0.15mg TJ to 0.15mg TJ
- 2.1.3. 0.3mg SDEAI to 0.3mg SDEAI
- 2.1.4. 0.3mg TJ to 0.3mg TJ

2.2. **Non-Like-for-Like Changeover**- includes the following configuration change-over:

- 2.2.1. 0.15mg SDEAI to 0.3mg SDEAI (*or*) 0.3mg SDEAI to 0.15mg SDEAI
- 2.2.2. 0.15mg TJ to 0.3mg TJ (*or*) 0.3mg TJ to 0.15mg TJ
- 2.2.3. 0.15mg SDEAI to 0.15mg TJ (*or*) 0.15mg TJ to 0.3mg SDEAI

Change Over – Quality Technician Process Steps
1) Obtain next work order
2) Enter work order into the finished lot log to ensure lot number is accurate
3) Print Batch Record and Batch Record Forms (as indicated in batch record applicable documents section)
4) Take work order and Batch Record to Change Over Cage & Bring the new cage into room (store in large locking area away from build line).
5) Stage the appropriate (dose configuration) labels in cage.
6) Once the last good CPJT assembly has been made remove remaining CPJTs from room (if applicable)
7) Ensure all correct configuration components and work instructions are present in cage (if applicable). Once the changeover cage/cart is stocked and verification is complete the PSS or QT is authorized to bring in new change-over cart.
8) Ensure the full line clearance has been completed and the line clearance F7.5335 is put in new batch record.
9) Remove the **"THIS LINE HAS BEEN CLEARED BY OPERATOR"** Green Circle from each station. (Reference picture)
10) Remove the previous lot changeover cart from assembly line (ie. Locked Cage).
11) Issue new lot of CPJTs (if applicable).
12) Verify that all labels have been signed off in the batch record and that all start-up checks (ie. BRF-0011) have been completed prior to start up.
13) Update information board with lot number, expiration, CPJT lot, expiration date, current build configuration.
14) Issue new forms and work instructions to the appropriate assembly stations (required in BR).
15) Verify and assist in any remaining batch record preparation activities.

Phillips	CHANGE-OVER / LINE CLEARANCE QUALITY TECHNICIAN INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5061	**REVISION DATE:**	XX/XX/XX
	PROCESS FLOW	**MACHINE ID(S):**	N/A

Remove the *"THIS LINE HAS BEEN CLEARED BY OPERATOR"* Green Circle after the line clearance has been fully completed from each station.

Verify the Wrap Label Reject Sheets and Case Bottom Label Reject Sheets have been removed from previous lot and that there are no "stranger" labels in the books, sheets, or within the AM-47 (Labeler).

When updating the information board with the new lot number, expiration, CPJT lot, and expiration date, also verify that the current build configuration is correctly displayed to the new lot configuration to be built.

Phillips	CHANGE-OVER / LINE CLEARANCE QUALITY TECHNICIAN INSTRUCTION DOCUMENT		
	CUSTOMER: Customer name is confidential	**PART NAME:**	Epinephrine Auto-Injector (All Platforms)
	DOC#: DOC7.5061	**REVISION DATE:**	XX/XX/XX
	PROCESS FLOW	**MACHINE ID(S):**	N/A

Change-Over Cart
(for Reference)

Appendix F: Future State Changeover List (required internal operations)

0.30mg Generic -to- 0.15mg Branded

1	AS-73 Generic Syringe Vision Challenge (Closeout) Line A
2	AS-75 Generic Final Vision Challenge (Closeout) Line A
3	AS-45 Generic Syringe Vision Challenge (Closeout) Line B
4	AS-50 Generic Final Vision Challenge (Closeout) Line B
5	AS-73 Branded Syringe Vision Challenge (Startup) Line A
6	AS-75 Branded Final Vision Challenge (Startup) Line A
7	AS-45 Branded Syringe Vision Challenge (Startup) Line B
8	AS-50 Branded Final Vision Challenge (Startup) Line B
9	Install 0.15mg Dose Block AS-41 Line A
10	Install 0.15mg Dose Block AS-58 Line B
11	AS-41 Setup / CPU-Interface Settings
12	AS-41 Vision Challenge (No Dose)
13	AS-58 Setup / CPU-Interface Settings
14	AS-58 Vision Challenge (No Dose)
15	AS-72 Glue Bead Startup Checks / Settings Verification
16	AS-52 Glue Bead Startup Checks / Settings Verification
17	AM-47 Setup
18	Line Clearance

0.15mg Generic -to- 0.30mg Generic

1	AS-45 Branded Syringe Vision Challenge (Closeout) Line B
2	AS-50 Branded Final Vision Challenge (Closeout) Line B
3	AS-50 Branded Final Vision Challenge (Startup) Line B
4	AS-75 SDEAI Final Vision Challenge (Closeout) Line A
5	AS-75 SDEAI Final Vision Challenge (Startup) Line A
6	AS-73 SDEAI Syringe Vision Challenge (Closeout) Line A
7	AS-73 SDEAI Syringe Vision Challenge (Startup) Line A
8	AS-45 Branded Syringe Vision Challenge (Startup) Line B
9	AS-41 Vision Challenge (No Dose) 0.15 Closeout
10	Install 0.3mg Dose Block AS-41 Line A
11	AS-41 Vision Challenge (No Dose) 0.30 Startup
12	AS-58 Vision Challenge (No Dose) 0.15 Closeout
13	Install 0.3mg Dose Block AS-58 Line B
14	AS-58 Vision Challenge (No Dose) 0.30 Startup
15	AM-47 Setup
16	Line Clearance