Equipment Decision for Biomedical Company Manufacturing Syringed Ophthalmic Solutions

by

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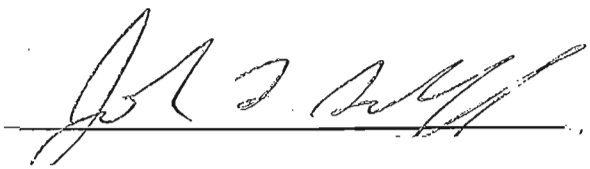

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Abstract

Despite tight economic times, Company ABC is experience strong growth. Expansion of their syringed product is forecasted to see growth of four to six times their current annual quantities. Finding manufacturing solutions to handle the increased capacity warrants the purchase of multiple new pieces of equipment. Internal processing requirements established the need to expand manufacturing capacities for the inspection, labeling, plunger-rod insertion, backstop placement, and pouching operations. Engineering has been asked to find a solution and make recommendations to upper management.

This study will find and analyze a list of available equipment manufacturers and make recommendations on the proposed equipment to upper management for a manufacturing company producing syringed, sodium hyaluronate products.

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Chapter I: Introduction

Today's economy is perhaps tighter than it has ever been. For those fortunate enough to maintain or even secure new business, they are forced to find faster, more cost-effective ways of manufacturing products to meet their customer's needs. The medical manufacturing field is no exception. With increased product scrutiny by regulatory bodies and demand for more affordable products, organizations are held to higher standards than ever before. Organizations can no longer survive simply having a single advantage such as quality, price or service. Today's customers require all of the above (Pinto, 2007). Meeting this demand puts a great deal of emphasize on operations and processes used to manufacture, assemble and package each product.

Background of Problem

Company ABC is a small biomedical company whose core business is the formulating and filling of sodium hyaluronate and similar solutions designed for use in ophthalmic, arthritic, veterinary and research applications. Sodium hyaluronate is a well-tolerated, non-immunogenic solution that typically does not cause any inflammatory reactions. The solution's properties play a protective, shock-absorbing and structure-stabilizing role in connective tissue. It can be manufactured in varied levels of viscosity and gravity. Its unique properties allow for injection through fine-gauge needles while maintaining a viscosity high enough to remain in contact with tissue for extended periods of time. The most common ophthalmic applications are cataract extraction, corneal transplants, glaucoma filtration and retinal surgeries (Spitzer et al., 2008).

The past three years has brought about many changes within the organization. Recent acquisitions have forced the arrival and departure of customers and processes. Most recently, Company ABC has received confirmation of two contracts with both a current and a new

customer. This will significantly increase the production of their filled syringe product. Currently Company ABC fills just shy of a half-million syringes annually. With the addition of the new contracts the estimated yield is slated to be as high as 2 to 3 million annually.

Aseptic Packaging, the department responsible for the syringe processing operations, currently employs six dedicated aseptic assembly and packaging technicians. An additional two technicians divide their time between syringe inspection processes and incoming raw material inspection. All eight technicians work full-time to deliver the almost half-million individually packaged syringes. Management and planning are concerned that current equipment and staff will be unable to support the future changes. It is thought that simply adding staff or technicians will not sustain the increase because certain operations working non-stop might not be able to support the projected numbers. This field project will seek the most cost-effective way to support future growth while meeting the needs and design requirements of the customer, regulatory bodies, and manufacturing. Equipment needs and technicians to support the new equipment and processes will be determined utilizing a variety of methods and tools.

Statement of Problem

Company ABC's existing operators, processes and equipment are likely unable to meet future assembly and packaging demands. The equipment and processes currently used were designed for smaller batch sizes that utilized hand assembly for much of the process. Operations that are semi-automated are constrained to low speeds and cannot operate at speeds fast enough to support future projections. This paper will make recommendations for purchase of equipment to meet future growth potential.

Purpose of Research

The purpose of this research project is to make the final recommendation to top management for the purchase of manufacturing equipment for processing, assembling and packaging of filled syringes. The objectives of the equipment will be judged on the option that will best meet the needs of a Company ABC's internal manufacturing requirements and that of their customer's design requirements.

Equipment for consideration will be required to process a filled syringe through a series of assembly and packaging operations. The primary functions will need to interact with each other or have the ability to allow for easy transition by operators between processing steps. Each process will be judged against current manual or semi-automated processes for justification. The operations required can be broken down into:

1. A processing operation to remove a filled syringe from a bulk tub and place in the appropriate configuration to best meet the needs of the inspection process
2. An inspection process detecting aspects related to the syringe body, integrity and fill
3. The application of syringe label
4. Insertion of a plunger-rod
5. Placement of a backstop or finger-grip
6. The insertion and sealing of the processed syringe into a tyvek/mylar, chevron pouch

The ideal flow will not allow for any breaks between processing, and will avoid as little human interference as possible. After the syringe is placed into the chevron pouch it will be sent out for a sterilization process. Upon return, it will undergo the final packaging operation before being distributed to the end user. Furthermore, the requirements and processes are considered clean operations in which cleanroom classification eight is required. Once the product is sealed

in the chevron pouch, it is sealed in a sterile barrier and can be brought outside the controlled areas. For confidentiality of the problem and company, all involved parties will be disguised with the primary organization referred to as Company ABC.

Chapter II: Literature Review

The need for operational improvements and equipment capacities increase with the expansion of manufacturing capacities. The need for an overall coordinated approach to production operations is essential. Incompatibilities of difficult units in an assembly line may not be apparent at slow speeds, but at high rates, uninterrupted flow becomes essential to efficient operation (Hanlon, Kelsey & Forcinio, 1998). Finding equipment and processes that can handle the increases requires in-depth research and consideration.

In addition to coordinating various pieces of machinery, there is also a need for a good union of materials and components that combines success in the equipment with form of the assembled product. Finding the right machinery, and people to run the machines is important. During development this interaction is an essential consideration that engineers must plan for in order to build a successful operation. Assembling lines must marry a multitude of factors that result in a process that limits the ability for people or machinery to adversely affect the quality or integrity of the product. Questions, such as the degree of sophistication the machine, and the skill of the technician operating the equipment are important considerations (Hanlon et al., 1998).

Preliminary factors are the first and easiest points to consider in design criteria. Factors for consideration include the following: number of pieces per hour the machine will be required to meet, price, level of automation, and the ability for future adaptability or retrofit-ability. For cost sensitive purchases, machines with a flexible level of adaptability will ensure that the equipment purchases will meet both current demands and those forecasted for future growth opportunities. Recognizing the needs in terms of equipment, the rates at which processing is required, and ballpark costs are usually enough to get a running start for preliminary investigations (Hanlon, et al., 1998).

The location and facility are additional considerations. The conditions of the facility have a bearing on the configuration and options possible in each piece of equipment. Considerations include, but are not limited to, dimensional constraints, available utilities such as electrical, compresses air or nitrogen, exhausting, drainage, and exhausting or blow off produced by equipment operation. Even such things as the amount of light and noise for operations have to be considered. As mandated by OSHA (Occupational Safety and health Administration) under Standard Number, 1910.95, protection against the effects of noise exposure shall be provided by an employer whenever employee noise exposure equals or exceeds an 8-hour time-weighted average sound level (TWA) of 85 decibels (Occupational Safety and Health Administration, retrieved May 4, 2010). The same types of standards can be found for required lighting for inspection areas as well as many other core safety areas.

Materials for construction are strong considerations, especially for organizations manufacturing sterile or aseptically produced products. While cleanliness is certainly a consideration for any manufacturing facility, for companies producing injectable drugs or devices the facility and equipment cleanliness guidelines become extremely important. ISO Standard 14644 "Classification of Air Cleanliness" contains very detailed requirements for the amount of particulate that can be introduced or generated in clean room environments. That standard breaks down the requirements into categories as Classifications of Air Cleanliness, Cleanroom Testing for Compliance, Cleanroom Design and Construction, Cleanroom Operations, Terms, Definitions and Units, and Minienvironments and Isolators. Meeting these standards requires operations, equipment, and people to operate at a level of extreme cleanliness and lends people, objects, and facilities to extreme cleaning techniques and methods. (Federal Standards 209E and ISO 14644, retrieved, March 30, 2010.). In order to accommodate cleaning

and particle generating standards, placement of equipment in a clean environment should include consideration materials of construction. Stainless steels or anodized aluminums should be used in place of corrosive metals. Belts and suction cups should be made of non-shedding rubbers and compounds, and plastics should typically be made of class VI medical grade materials such as Delrin®, Teflon®, PVDF, or class VI polypropylene and polyethylene.

The flow of material can play a decisive role in the efficiency of a work center or production line. Assembly line flow is an increasingly crucial factor when multiple operations or workstations are involved in a process. Whether trying to achieve true one-piece flow or simple striving to eliminate bottlenecks and streamline material transfers, the layout design places importance between the facility, people, equipment and processes. Layouts that utilize a straight line, U-shape, or W-shape are typically the most ideal. Adequate design is a key consideration to leaving enough room to process all operations, designating room for both incoming raw materials, and outgoing finished products (Hanlon et al., 1998).

To touch lightly on the subject, ensuring the safety and operability of the equipment are factors that benefit both worker and employer. Emergency-stops on each machine located in prominent and easily available locations are essential. For larger cabinets or pieces of equipment, a cable e-stop that runs around the entire line and halts all equipment by a pull on the cable in any location is safer, faster, and more convenient. Safety engineers should ensure that any movable parts that could cause injury to operators be adequately contained. Identifying pinch points, sharp or hot components, trip hazards or open electrical hazards are just a few considerations that need to be investigated by a safety engineer. Each piece of equipment must also be analyzed with the operating technician in mind. Work stations need to be designed so

that operators are comfortable doing their jobs and free of any activity that can cause strain or fatigue in both the short and long term (Hanlon et al., 1998).

Good Manufacturing Practices (GMP) are requirements that compel domestic or foreign manufacturers to have a quality system. GMP is primarily for the design and production of medical devices, pharmaceuticals, or food intended for commercial distribution in the United States. The requirements can be found in Part 820 of Title 21 of the Code of Federal Regulations (CFR). In its simplest definition, it helps assure that medical devices are safe and effective for their intended use. It is ultimately up to the manufacturer to establish and maintain a quality system that is appropriate for their specific devices(s). Because of the broad array of products, operating within the term appropriate, it is essentially the responsibility of them to establish requirements for each type, or family of, devices that result in devices that are safe and effective. Each manufacturer must initiate and follow their own processes ensuring their compliance with GMP regulations (U.S. Food and Drug Administration, retrieved, May 10, 2010).

An important criterion, and the backbone of the machine itself, is the manufacturer. In very specific situations it is possible that only one supplier can provide the piece of technology required. In most cases, however, there are many manufacturers that can provide the same or similar piece of equipment. Through examination of their organization, programs, and current field equipment individuals can help distinguish between mediocre and exceptional suppliers. Current material suppliers can also be good sources for advice. They typically are affiliated with, or know of, equipment suppliers that commonly work well with their materials. In some cases larger suppliers will even have one or more equipment specialist on staff to advise customers in such matters.

One of the best ways to investigate an equipment supplier is to inquire with their current and past customers. Assess them largely on their past performance in the packaging field, and their experience with similar products and materials. Although a supplier's unique operations and features are significant performance characteristics, their reputation is the most important of all criteria. Request references and follow up with them. If they allow, it is even more helpful to see the machines in operation. When visiting, discussions with operators and overviews of setup and changeover go beyond simply seeing the machine in production mode. If past customers are unable to provide access to their machines go to the supplier and ask to see floor models or equipment in production for other customers. For cases that involve more or specific technology it can be common to develop tooling or operations that run on similar available platforms. If the supplier can't achieve success, customers typically only risking development of that operation rather than the risk of purchasing a complete piece of equipment that doesn't meet their needs. If they can achieve success, the development pieces can usually be incorporated in the final piece of equipment (Hanlon et al., 1998).

Extensive preliminary research and fact-finding provides for a greater chance of locating the best fit and function of the supplier chosen. It's important to thoroughly examine all available equipment possibilities, both in terms of style and manufacturer. When visiting suppliers, make sure that you are well prepared. Engineers should have available specification sheets for informing the suppliers regarding all details related to machine size, utilities, operation, speed, performance and juxtaposition to other machines in the line. If materials and the product to be packaged are available, samples of all size ranges and their tolerances need to be provided (Hanlon et al., 1998).

Once the decision to acquire new technology or service has been identified and all applicable research has been performed, the process for making decisions follows. Making decisions can have small or large consequences. Typically the decisions involving new pieces of equipment used for processing product can have large consequences and risks. Evaluating situations and utilizing tools to properly make important decision cannot be taken lightly. According to Krajewski and Ritzman (1999), there are three basic steps for making decisions. The first step is to recognize and clearly define the problem. The second step is to collect all plausible information for analysis. The final step is to choose and implement the most feasible option. The final step involves more than simply implementing the most feasible option. The information from step two must be carefully analyzed before making a recommendation and purchasing. Implementation occurs at the tail end of the activity and if the prior steps have been adequately performed, this process will be much easier than decisions made blindly. Almost all companies will find that the third step is the most difficult.

There are a variety of models that can be utilized when making a decision. Finding the right model for the problem and application can be as important as the information itself. According to Pinto (2007), there are six important issues that must be considered when evaluating screening models for projects. They are as follows:

1. Realism: An effective model needs to realistically reflect the objectives of the project. Criteria must be reasonable in light of such resources such as money and personnel. Risks, performance, cost and timing must be taken into account. Scope, timing and cost have to be evaluated to determine is there are possibilities for slippage or overages.
2. Capability: Models need to be flexible and able to respond to changes in conditions and allow comparison of project length, various technologies, capabilities or commercial

objectives. To cover the full extent of project types it has to cover new criteria and constraints.

3. Flexibility: Allowing for change throughout the process such as currency exchange rates, building codes, regulations and so forth are needed to ensure a flexible model.
4. Ease of Use: Multiple people within the organization will be using the model. It must be simple for both those in specific project roles and in related functional positions and generate results in a timely manner. Choices made for selection should be clean and easily understandable by all organizational members.
5. Cost: Screening models need be cost effective. If a selection approach is expensive in terms of time or money, people are not likely to adopt or use them.
6. Comparability: A useful model must be able to generate consistent and comparable information between project alternatives. Narrow or project specific models can potentially foster biases.

Utilizing these steps aids users in identifying important issues that need to be considered when evaluating the many screening models available. Companies typically spend large amounts of time and energy identifying the objectives that need to be analyzed, however finding a model to accurately evaluate the complex criteria can be just as important as the criteria itself (Pinto, 2007).

There are many different types of models that can aid in the decision making process. In Operations Management, Krajewski and Ritzman (1999) define four common formal model procedures available. They are break-even analysis, the preference matrix, decision theory, and decision trees. Each model lends itself to different decision-making scenarios.

Break-even analysis aims to identify how much change in volume or demand is necessary before a second alternative becomes better than the first. The break-even point of a new product or service is when the total revenues equal the total costs. Break-even analysis determines this point and is used to compare production methods by finding the volume at which two different processes have equal total costs. Break-even analysis techniques help to answer question such as: is the predicted sales volume of the product or service sufficient to break even-even, how long will it take, how low must the fixed cost be in order to break even and how do various price levels affect the break-even volume (Krajewski & Ritzman, 1999).

A decision theory model identifies the best alternative when outcomes are uncertain. This method is best used with decisions on process, capacity, location, and inventory. The first step in this method is listing all the feasible alternatives. It assumes the number of alternative is finite and should always include the option to do nothing. The next step in the process involves listing the unknowns or events such as future order quantities. Events should be grouped but cover all eventualities. After establishing each of the events, the calculated payoffs for each event need to be determined. When determining multiple criterions with important qualitative factors, weighted score of a preference matrix should be used. Next, the possibility of each event needs to be calculated and expressed as a probability. Finally, decision rules are selected for evaluating the alternatives. Decisions should be based on the lowest cost or highest return (Krajewski & Ritzman, 1999).

Decision trees are useful when decisions are made sequentially or when today's best decision depends on tomorrow's decisions and events. Decision trees can be used for a wide range of decisions including product planning, process management, capacity and location. As with decision theory it can be useful when future demands are unknown. The model itself is a

schematic model of alternatives along with their consequences. In this model, decision nodes are created that read from left to right by branches representing alternatives. Probabilities represent each alternative with the sum of each alternative for a decision equaling a sum of 1.0. Furthermore each alternative has an associated payoff. After drawing the decision, the payoffs for each event are multiplied by the probability. The best expected payoff is chosen. If alternatives lead to an event node, its payoff is equal to that node's expected payoff. All other branches not chosen are removed or "pruned". The process is continued until the furthest node is reached. The un-pruned branch extending from it is the best alternative (Krajewski & Ritzman, 1999).

Preference matrixes or decision models are used when multiple criteria, each with a unique level of importance, is required for analysis. Criteria are anything that can be deemed important to the operation or function of the equipment that the purchaser would want to consider when making a decision. These models are simple, common, and can be called many different things including: decision matrix, rating grid, scoring matrix or weighted criteria matrix, comparison matrix, opportunity analysis and more (Krajewski & Ritzman, 1999). For consistency, the remainder of this paper will refer to this technique as a decision matrix.

In assembling a decision matrix, weighted factors are used to define and assign a level of importance to a list of criteria. Criteria can be as basic as time and cost, or much more descriptive depicting very specific features or options. Assigning meaning to weighting factors needs to be objective and consistent throughout each alternative in comparison. Because this process is objective, somewhat simple or small weighting factors should typically be used. It is uncommon to find a scale using dispersion greater than ten units. If a particular criteria such as cost or quality is very important in the decision making process, assigning a high value such as

10 on a scale from 1 to 10 is recorded. The responsibility of the weight designation needs to be considered by a variety of members within the project who thoroughly understand the trade-offs and implications of each criteria (Tague, 2005). It is important to assign and pay close attention to what is important so that each factor is not rated relatively closely. Furthermore, it is important that each member understand the grading scale. For example if low cost is important, ensure everyone knows that low cost is represented by a high value on the scale.

According to Tague (2005), there are six steps taken to develop a decision matrix procedure. There are as follows:

1. Brainstorm the evaluation criteria appropriate to the situation. If possible, involve customers in this process.
2. Discuss and refine the list of criteria. Identify any criteria that must be included and any that must not be included. Reduce the list of criteria to those that the team believes are most important. Tools such as list reduction and multivoting may be useful here.
3. Assign a relative weight to each criterion; based on how important that criterion is to the situation. Do this by distributing 10 points among the criteria. The assignment can be done by discussion and consensus. Or each member can assign weights, then the numbers for each criterion are added for a composite team weighting.
4. Draw an L-shaped matrix. Write the criteria and their weights as labels along one edge and the list of options along the other edge. Usually, whichever group has fewer items occupies the columns.

5. Evaluate each choice against the criteria. There are three ways to do this: Method 1: Establish a rating scale for each criterion. Some options are:

1, 2, 3:	1 = slight extent, 2 = some extent, 3 = great extent
1, 2, 3:	1 = low, 2 = medium, 3 = high
1, 2, 3, 4, 5:	1 = little to 5 = great
1, 4, 9	1 = low, 4 = moderate, 9 = high

   Make sure that your rating scales are consistent. Word your criteria and set the scales so that the high end of the scale (5 or 3) is always the rating that would tend to make you select that option: most impact on customers, greatest importance, least difficulty, greatest likelihood of success.

   Method 2: For each criterion, rank-order all options according to how well each meets the criterion. Number them with 1 being the option that is least desirable according to that criterion.

   Method 3, Pugh matrix: Establish a baseline, which may be one of the alternatives or the current product or service. For each criterion, rate each other alternative in comparison to the baseline, using scores of worse (–1), same (0), or better (+1). Finer rating scales can be used, such as 2, 1, 0, –1, –2 for a five-point scale or 3, 2, 1, 0, –1, –2, –3 for a seven-point scale. Again, be sure that positive numbers reflect desirable ratings.

6. Multiply each option's rating by the weight. Add the points for each option. The option with the highest score will not necessarily be the one to choose, but the relative scores can generate meaningful discussion and lead the team toward consensus.

A decision matrix works well when one improvement opportunity or problem must be chosen, and only one solution can be implemented or developed. Criteria weight is based on interpretation of data, thus the matrixes are ultimately based off the opinions of those inputting the figures. When possible it is better to try and summarize the data with as little interpretation or opinion possible. The more informed the team, the better and more accurate the data will be. Ratings are only as good as the assumptions about the solutions. It is recommended that if individuals on the team differ in their rating designation to discuss the options and learn from others views to form a consensus within the team. It is not recommended to average or vote for the most popular choice. Decision matrixes can be very versatile and if used correctly are very good indicators of the best option (Tague, 2005).

Once a decision matrix has been created and the criterion has been inputted, users can begin to identify the best options. Further analysis can be obtained through sensitivity analysis. As defined by Pinto (2007), sensitivity analysis is a quantitative risk analysis and modeling technique used to help determine which risks have the most potential impact on a project. It examines the extent to which the uncertainty of each project element affects the objective being examined when all other uncertain elements are held at their baseline values. Tornado diagrams are the most common ways to graphically represent the results. By manipulating the weights of a category or score of an option, results can indicate how manipulating inputs affect the model and sum scores.

Sensitivity analysis of a decision matrix answers the questions to all of the "what if" questions presented. Through systematically changing different ratings and criteria weighting users can witness the subsequent changes. In the instance of a decision matrix, changing or eliminating an important criteria's weight can significantly impact the result. For models that

don't offer definitive results, users can ask questions such as "what if price didn't matter" or "what if we didn't score quality as high". Controversial weights or scoring are most important to analyze. If there were strong opposing feeling regarding the score or weight factor during construction of the model, performing sensitivity analysis on those criteria can help display to others how it can affect and influence overall scores (Shin & Trappery, 2008).

Chapter III: Methodology

It is believed that Company ABC lacks the ability to meet future demands based on their current equipment and process capabilities. Before they can refine or expand their processes, they need processes and equipment that can handle the requirements projected for the next couple of years. This project will analyze the current capacities and recommend the most appropriate equipment to meet the future needs of the customer and internal requirements.

Forming Design Requirements

To begin the process a team was constructed and a reoccurring capacity meeting was setup. The purpose of the team was to determine the current constraints, facilitate in determining the machines needs and requirements, and ultimately arrive at recommendations for upper management. Present in these meetings were representatives from the engineering group, which included members from facilities, calibration and maintenance, finance, purchasing, materials, quality assurance and regulatory. The primary goal of the meetings was to confirm that our current operation was not going to support future expansion. The next goal was to establish requirements for each piece of purchased equipment. Lastly criteria that were determined to have an acceptance range were identified. These items were used as factors to rate the various pieces of equipment after each had been determined to meet all applicable requirements. The final meetings were dedicated to analyzing the decision matrix and arriving at a consensus for recommendations.

To provide a baseline, each process was looked at to determine the current capacity and bottlenecks. Historical data was studied at from a broad view to roughly determine capacity per lot size. Further data was pulled from capacity spreadsheets used by the aseptic packaging group derived from past estimates and manufacturing data. Time studies were also performed to verify

that recorded numbers reflected the current actual numbers. Operations were broken down and analyzed by personal or equipment constraints. One focus for bottlenecks was the pouching operation.

Workflow for each operation in the process was next laid out to provide a simple diagram and to make interpretation of the data more manageable. Every operation was estimated upon the number of units per person per hour. For operations that were dependant on equipment, throughput was identified as a number of units per hour accompanied by the number of operators required to setup and run each piece of equipment. Each process was divided into the single simplest operation.

Criteria or Factor Consideration

The requirements for each piece of equipment then had to be chosen carefully. The most difficult process was ensuring that each requirement was in fact an important consideration. Furthermore, care had to be taken not to add any requirements that would eliminate a piece of equipment that would otherwise be a good alternative. The primary requirements for each piece of equipment fell into the following groups:

- Safety and Ergonomics
- Facilities and Utilities
- Product Compatibility
- Clean-room and GMP compliance

Each group was further broken down into specific requirements that each piece of equipment had to meet. The categories shared many similarities, but were broken down and included for equipment to maintain consistency within all groups.

The next phase was to establish a list of criteria that could differentiate the pieces of equipment found to possess all the necessary requirements. This data was compiled and open to interpretation by the whole team. The criterion was selected with consideration. Each criterion needed to have the ability to be differentiated between each piece of equipment. Furthermore, each piece had to represent a significant importance. Each criterion was then further defined by its importance as represented by the weight factor assigned. The final step was to transfer the criteria into the decision matrix, assign a weight and designate a score for each piece of equipment. This process involved many meetings and discussion between the team. Evaluation and explanation of the manufacturer's information and quote was provided by both the engineering department and supplier.

Once the decision matrix was completed the results were analyzed and discussed amongst the group members. Each team member was given the opportunity to dispute weighted scoring within each criterion and the score associated with each individual piece of equipment. Data was manipulated to identify results when a variety of factors and scores were changed. If changes resulted in significantly different overall scores, inputs were revisited and further discussed to insure that each was reflecting the most appropriate score. Once the group was satisfied with the results, the piece of equipment that had the highest score within each group was chosen. These pieces of equipment were recommended to upper management for purchase.

Chapter IV: Results

The primary goal of this study was to recommend the best pieces of equipment for accommodating future growth of Company ABC. The first step involved forming the team and generating a list of design requirements for each category of equipment. Next began the process of meeting with potential suppliers and deciphering all of the applicable data from each. The supplier's equipment was analyzed as best possible with the information provided. When possible potential equipment suppliers were visited and the supplier's current customers were contacted for reference. The data gathered was analyzed against the design requirements within each category of equipment and given a Yes or No. The final step compared the approved potential suppliers. Simple sensitivity analysis was also used in the labeler, plunger-rod, and backstop category. Each supplier was kept confidential and referred to as either a supplier or an alternative. Some offered equipment for multiple categories. They are listed and referred to as suppliers A through K.

After evaluating each supplier against the design requirements only three suppliers did not meet all the criteria of the four equipment categories. Of the three non-compliant pieces of equipment, two were ultimately not used during the decision rating exercise. In each of the three instances price was the eliminating factor. One supplier did not meet the criteria of an ergonomically friendly configuration. In total eleven different suppliers were examined. Some suppliers could offer equipment in multiple categories. In fact, supplier or alternative B was found to offer equipment for three of the categories. Additionally, three more suppliers (A, G, and J) offered equipment for two categories. Each category of equipment had at least three choices for the decision matrix with the denester and the labeler, plunger-rod, backstop machine offering four alternatives.

The one exception for the design requirements was a pouch sealer supplier. They were used in the decision matrix despite not passing all of the design requirements to provide a better platform for comparison. Below is a list of suppliers considered for each equipment.

Table 1

Equipment's Associated Supplier

	Denester	Inspection	Label, Plunger-rod, Backstop	Pouch Sealer
Alternative A	X		X	
Alternative B	X	X	X	
Alternative C		X		
Alternative D		X		
Alternative E				X
Alternative F				X
Alternatvie G	X		X	
Alternative H				XO
Alternative I		O		
Alternative J	X		X	
Alternative K	O			

X= Met design requirements
O= Failed to met design requirements
XO= Failed but still considered in decision matrix

Denester

The denesting equipment was the first component in the new process. Originally five suppliers were found to offer an acceptable method of removing syringes from a tub and preparing for the downstream equipment. Those alternatives were A, B, G, J, and K. One company did not pass design requirements. Supplier or alternative K failed to meet the allocated cost. The remaining four were found to meet all of the requirements and were analyzed in the decision matrix.

Alternative A received the highest score from the decision matrix. Although this supplier was one of the more expensive options, it ranked highly enough in other categories to offset the additional cost. This was one of the better-known suppliers of Company ABC and received high scores in the requirement and customer relations categories because of exceptional past performance. Although a strong effort was taken to provide consistent scores to known and unknown suppliers alike, it was hard not to provide high marks in areas that we had a strong history. After running the numbers, the group was satisfied with their decision.

Inspection Equipment

The next piece of equipment in the planned process flow was the syringe inspection machine. Four suppliers were found for this category: B, C, D, and I. Alternative I was found deficient in two categories. The first was economics. It was determined that they were too expensive. Additionally they did not provide a machine that the group felt was ergonomically friendly for the operator to use. It was deemed that the twisting and reach requirements exceeded what was acceptable. The remaining suppliers, B, C, and D were found to meet all of the requirements and used in the decision matrix.

Alternative B received the best cumulative score with just over 1400 points. Economically it was not the best option, but it was not the most expensive either. None of the potential suppliers in this category were well known to Company ABC and they did offer a great deal of differentiation between one another. Although the basic operating functions were very similar, a variety of lighting techniques, syringe handling, and reject options made weighting the differences a little easier than other groups. Judging the supplier characteristics and history was more difficult and relied heavily upon information gathered from supplier surveys.

Labeler, Plunger-rod and Backstop

The next step was choosing the equipment designed for labeling a syringe, inserting a plunger-rod, and affixing a backstop. This was the most expensive and most intimately considered piece of equipment. Suppliers A, B, G, and J were found to be acceptable alternatives and passed all aspects of the design requirements.

With just over 1400 points, alternative A led this category with alternative J a close second. Although alternative B was the lowest scoring option, they were by far the least expensive. Because the results were relatively close and the equipment was the largest investment, simple sensitivity analysis was used to reanalyze the results, putting more emphasize on the cost criteria. The overall important factor for the economics category was doubled to a value of 2.0. In addition the purchase cost was increased to 10 from 5 within that group. The numbers were calculated again and supplier A maintained their significant advantage. However, after recalculating, supplier B went from last place to second. Their lower price tag was enough to catapult them past the other two suppliers. Following the sensitivity analysis, the team was satisfied with the results and agreed with the recommendation of supplier A.

Pouching Equipment

The last equipment analyzed was the pouch sealer. Three suppliers were found to provide an alternative for this process. Those were suppliers E, F, and H. Supplier H did not meet the cost requirement but was used anyway. Lack of sufficient suppliers in this category limited the selection. It was decided supplier H would be included in the decision matrix to determine if they would possess advantages that could potentially outweigh the economic shortcomings.

Alternative E received the best score in the pouching category with just over 1660 of 2060 points. Alternative H did not have enough features to outweigh the additional cost. Not only did alternative E come in significantly higher, but so did supplier H. more....

Conclusion of Recommendations

All but labeler, plunger-rod, and backstop machine recommendations were concluded by the initial feedback provided by the decision matrix. The team found that the decisions of the denester, the inspection equipment, and the pouch sealer groups were sufficient upon initial analysis. The scores and information provided by their suppliers provided a feeling of confidence for the group as a whole. The decision regarding the labeler, plunger-rod, and backstop equipment was reanalyzed with more weight put on the economics category and favored alternative A in both matrixes. The group will recommend alternative A for the denesting machine, alternative B for the inspection equipment, alternative A for the labeler, plunger-rod, and backstop machine, and alternative E for the pouch sealer. These four pieces of equipment will combine to form a new process flow and are found as ideal solutions to meeting future capacity forecasts.

Chapters V: Discussion

From the onset, all of the suppliers sought were thought to produce the required equipment and meet the list of design requirements. In addition they had worked with similar applications and had sound histories. Very little time or resource was put into any suppliers that were unlikely candidates. Although the goal was to evaluate a variety of equipment and suppliers, because of the specific nature of each, there only existed a limited amount of variance in overall operation of each piece of equipment. This was clearly seen when looking at the equipment and design requirements. Except in one instance, the only eliminating factors for each machine was cost. Even the ergonomic dismissal was subjective. Upfront research of suppliers in tandem with the creation of design requirements made for easy selection and a high probability of approved suppliers.

Most Influential Inputs

Although the individual criterion was important to the decision matrix results, the importance factor was the most distinguishing in establishing each final decision. Every equipment category had its own level of importance based on the requirements and importance deemed by the group for the particular use. Although most are consistent and some remain the same across each piece of equipment, they do differ in some of the more pertinent or important categories. For instance, the labeler, plunger-rod, and backstop equipment had a much larger budget than the pouching or denesting machines. The economics were there for more important. Some of the ranges in price for those pieces of equipment could virtually purchase a pouching or denesting machine. Reevaluating this category with more emphasis on economics was important to ensure that the decision was accurately reflecting what the group desired. Changing the importance factor and purchase price had a substantial effect on the results. Alternative B was

the lowest score initially, however upon placing more emphasize on the economics, it nearly jumped into first lagging slightly over 50 points behind alternative A and stole second place honors.

Overall, the most distinguishing categories for the remaining decision matrices were consistent with each other and the labeler, plunger rod, and backstop machine. Small differences were found in each, but the categories that showed the highest importance where: Customer Relations, Functional Requirements, Economics, Performance, Worker Safety / Ergonomics, and Materials of Construction. Economics and Performance were the two most important categories. They were the only groups to get scores of 1.0 for every matrix completed. It was difficult to have a high cumulative score without scoring well in either of these categories,

Advantages of New Process

There are many significant advantages to the new equipment. The first will be an overall reduction in labor required to perform each operation. Technician's focus will shift from performing the manual operations, lengthy setups, and redundant accountabilities to significantly quicker setups, limited support and monitoring during operation, and reduced in process tasks like inspection or pouch loading. This limits the number of operators and allows the same number of employees to significantly increase their rate or capacity.

Process flow was also significantly improved. Process flow and lean manufacturing were two of the major results of the new system. The new equipment allowed for a one piece flow and greatly simplified or eliminated unproductive downtime associated with in-process inventory, wasted floor space, and lengthy set up procedures. The old process had technicians handling the syringe during all aspects of processing. Buildup of in-process inventory required other jobs be put on hold. The reduced setup time will be attributed to simplification and

elimination of constant job shuffling. The new flow only relies upon technicians to handle the syringe prior to the pouching operation. Although the buildup of inventory is still a possibility, the other eliminations and savings are still consistent.

As touched on earlier, the accountability will also significantly improve. Instead of the variability of technician's hand-counting the parts, the accepted and rejected syringes in the new system is all be recorded in a database for complete tracking and accountability. Not only does this eliminate the human factor, it creates a validatable process. Each piece of equipment provides a number of pass and rejected syringes so accountability at the end is summarizing two numbers from each of two machines and comparing against the incoming product's accountabilities log.

A new flowchart was produced to compare the new and old processes. The results can be found in Appendices J and K. The first represents the old material flow with the second representing the new flow. The new flow shows a drastic improvement in both simplicity and number of tasks performed. Each machine performs its function and seamlessly transports product to the next in a linear flow without excess in process inventory and accountability.

Results/Advantages Specific to Individual Equipment

When judging the alternatives in the labeling, plunger-rod, and backstop category, the most important category was economics. Although importance and weighting factors were not to exceed 1.0 and 5 respectively, it was felt that they needed heightened weighting because of the hefty price. The maximum importance factor of 1.0 was doubled to 2.0, while purchase price was also doubled to provide a weighting of 10. This was required to ensure that the price of Alternative B did not outweigh lower scores in other categories. Upon doubling these categories it was still clear that Alternative A came out on top with a score of 1661 of 2060 points.

However, had the purchase price category been doubled again, Alternative B would have scored highest. These simple changes actually increased the potential points by over 15% and brought the margins between Alternative A and B much closer. Although with more of an important rating Alternative B would have actually surpassed Alternative A, it was felt that the final adjusted inputs were enough to secure Alternative A's spot at the top. One group member pointed out that even if alternative B were free, if it performs poorly it is not worth the savings.

The labeler, plunger-rod, and backstop machine were perhaps the most involved process. The procedure is currently broken up into multiple operations. The first function, following an extensive setup procedure, involves the manual loading of syringes onto a conveyor. The equipment labels the syringes and the syringes exit the machine and drop into a bulk container. Another inspection of the label and accountability is required before operators manually insert the plunger-rods and backstops onto each syringe placing them back into tubs of 100. The rate on the labeling is around 1500 with two operators. Inspection of the labels is completed by technicians at an individual rate of approximately 800 per hour. The backstop placement and plunger-rod insertion is also completed by individual operators at a rate of 600 an hour. The new equipment will complete all of the functions and perform the tasks with an hourly rate up to 4,000, requiring a maximum of two operators to monitor operation and refill hoppers. To put things in perspective, current operations require fourteen technicians to achieve a rate of 1500 per hour. The new machine will require two technicians while realizing rates over twice the speed. Upon implementation, the benefit of this equipment can be realized quite quickly.

The remaining decision matrixes followed the original plan. None exceeded an importance factor or one or a weight of five. Most of the results were congruent with the thoughts from the group initially heading into the exercise. Whether it was a known supplier or a

new, through the process of gathering data and communicating with each supplier grew feelings about each. The three initial decisions rendered from the decision matrixes meshed well with the majority of the group and did not require further analysis.

Of the four pieces of equipment chosen, the denesting equipment served the simplest function. It simply took a tub of 100 syringes, removed the syringes from the tub, organized them in a linear flow, and presented them per a rail to the inspection equipment. The two most distinguishing categories for the denester were the Supplier Requirements and Customer Relations. Performance and Economics were important, but because of the similarities in equipment did not successfully distinguish one piece of equipment from the next. The purchase of the denester will aid manufacturing in feeding the other operations at a speed that each machine is capable of. Payback on this equipment will be realized quickly.

The inspection machine will act as the second piece in the new flow. The choice of alternative B for the inspection equipment was arrived at by high scoring primarily within the Supplier Requirements and Customer Relations categories. Current operators inspect at a rate of approximately 500 syringes an hour. They are forced to manually handle all syringes as they inspect for particulate, defects in the glass, and defects related to other components such as the stopper and tip-cap assemblies. Holding up against a black/white board, their only light source comes from a single florescent bulb. The new process will only require them to observe the syringe as it passes through a well-lit viewing station. The syringe will be spun and presented at angles that easily allow operators to inspect many times the current speed. Rejecting syringes will be as easy as pressing a button and accountability will be tracked by the equipment.

Despite not meeting the purchase price requirements for the pouching operation, alternative H was used to ensure that other factors would not outweigh the added cost and

provide at least three alternatives to compare. Scoring the lowest in the economics category, the other important or high scoring factors were not enough to offset the score of alternative E. Alternative E only maintains a semi-automated operation; however the increase in capacity is still significant. The new machine will achieve ~1200 pouches per hour. Current operations require operators to hand-load a pouch and then seal one edge. This is rated at around 350 units per hour. Implementation of the new pouch sealer will reduce the number of operators from greater than four down to one. In addition, it will significantly reduce the total footprint required for the operation, freeing up room for expansion in other areas. Maintaining cleanroom operation is expensive and utilizing extra real estate for other applications is a huge benefit. In addition to facility and labor savings, the new equipment also uses an alternative media that reduces the supplier's required manufacturing operations that should reduce the raw material cost. Instead of ordering a preformed pouch and sealing the open edge, this operation is a true form, fill, seal. The product is inserted into the equipment and the pouch is formed around it. Flexibility in ordering and reduction of additional supplier performed labor should reduce material cost by upwards of 20%.

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Appendix A: Denester Design Requirements

Requirement	Design Criteria	Alt. A	Alt. B	Alt. G	Alt. J	Alt. K
User Needs, Indications for Use	Equipment to receive a bulk tub of syringes, remove the syringes and orientate in a linear flow to feed downstream equipment.	Yes	Yes	Yes	Yes	Yes
Construction Requirements	Equipment's moving parts must be easily assessed or able to be dismantled for maintenance or cleaning.	Yes	Yes	Yes	Yes	Yes
	Equipment must be constructed with materials that withstand typical cleanroom cleaning chemicals (70% IPA, Sporicide, Bleach).	Yes	Yes	Yes	Yes	Yes
	Equipment product contact points must be FDA accepted non-oxidizing materials.	Yes	Yes	Yes	Yes	Yes
	Equipment must be constructed with non-particle shedding materials.	Yes	Yes	Yes	Yes	Yes
	Changeover time must not exceed fifteen minutes.	Yes	Yes	Yes	Yes	Yes
	Equipment must be capable of being retrofitted for full automation.	Yes	Yes	Yes	Yes	Yes
Documentation Requirements	Company must provide FAT/SAT services.	Yes	Yes	Yes	Yes	Yes
	Equipment must be accompanied by a fully documented manual (specific requirements to be provided).	Yes	Yes	Yes	Yes	Yes
Economic Requirements	Equipment must not require more than one operator.	Yes	Yes	Yes	Yes	Yes
	Equipment must not exceed the final cost required by Company ABC.	Yes	Yes	Yes	Yes	**NO**
	Must agree to a minimum 50/40/10 payment schedule with final 10% 30 days after receipt.	Yes	Yes	Yes	Yes	Yes
Facility Requirements	Equipment must not require more than 100 psi for operation.	Yes	Yes	Yes	Yes	Yes
	Equipment must be able to run on 120, 230 or 480 voltage.	Yes	Yes	Yes	Yes	Yes

Functional Requirement	Equipment must be capable of handling the following syringe sizes: 1ml long, 2.25ml, and 3ml.	Yes	Yes	Yes	Yes	Yes
	Equipment must be able to be purchased with a manual or automatic load station.	Yes	Yes	Yes	Yes	Yes
	Equipment must be capable of operating intermittently.	Yes	Yes	Yes	Yes	Yes
	Equipment must be able to accept 100-pack tubs of syringes (specifications to be provided).	Yes	Yes	Yes	Yes	Yes
	Equipment must process syringes to an inline rail.	Yes	Yes	Yes	Yes	Yes
	Equipment must handle a minimum in feed of four tubs per in feed conveyor.	Yes	Yes	Yes	Yes	Yes
Performance Requirements	Equipment must be capable of processing a minimum of 4000 syringes/hour.	Yes	Yes	Yes	Yes	Yes
	Equipment must be able to detect all failure and acceptance criteria per Company ABC specifications (to be provided).	Yes	Yes	Yes	Yes	Yes
Safety/ Ergonomic Requirements	Equipment will be in accordance with Prevailing Safety Regulations for packaging machines and auxiliary equipment. Meets or exceeds OSHA, GS, GMP, etc. regulations.	Yes	Yes	Yes	Yes	Yes
	Equipment must incorporate security interlocks and emergency stops.	Yes	Yes	Yes	Yes	Yes
	Equipment must be ergonomically friendly to operator.	Yes	Yes	Yes	Yes	Yes
Software/ Hardware Requirements	If PLC chosen stores product specific information it must be compliant with 21 CFR part 11.	Yes	Yes	Yes	Yes	Yes
	If applicable equipment must incorporate Allen-Bradley controls.	Yes	Yes	Yes	Yes	Yes
Acceptance Criteria	To successfully meet all performance and physical requirements described above.	Yes	Yes	Yes	Yes	Yes

Appendix B: Inspection Design Requirements

Requirement	Design Criteria	Alt. A	Alt. B	Alt. D	Alt. I
User Needs, Indicators for Use	Equipment to handle a syringe for inspection by a technician. Equipment must clearly illuminate and present the syringe to an operator who can view all parts of the syringe without any physical handling. 'Hands free operation'.	Yes	Yes	Yes	Yes
Construction Requirements	Equipment's moving parts must be easily assessed or able to be dismantled for maintenance or cleaning.	Yes	Yes	Yes	Yes
	Equipment must be constructed with materials that withstand typical cleanroom cleaning chemicals (70% IPA, Sporicide, Bleach).	Yes	Yes	Yes	Yes
	Equipment product contact points must be FDA accepted non-oxidizing materials.	Yes	Yes	Yes	Yes
	Equipment must to be constructed with non-particle shedding materials.	Yes	Yes	Yes	Yes
	Changeover time must not exceed 30 minutes.	Yes	Yes	Yes	Yes
Documentation Requirements	Company must provide FAT/SAT services.	Yes	Yes	Yes	Yes
	Equipment must be accompanied by a fully documented manual (specific requirements to be provided).	Yes	Yes	Yes	Yes
Economic Requirements	Equipment must not require more than one operator per station.	Yes	Yes	Yes	Yes
	Equipment must not exceed the final cost required by Company ABC.	Yes	Yes	Yes	**NO**
	Must agree to a minimum of 50/40/10 payment schedule with final 10% 30 days after receipt.	Yes	Yes	Yes	Yes
Facility Requirements	Equipment must not require more than 100 psi for operation.	Yes	Yes	Yes	Yes
	Equipment must be able to run on 120, 230 or 480 voltage.	Yes	Yes	Yes	Yes

Functional Requirements	Equipment must be capable of handling the following syringe sizes: 1ml long, 2.25ml, and 3ml.	Yes	Yes	Yes	Yes
	Equipment must be able to position and manipulate the syringe so the operator can view all surfaced and contents (specific requirements to be provided).	Yes	Yes	Yes	Yes
	Equipment must incorporate a reject function or accommodate removal of non-compliant syringes.	Yes	Yes	Yes	Yes
	Equipment must be able to operate intermittently.	Yes	Yes	Yes	Yes
	Equipment must be able to accept syringes per rail-fed in feed.	Yes	Yes	Yes	Yes
	Equipment must be able to present the syringe in either a needle up or down position.	Yes	Yes	Yes	Yes
	Equipment must shield viewing station from outside light glare.	Yes	Yes	Yes	Yes
	Equipment must track and count accepted and rejected syringes.	Yes	Yes	Yes	Yes
	Equipment must transport the syringe out of the inspection machine in a needle down orientation.	Yes	Yes	Yes	Yes
	Equipment must present each syringe to the technician individually.	Yes	Yes	Yes	Yes
	Equipment must illuminate syringe so that all surfaces and contents are easily viewable for adequate syringe inspection. (specific requirements to be provided).	Yes	Yes	Yes	Yes
Performance Requirements	Equipment must be capable of processing a minimum of 1500 syringes/hour (actual operational speed may be operator restricted).	Yes	Yes	Yes	Yes
	Equipment must be able to detect all failure modes provided by Company ABC (specific requirements to be provided).	Yes	Yes	Yes	Yes
Safety/ Ergonomic Requirements	Equipment will be in accordance with Prevailing Safety Regulations for packaging machines and auxiliary equipment. Meets or exceeds OSHA, GS, GMP, etc. regulations.	Yes	Yes	Yes	Yes
	Equipment must incorporate security interlocks and emergency stops.	Yes	Yes	Yes	Yes
	Equipment must be ergonomically friendly to operator.	Yes	Yes	Yes	**NO**

Software/ Hardware Requirements	If PLC chosen stores product specific information it must be compliant with 21 CFR part 11.	Yes	Yes	Yes	Yes
	If applicable equipment must incorporate Allen-Bradley controls.	Yes	Yes	Yes	Yes
	Equipment PLC must be able to be networked to an external database.	Yes	Yes	Yes	Yes
Acceptance Criteria	To successfully meet all performance and physical requirements described above.	Yes	Yes	Yes	Yes

Appendix C: Labeler, Plunger-rod and Backstop Design Requirements

Requirement	Design Criteria	Alt. A	Alt. B	Alt. G	Alt. J
User Needs, Indications for Use	The equipment will be required to apply and inspect a syringe label, insert a plunger-rod, and apply a backstop onto a finger-flange.	Yes	Yes	Yes	Yes
Construction Requirements	Equipment's moving parts must be easily assessed or able to be dismantled for maintenance or cleaning.	Yes	Yes	Yes	Yes
	Equipment must be capable of being retrofitted for additional syringe sizes.	Yes	Yes	Yes	Yes
	Equipment must include quick-change components and change parts.	Yes	Yes	Yes	Yes
	Equipment to be constructed with materials that withstand typical cleanroom cleaning chemicals (70% IPA, Sporicide, Bleach).	Yes	Yes	Yes	Yes
	Equipment product contact points must be FDA accepted non-oxidizing materials.	Yes	Yes	Yes	Yes
	Equipment must be constructed with non-particle shedding materials.	Yes	Yes	Yes	Yes
	Component change-over time must not exceed 30 minutes.	Yes	Yes	Yes	Yes
Documentation Requirements	Company must provide FAT/SAT services.	Yes	Yes	Yes	Yes
	Equipment must be accompanied by a fully documented manual (specific requirements to be provided).	Yes	Yes	Yes	Yes
	Equipment must number all internal wiring and fully document.	Yes	Yes	Yes	Yes
Economic Requirements	Equipment must not require more than two operators.	Yes	Yes	Yes	Yes
	Equipment must not exceed the final cost required by Company ABC.	Yes	Yes	Yes	Yes
	Must agree to a minimum of 50/40/10 payment with final 10% 30 days after receipt.	Yes	Yes	Yes	Yes
Facility Requirements	Equipment must not require more than 100 psi for operation.	Yes	Yes	Yes	Yes
	Equipment must be able to run on 120, 230 or 480 voltage.	Yes	Yes	Yes	Yes

Functional Requirements	Equipment must be capable of processing following syringe sizes: 1ml long, 2.25ml, and 3ml.	Yes	Yes	Yes	Yes
	Equipment capable of printing lot and expiration date per Company ABC's specifications (documentation to be provided to suppliers).	Yes	Yes	Yes	Yes
	Equipment to include black printing capabilities with the ability to be retrofitted in the future for printing barcodes.	Yes	Yes	Yes	Yes
	Equipment must be capable of verifying printed syringe information and label related defects.	Yes	Yes	Yes	Yes
	Equipment must reject non-conforming product (specific requirements to be provided).	Yes	Yes	Yes	Yes
	Equipment must be capable of detecting missing tip caps or PRTC.	Yes	Yes	Yes	Yes
	Equipment must be capable of detecting missing plunger rods or backstops.	Yes	Yes	Yes	Yes
	Equipment to be capable of operating intermittently.	Yes	Yes	Yes	Yes
	Equipment must position the syringes in the same orients per rail-fed out feeds.	Yes	Yes	Yes	Yes
	Equipment must accept syringes per rail-fed in feed and process in a one-piece flow.	Yes	Yes	Yes	Yes
	Equipment must have low level alarms for plunger-rod and backstop hoppers.	Yes	Yes	Yes	Yes
	Equipment must accept bulk loaded plunger-rods and backstops.	Yes	Yes	Yes	Yes
	Equipment must be capable of placing a minimum of two variations of backstops to the flange of the syringe. (samples to be provided).	Yes	Yes	Yes	Yes
	Equipment must be capable of inserting a minimum of two variations of plunger-rods into the syringe stopper with appropriate torque (samples to be provided).	Yes	Yes	Yes	Yes

Performance Requirements	Equipment must be capable of processing a minimum of 50 syringes per minute (3,000/Hour).	Yes	Yes	Yes	Yes
	Equipment must be capable of applying printed labels within a 1/16" vertical tolerance.	Yes	Yes	Yes	Yes
	Labeling process must apply labels free of wrinkling, bubbles or skewing.	Yes	Yes	Yes	Yes
	Equipment must not over torque plunger-rods causing stopper to rotate during insertion.	Yes	Yes	Yes	Yes
Safety/ Ergonomic Requirements	Equipment will be in accordance with Prevailing Safety Regulations for packaging machines and auxiliary equipment. Meets or exceeds OSHA, GS, GMP, etc. regulations.	Yes	Yes	Yes	Yes
	Equipment must incorporate security interlocks and emergency stops.	Yes	Yes	Yes	Yes
	Equipment must be ergonomically friendly to operator.	Yes	Yes	Yes	Yes
Software/ Hardware Requirements	PLC must be 21 CFR part 11 compliant.	Yes	Yes	Yes	Yes
	Equipment must incorporate Allen-Bradley controls.	Yes	Yes	Yes	Yes
	Must be able to communicate with external database.	Yes	Yes	Yes	Yes
Acceptance Criteria	To successfully meet all performance and physical requirements described above.	Yes	Yes	Yes	Yes

Appendix D: Pouch Sealer Design Requirements

Requirement	Design Criteria	Alt. E	Alt. F	Alt. H
User Needs, Indications for Use	Equipment must be capable sealing a syringe in a Tyvek®/Mylar pouch.	Yes	Yes	Yes
Construction Requirements	Equipment to be capable of being retrofitted for printing capabilities.	Yes	Yes	Yes
	Equipment must be capable of being retrofitted for full automation.	Yes	Yes	Yes
	Equipment must to be constructed with non-particle shedding materials.	Yes	Yes	Yes
	Equipment must be constructed with materials that withstand typical cleanroom cleaning chemicals (70% IPA, Sporicide, Bleach).	Yes	Yes	Yes
	Equipment product contact points must be FDA accepted non-oxidizing materials.	Yes	Yes	Yes
Documentation Requirements	Company must provide FAT/SAT services.	Yes	Yes	Yes
	Equipment must be accompanied by a fully documented manual (specific requirements to be provided).	Yes	Yes	Yes
Economic Requirements	Equipment must not require more than one operator.	Yes	Yes	Yes
	Equipment must not exceed the final cost required by Company ABC.	Yes	Yes	**NO**
	Must agree to a minimum of 50/40/10 payment with final 10% 30 days after receipt.	Yes	Yes	Yes
Facility Requirements	Equipment must not require more than 100 psi for operation.	Yes	Yes	Yes
	Equipment must be able to run on 120, 230 or 480 voltage.	Yes	Yes	Yes

Functional Requirements	Equipment must be capable of sealing Mylar/Tyvek® pouches (specifications to be provided).	Yes	Yes	Yes
	Equipment must be capable of sealing with a minimum pressure of 70 psi.	Yes	Yes	Yes
	Equipment must be capable of sealing at a minimum temperature of 270°F.	Yes	Yes	Yes
	Equipment must be capable of maintaining a minimum temperature tolerance of no greater than +/- 10°F.	Yes	Yes	Yes
	Equipment must be capable of processing a minimum pouch width of 3 3/8".	Yes	Yes	Yes
	Equipment must be capable of processing a minimum pouch length of 9".	Yes	Yes	Yes
	Equipment must be capable of handling a 12" diameter roll-stock.	Yes	Yes	Yes
	Equipment must place pouched syringes into a tote capable of handling 300 units.	Yes	Yes	Yes
	Equipment must be capable of semi-automated loading and operation.	Yes	Yes	Yes
	Equipment must seal pouches consistently without channels, voids or wrinkles. Must pass Company ABC's die penetration testing (specification to be provided).	Yes	Yes	Yes
	If automated must be able to process syringes: 1ml long 2.25ml, and 3ml.	Yes	Yes	Yes
	Equipment must be capable of removing 3/8" material from between the pouch web material post pouch sealing or forming.	Yes	Yes	Yes
	Equipment must not cause damage to the syringe during operation (further explanation to be provided).	Yes	Yes	Yes
	If purchased or retrofitted for full automation machine must be able to accept syringes per inline rail-fed in feed.	Yes	Yes	Yes

Performance Requirements	Equipment must be capable of processing: 1,800/hour if fully automated or 1,200 for manual operation.	Yes	Yes	Yes
	Sealed pouches must pass a minimum of 1.5 lb burst or peel test.	Yes	Yes	Yes
	Sealed pouches must pass Company ABC's die penetration requirements (standard to be provided).	Yes	Yes	Yes
Safety/ Ergonomic Requirements	Equipment will be in accordance with Prevailing Safety Regulations for packaging machines and auxiliary equipment. Meets or exceeds OSHA, GS, GMP, etc. regulations.	Yes	Yes	Yes
	Equipment must incorporate security interlocks and emergency stops.	Yes	Yes	Yes
	Equipment must be ergonomically friendly to operator.	Yes	Yes	Yes
Software/ Hardware Requirements	If PLC chosen stores product specific information it must be compliant with 21 CFR part 11.	Yes	Yes	Yes
	If applicable equipment must incorporate Allen-Bradley controls.	Yes	Yes	Yes
Acceptance Criteria	To successfully meet all performance and physical requirements described above.	Yes	Yes	Yes

Appendix E: Denester Decision Matrix

Denester	Rankings (1 - 10)									
	Weighting Factor	Alternative A	Weighted Score	Alternative B	Weighted Score	Alternative J	Weighted Score	Alternative G	Weighted Score	Available Score
Supplier Requirements										
Competitiveness	3	10	30	3	9	5	15	5	15	30
Company history	3	10	30	3	9	5	15	5	15	30
Current performance	5	10	50	4	20	6	30	7	35	50
Development and technology	5	9	45	7	35	7	35	8	40	50
Quality management	5	9	45	6	30	4	20	5	25	50
Total	21		200		103		115		130	210
Importance Factor	0.5									
Adjusted Score	10.5		100	Total	51.5	Total	57.5	Total	65	105
Customer Relations										
Support	5	9	45	9	45	5	25	5	25	50
Training and education	5	10	50	3	15	5	25	5	25	50
Documentation and instructions	5	9	45	5	25	7	35	5	25	50
Installation and Commissioning	3	9	27	5	15	7	21	7	21	30
Validation assistance	3	10	30	3	9	5	15	7	21	30
FAT/SAT testing	3	10	30	6	18	6	18	7	21	30
Total	24		227		127		139		138	240
Importance Factor	0.7									
Adjusted Score	16.8		158.9		88.9		97.3		96.6	168
Functional Requirements										
Construction/architecture	5	9	45	5	25	10	50	9	45	50
Usability/ease of operation	5	10	50	10	50	10	50	10	50	50
Integration with tooling	5	10	50	10	50	10	50	10	50	50
Scalability	3	7	21	6	18	7	21	6	18	30
Changeover complexity	3	10	30	6	18	10	30	8	24	30
Total	21		198		161		201		187	210
Importance Factor	0.8									
Adjusted Score	16.8		156.8		128.8		160.8		149.6	168
Facility Integration										
Fit and Finish	5	10	50	7	35	9	45	9	45	50
Database Interface	5	1	5	1	5	1	5	1	5	50
Electrical requirements	1	10	10	10	10	10	10	10	10	10
Compressed air/nitrogen require.	3	10	30	10	30	10	30	10	30	30
Total	14		95		80		90		90	140
Importance Factor	0.4									
Adjusted Score	5.6		38		32		36		36	56
Environmental										
Pneumatic Exhausting	3	10	30	10	30	10	30	10	30	30
Heat Dissipation	3	10	30	10	30	10	30	10	30	30
Air Disruption (fans, etc.)	3	8	24	8	24	8	24	8	24	30
Shedding/corrosion resistant	5	10	50	3	15	10	50	10	50	50
Portability	1	5	5	8	8	5	5	7	7	10
Total	15		139		107		139		141	150
Importance Factor	0.5									
Adjusted Score	7.5		69.5		53.5		69.5		70.5	75
Economics										
Labor costs	5	10	50	10	50	10	50	10	50	50
Material costs	5	10	50	10	50	10	50	10	50	50
Compliance costs	5	10	50	10	50	10	50	10	50	50
Purchase cost	5	5	25	10	50	1	5	5	25	50
Payment terms	3	10	30	10	30	10	30	10	30	30
Delivery/shipping/crating	1	3	3	10	10	3	3	5	5	10
Total	24		208		240		188		210	240
Importance Factor	1.0									
Adjusted Score	24		208		240		188		210	240
Performance										
Throughput	5	8	40	10	50	10	50	10	50	50
Setup and teardown time	5	8	40	6	30	8	40	5	25	50
Flexibility (ability to operation function independently)	5	5	25	5	25	5	25	3	15	50
Consistency/repeatability	5	10	50	7	35	10	50	10	50	50
Retrofitability	3	5	15	8	24	8	24	8	24	30
Total	23		170		164		189		164	230
Importance Factor	1.0									
Adjusted Score	23		170		164		189		164	230

Worker Safety / Ergonomics											
Changeover complexity	3	8	24	4	12	8	24	6	18	30
Safety features	5	10	50	10	50	10	50	6	30	50
Guarding	5	7	35	8	40	6	30	6	30	50
Burn potential	3	10	30	10	30	10	30	10	30	30
Sharps potential	3	7	21	7	21	7	21	7	21	30
Pinch points	3	4	12	7	21	4	12	8	24	30
Reach requirements	5	7	35	7	35	7	35	8	40	50
Lifting requirements	5	5	25	5	25	5	25	5	25	50
Total	32		232		234		227		218	320
Importance Factor	0.8									
Adjusted Score	25.6		185.6		187.2		181.6		174.4	256
Materials of Construction										
Clean ability	5	8	40	8	40	8	40	8	40	50
Assess ability	3	8	24	6	18	8	24	6	18	30
Compliance with cleaning agents	5	8	40	6	30	8	40	8	40	50
Surface exposure	3	5	15	5	15	5	15	5	15	30
Appearance	1	10	10	7	7	10	10	10	10	10
Total	17		129		110		129		123	170
Importance Factor	0.8									
Adjusted Score	13.6		103.2		88		103.2		98.4	136
Preventative Maintenance										
General requirements	3	10	30	7	21	10	30	10	30	30
Recommended frequency	1	9	9	7	7	9	9	10	10	10
Availability of procedures	3	8	24	8	24	8	24	8	24	30
Total	7		63		52		63		64	70
Importance Factor	0.2									
Adjusted Score	1.4		12.6		10.4		12.6		12.8	14
Calibration										
Ease of procedure	3	5	15	8	24	5	15	5	15	30
Availability of plug-in ports	3	5	15	5	15	5	15	5	15	30
Assess ability	1	10	10	10	10	10	10	10	10	10
Total	7		40		49		40		40	70
Importance Factor	0.5									
Adjusted Score	3.5		20		24.5		20		20	35
Warranty										
Coverage	5	10	50	10	50	10	50	10	50	50
Duration	5	5	25	5	25	5	25	5	25	50
Total	10		75		75		75		75	100
Importance Factor	0.4									
Adjusted Score	4		30		30		30		30	40
Availability										
Lead-time	5	1	5	3	15	10	50	5	25	50
Payment options	3	10	30	10	30	8	24	10	30	30
Short-term lease availability	1	1	1	1	1	10	10	10	10	10
Total	9		36		46		84		65	90
Importance Factor	0.3									
Adjusted Score	2.7		10.8		13.8		25.2		19.5	27
Software										
PLC options	3	10	30	10	30	10	30	3	9	30
Software options	3	5	15	5	15	5	15	5	15	30
Software security	5	10	50	10	50	10	50	10	50	50
Support	5	9	45	9	45	5	25	3	15	50
Validity/License	5	5	25	5	25	5	25	5	25	50
Total	21		165		165		145		114	210
Importance Factor	0.1									
Adjusted Score	2.1		16.5		16.5		14.5		11.4	21
TOTALS	157.1		1279.9		1129.1		1185.2		1158.2	1571

Appendix F: Inspection Decision Matrix

Inspection	Rankings (1 - 10)							
	Weighting Factor	Alternative A	Weighted Score	Alternative B	Weighted Score	Alternative C	Weighted Score	Available Score
Supplier Requirements								
Competitiveness	3	10	30	3	9	6	18	30
Company history	3	10	30	3	9	5	15	30
Current performance	5	10	50	4	20	5	25	50
Development and technology	5	9	45	7	35	7	35	50
Quality management	5	9	45	6	30	6	30	50
Total	21		200		103		123	210
Importance Factor	0.6							
Adjusted Score	12.6		120	Total	61.8	Total	73.8	126
Customer Relations								
Support	5	9	45	9	45	5	25	50
Training and education	5	9	45	3	15	8	40	50
Documentation and instructions	5	9	45	5	25	8	40	50
Installation and Commissioning	3	9	27	5	15	8	24	30
Validation assistance	3	9	27	3	9	8	24	30
FAT/SAT testing	3	10	30	6	18	8	24	30
Total	24		219		127		177	240
Importance Factor	0.8							
Adjusted Score	19.2		175.2		101.6		141.6	192
Functional Requirements								
Construction/architecture	5	9	45	6	30	10	50	50
Usability/ease of operation	5	10	50	9	45	9	45	50
Integration with tooling	5	10	50	10	50	10	50	50
Scalability	3	8	24	8	24	8	24	30
Changeover complexity	3	10	30	7	21	9	27	30
Total	21		199		170		196	210
Importance Factor	0.9							
Adjusted Score	18.9		179.1		153		176.4	189
Facility Integration								
Fit and Finish	5	10	50	8	40	9	45	50
Database interface	5	10	50	10	50	10	50	50
Electrical requirements	1	10	10	10	10	10	10	10
Compressed air/nitrogen require.	3	10	30	10	30	10	30	30
Total	14		140		130		135	140
Importance Factor	0.5							
Adjusted Score	7		70		65		67.5	70
Environmental								
Pneumatic Exhausting	3	10	30	10	30	10	30	30
Heat Dissipation	3	10	30	10	30	10	30	30
Air Disruption (fans, etc.)	3	8	24	8	24	8	24	30
Shedding/corrosion resistant	5	10	50	8	40	10	50	50
Portability	1	2	2	2	2	2	2	10
Total	15		136		126		136	150
Importance Factor	0.5							
Adjusted Score	7.5		68		63		68	75
Economics								
Labor costs	5	10	50	10	50	10	50	50
Material costs	5	10	50	10	50	10	50	50
Compliance costs	5	10	50	10	50	10	50	50
Purchase cost	5	2	10	10	50	1	5	50
Payment terms	3	10	30	10	30	10	30	30
Delivery/shipping/crating	1	3	3	10	10	3	3	10
Total	24		193		240		188	240
Importance Factor	1.0							
Adjusted Score	24		193		240		188	240
Performance								
Throughput	5	10	50	10	50	10	50	50
Setup and teardown time	5	7	35	6	30	7	35	50
Flexibility (ability to operation function independently)	5	5	25	5	25	5	25	50
Consistency/repeatability	5	8	40	8	40	8	40	50
Retrofitability	3	10	30	10	30	5	15	30
Total	23		180		175		165	230
Importance Factor	1.0							
Adjusted Score	23		180		175		165	230

Worker Safety / Ergonomics									
	Changeover complexity	3	5	15	5	15	5	15	30
	Safety features	5	8	40	8	40	6	30	50
	Guarding	5	8	40	8	40	8	40	50
	Burn potential	3	10	30	10	30	10	30	30
	Sharps potential	3	5	15	5	15	5	15	30
	Pinch points	3	3	9	3	9	3	9	30
	Reach requirements	5	8	40	8	40	10	50	50
	Lifting requirements	5	10	50	10	50	10	50	50
	Total	32		239		239		239	320
	Importance Factor	0.8							
	Adjusted Score	25.6		191.2		191.2		191.2	256
Materials of Construction									
	Clean ability	5	10	50	8	40	9	45	50
	Assess ability	3	8	24	8	24	8	24	30
	Compliance with cleaning agents	5	5	25	5	25	5	25	50
	Surface exposure	3	5	15	5	15	5	15	30
	Appearance	1	10	10	10	10	10	10	10
	Total	17		124		114		119	170
	Importance Factor	0.8							
	Adjusted Score	13.6		99.2		91.2		95.2	136
Preventative Maintenance									
	General requirements	3	10	30	10	30	8	24	30
	Recommended frequency	1	8	8	8	8	8	8	10
	Availability of procedures	3	10	30	10	30	10	30	30
	Total	7		68		68		62	70
	Importance Factor	0.1							
	Adjusted Score	0.7		6.8		6.8		6.2	7
Calibration									
	Ease of procedure	3	7	21	9	27	7	21	30
	Availability of plug-in ports	3	10	30	10	30	10	30	30
	Assess ability	1	9	9	10	10	9	9	10
	Total	7		60		67		60	70
	Importance Factor	0.2							
	Adjusted Score	1.4		12		13.4		12	14
Warranty									
	Coverage	5	10	50	10	50	10	50	50
	Duration	5	5	25	5	25	5	25	50
	Total	10		75		75		75	100
	Importance Factor	0.4							
	Adjusted Score	4		30		30		30	40
Availability									
	Lead-time	5	8	40	10	50	4	20	50
	Payment options	3	10	30	10	30	10	30	30
	Short-term lease availability	1	10	10	1	1	1	1	10
	Total	9		80		81		51	90
	Importance Factor	0.3							
	Adjusted Score	2.7		24		24.3		15.3	27
Software									
	PLC options	3	10	30	10	30	10	30	30
	Software options	3	5	15	5	15	5	15	30
	Software security	5	10	50	10	50	10	50	50
	Support	5	9	45	7	35	8	40	50
	Validity/License	5	9	45	8	40	9	45	50
	Total	21		185		170		180	210
	Importance Factor	0.3							
	Adjusted Score	6.3		55.5		51		54	63
	TOTALS	166.5		1404		1267.3		1284.2	1665

Appendix G: Labeler, Plunger-rod and Backstop Decision Matrix

Label, Plunger-rod, Backstop	Rankings (1 - 10)									
	Weighting Factor	Alternative A	Weighted Score	Alternative B	Weighted Score	Alternative C	Weighted Score	Alternative D	Weighted Score	Available Score
Supplier Requirements										
Competitiveness	3	10	30	3	9	5	15	9	27	30
Company history	3	10	30	3	9	5	15	10	30	30
Current performance	5	10	50	4	20	6	30	10	50	50
Development and technology	5	9	45	7	35	7	35	10	50	50
Quality management	5	9	45	6	30	4	20	8	40	50
Total	21		200		103		115		197	210
Importance Factor	0.7									
Adjusted Score	14.7		140		72.1		80.5		137.9	147
Customer Relations										
Support	5	9	45	9	45	5	25	8	40	50
Training and education	5	10	50	3	15	5	25	10	50	50
Documentation and instructions	5	9	45	5	25	7	35	9	45	50
Installation and Commissioning	3	9	27	5	15	7	21	8	24	30
Validation assistance	3	10	30	3	9	5	15	8	24	30
FAT/SAT testing	3	10	30	6	18	6	18	8	24	30
Total	24		227		127		139		207	240
Importance Factor	0.8									
Adjusted Score	19.2		181.6		101.6		111.2		165.6	192
Functional Requirements										
Construction/architecture	5	10	50	8	40	10	50	10	50	50
Usability/ease of operation	5	8	40	6	30	8	40	8	40	50
Integration with tooling	5	10	50	10	50	10	50	10	50	50
Scalability	3	5	15	5	15	5	15	5	15	30
Changeover complexity	3	7	21	7	21	7	21	6	18	30
Total	21		176		156		176		173	210
Importance Factor	1.0									
Adjusted Score	21		176		156		176		173	210
Facility Integration										
Fit and Finish	5	10	50	8	40	10	50	10	50	50
Database Interface	5	10	50	10	50	10	50	10	50	50
Electrical requirements	1	10	10	10	10	10	10	10	10	10
Compressed air/nitrogen require.	3	10	30	10	30	10	30	10	30	30
Total	14		140		130		140		140	140
Importance Factor	0.6									
Adjusted Score	8.4		84		78		84		84	84
Environmental										
Pneumatic Exhausting	3	10	30	8	24	10	30	10	30	30
Heat Dissipation	3	9	27	9	27	9	27	9	27	30
Air Disruption (fans, etc.)	3	8	24	8	24	6	18	8	24	30
Shedding/corrosion resistant	5	10	50	7	35	10	50	10	50	50
Portability	1	1	1	1	1	1	1	1	1	10
Total	15		132		111		126		132	150
Importance Factor	0.4									
Adjusted Score	6		52.8		44.4		50.4		52.8	60
Economics										
Labor costs	5	10	50	10	50	10	50	10	50	50
Material costs	5	10	50	10	50	10	50	10	50	50
Compliance costs	5	10	50	10	50	10	50	10	50	50
Purchase cost	5	3	15	10	50	1	5	1	5	50
Payment terms	3	10	30	10	30	10	30	10	30	30
Delivery/shipping/crating	1	3	3	10	10	3	3	4	4	10
Total	24		198		240		188		189	240
Importance Factor	1.0									
Adjusted Score	24		198		240		188		189	240
Performance										
Throughput	5	10	50	10	50	10	50	10	50	50
Setup and teardown time	5	7	35	7	35	7	35	8	40	50
Flexibility (ability to operation function independently)	5	8	40	8	40	8	40	7	35	50
Consistency/repeatability	5	10	50	8	40	10	50	10	50	50
Retrofitability	3	4	12	4	12	4	12	4	12	30
Total	23		187		177		187		187	230
Importance Factor	1.0									
Adjusted Score	23		187		177		187		187	230

Worker Safety / Ergonomics										
Changeover complexity	3	10	30	8	24	6	18	9	27	30
Safety features	5	10	50	10	50	10	50	9	45	50
Guarding	5	8	40	8	40	8	40	9	45	50
Burn potential	3	10	30	10	30	10	30	10	30	30
Sharps potential	3	7	21	7	21	7	21	5	15	30
Pinch points	3	5	15	7	21	5	15	7	21	30
Reach requirements	5	5	25	5	25	5	25	6	30	50
Lifting requirements	5	5	25	5	25	5	25	4	20	50
Total	32		236		236		224		233	320
Importance Factor	0.8									
Adjusted Score	25.6		188.8		188.8		179.2		186.4	256
Materials of Construction										
Clean ability	5	9	45	7	35	7	35	9	45	50
Assess ability	3	7	21	8	24	6	18	7	21	30
Compliance with cleaning agents	5	8	40	6	30	8	40	9	45	50
Surface exposure	3	5	15	5	15	5	15	5	15	30
Appearance	1	10	10	3	3	10	10	10	10	10
Total	17		131		107		118		136	170
Importance Factor	0.8									
Adjusted Score	13.6		104.8		85.6		94.4		108.8	136
Preventative Maintenance										
General requirements	3	10	30	10	30	10	30	10	30	30
Recommended frequency	1	8	8	10	10	8	8	10	10	10
Availability of procedures	3	5	15	10	30	7	21	5	15	30
Total	7		53		70		59		55	70
Importance Factor	0.2									
Adjusted Score	1.4		10.6		14		11.8		11	14
Calibration										
Ease of procedure	3	8	24	6	18	6	18	6	18	30
Availability of plug-in ports	3	7	21	7	21	7	21	6	18	30
Assess ability	1	8	8	8	8	8	8	7	7	10
Total	7		53		47		47		43	70
Importance Factor	0.3									
Adjusted Score	2.1		15.9		14.1		14.1		12.9	21
Warranty										
Coverage	5	10	50	10	50	10	50	10	50	50
Duration	5	5	25	5	25	5	25	5	25	50
Total	10		75		75		75		75	100
Importance Factor	0.4									
Adjusted Score	4		30		30		30		30	40
Availability										
Lead-time	5	1	5	3	15	10	50	1	5	50
Payment options	3	10	30	10	30	8	24	5	15	30
Short-term lease availability	1	1	1	1	1	10	10	1	1	10
Total	9		36		46		84		21	90
Importance Factor	0.3									
Adjusted Score	2.7		10.8		13.8		25.2		6.3	27
Software										
PLC options	3	10	30	10	30	10	30	10	30	30
Software options	3	8	24	4	12	8	24	10	30	30
Software security	5	10	50	10	50	10	50	10	50	50
Support	5	9	45	9	45	5	25	7	35	50
Validity/License	5	5	25	5	25	5	25	5	25	50
Total	21		174		162		154		170	210
Importance Factor	0.3									
Adjusted Score	6.3		52.2		48.6		46.2		51	63
TOTALS	172		1432.5		1264		1278		1395.7	1720

Appendix H: Pouch Sealer Decision Matrix

Pouch Sealer	Rankings (1 - 10)							
	Weighting Factor	Alternative A	Weighted Score	Alternative B	Weighted Score	Alternative C	Weighted Score	Available Score
Supplier Requirements								
Competitiveness	3	8	24	3	9	7	21	30
Company history	3	8	24	4	12	8	24	30
Current performance	5	8	40	8	40	9	45	50
Development and technology	5	9	45	5	25	10	50	50
Quality management	5	7	35	10	50	9	45	50
Total	21		168		136		185	210
Importance Factor	0.6							
Adjusted Score	12.6		100.8	Total	81.6	Total	111	126
Customer Relations								
Support	5	5	25	9	45	6	30	50
Training and education	5	5	25	7	35	7	35	50
Documentation and instructions	5	4	20	7	35	7	35	50
Installation and Commissioning	3	9	27	8	24	6	18	30
Validation assistance	3	7	21	5	15	9	27	30
FAT/SAT testing	3	10	30	8	24	7	21	30
Total	24		148		178		166	240
Importance Factor	0.8							
Adjusted Score	19.2		118.4		142.4		132.8	192
Functional Requirements								
Construction/architecture	5	9	45	3	15	10	50	50
Usability/ease of operation	5	7	35	9	45	9	45	50
Integration with tooling	5	10	50	10	50	10	50	50
Scalability	3	5	15	3	9	1	3	30
Changeover complexity	3	5	15	8	24	3	9	30
Total	21		160		143		157	210
Importance Factor	0.9							
Adjusted Score	18.9		144		128.7		141.3	189
Facility Integration								
Fit and Finish	5	8	40	3	15	10	50	50
Database interface	5	5	25	5	25	10	50	50
Electrical requirements	1	10	10	10	10	10	10	10
Compressed air/nitrogen require.	3	10	30	10	30	10	30	30
Total	14		105		80		140	140
Importance Factor	0.5							
Adjusted Score	7		52.5		40		70	70
Environmental								
Pneumatic Exhausting	3	5	15	5	15	5	15	30
Heat Dissipation	3	2	6	9	27	2	6	30
Air Disruption (fans, etc.)	3	5	15	6	18	3	9	30
Shedding/corrosion resistant	5	8	40	8	40	8	40	50
Portability	1	10	10	5	5	1	1	10
Total	15		86		105		71	150
Importance Factor	0.5							
Adjusted Score	7.5		43		52.5		35.5	75
Economics								
Labor costs	5	10	50	9	45	10	50	50
Material costs	5	10	50	5	25	10	50	50
Compliance costs	5	10	50	10	50	10	50	50
Purchase cost	5	10	50	8	40	1	5	50
Payment terms	3	10	30	10	30	5	15	30
Delivery/shipping/crating	1	10	10	10	10	3	3	10
Total	24		240		200		173	240
Importance Factor	1.0							
Adjusted Score	24		240		200		173	240
Performance								
Throughput	5	8	40	6	30	10	50	50
Setup and teardown time	5	7	35	9	45	7	35	50
Flexibility (ability to operation function independently)	5	1	5	3	15	1	5	50
Consistency/repeatability	5	5	25	8	40	7	35	50
Retrofitability	3	10	30	6	18	2	6	30
Total	23		135		148		131	230
Importance Factor	1.0							
Adjusted Score	23		135		148		131	230

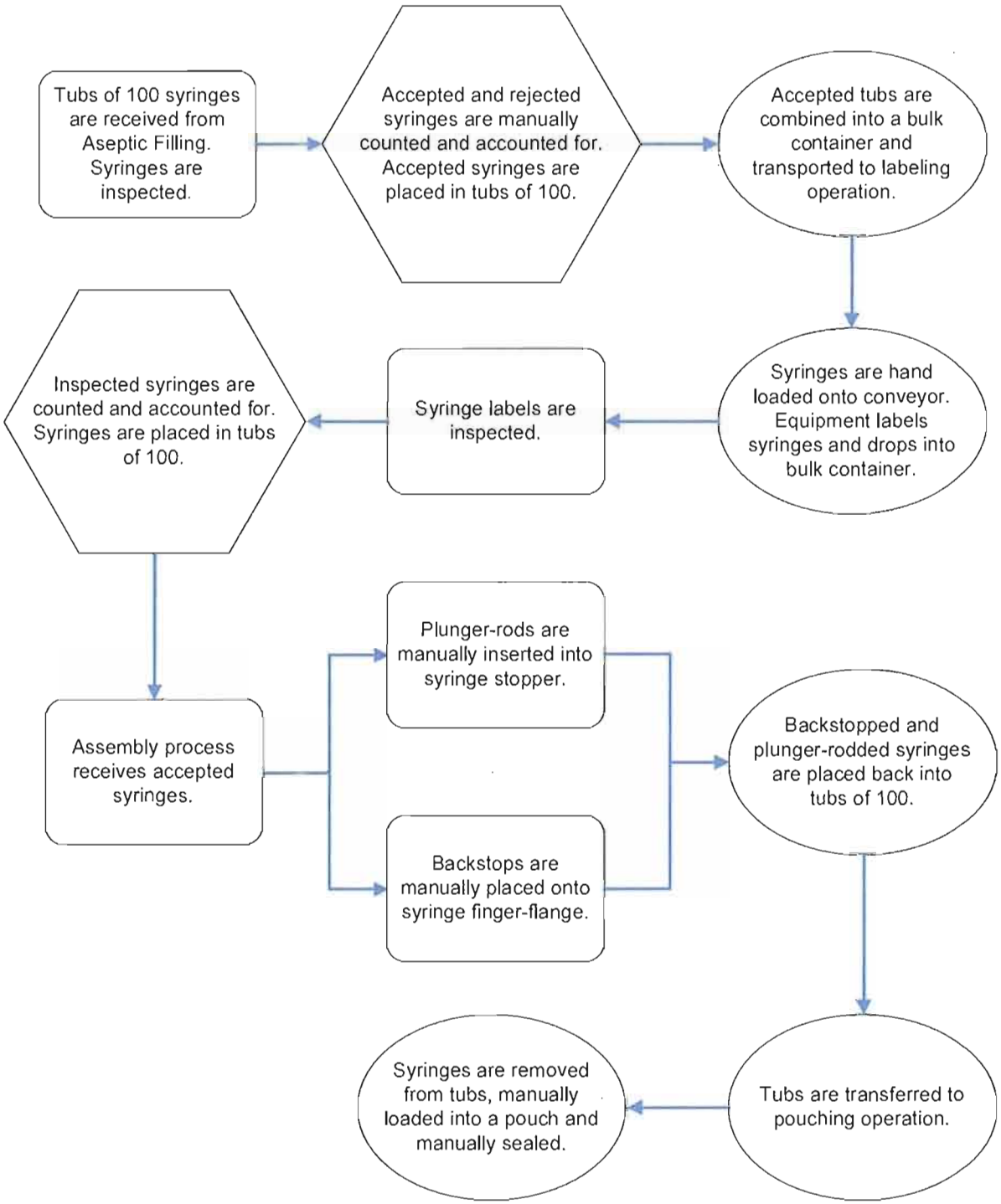
Worker Safety / Ergonomics									
	Changeover complexity	3	8	24	5	15	5	15	30
	Safety features	5	8	40	7	35	7	35	50
	Guarding	5	8	40	8	40	8	40	50
	Burn potential	3	4	12	8	24	4	12	30
	Sharps potential	3	4	12	4	12	4	12	30
	Pinch points	3	5	15	3	9	3	9	30
	Reach requirements	5	5	25	5	25	5	25	50
	Lifting requirements	5	8	40	10	50	10	50	50
	Total	32		208		210		198	320
	Importance Factor	0.8							
	Adjusted Score	25.6		166.4		168		158.4	256
Materials of Construction									
	Clean ability	5	5	25	5	25	5	25	50
	Assess ability	3	5	15	5	15	5	15	30
	Compliance with cleaning agents	5	10	50	4	20	10	50	50
	Surface exposure	3	5	15	5	15	5	15	30
	Appearance	1	10	10	5	5	10	10	10
	Total	17		115		80		115	170
	Importance Factor	0.8							
	Adjusted Score	13.6		92		64		92	136
Preventative Maintenance									
	General requirements	3	10	30	10	30	10	30	30
	Recommended frequency	1	8	8	8	8	8	8	10
	Availability of procedures	3	5	15	10	30	5	15	30
	Total	7		53		68		53	70
	Importance Factor	0.1							
	Adjusted Score	0.7		5.3		6.8		5.3	7
Calibration									
	Ease of procedure	3	5	15	10	30	7	21	30
	Availability of plug-in ports	3	10	30	10	30	10	30	30
	Assess ability	1	9	9	9	9	9	9	10
	Total	7		54		69		60	70
	Importance Factor	0.2							
	Adjusted Score	1.4		10.8		13.8		12	14
Warranty									
	Coverage	5	10	50	10	50	10	50	50
	Duration	5	5	25	5	25	5	25	50
	Total	10		75		75		75	100
	Importance Factor	0.4							
	Adjusted Score	4		30		30		30	40
Availability									
	Lead-time	5	10	50	3	15	3	15	50
	Payment options	3	5	15	10	30	8	24	30
	Short-term lease availability	1	10	10	1	1	1	1	10
	Total	9		75		46		40	90
	Importance Factor	0.3							
	Adjusted Score	2.7		22.5		13.8		12	27
Software									
	PLC options	3	5	15	5	15	10	30	30
	Software options	3	2	6	5	15	8	24	30
	Software security	5	7	35	10	50	10	50	50
	Support	5	5	25	10	50	5	25	50
	Validity/License	5	5	25	5	25	5	25	50
	Total	21		106		155		154	210
	Importance Factor	0.3							
	Adjusted Score	6.3		31.8		46.5		46.2	63
	TOTALS	166.5		1192.5		1136.1		1150.5	1665

Appendix I: Labeler, Plunger-rod and Backstop Decision Matrix after Sensitivity Analysis

Label, Plunger-rod, Backstop	Rankings (1 - 10)									
	Weighting Factor	Alternative A	Weighted Score	Alternative B	Weighted Score	Alternative C	Weighted Score	Alternative D	Weighted Score	Available Score
Supplier Requirements										
Competitiveness	3	10	30	3	9	5	15	9	27	30
Company history	3	10	30	3	9	5	15	10	30	30
Current performance	5	10	50	4	20	6	30	10	50	50
Development and technology	5	9	45	7	35	7	35	10	50	50
Quality management	5	9	45	6	30	4	20	8	40	50
Total	21		200		103		115		197	210
Importance Factor	0.7									
Adjusted Score	14.7		140		72.1		80.5		137.9	147
Customer Relations										
Support	5	9	45	9	45	5	25	8	40	50
Training and education	5	10	50	3	15	5	25	10	50	50
Documentation and instructions	5	9	45	5	25	7	35	9	45	50
Installation and Commissioning	3	9	27	5	15	7	21	8	24	30
Validation assistance	3	10	30	3	9	5	15	8	24	30
FAT/SAT testing	3	10	30	6	18	6	18	8	24	30
Total	24		227		127		139		207	240
Importance Factor	0.8									
Adjusted Score	19.2		181.6		101.6		111.2		165.6	192
Functional Requirements										
Construction/architecture	5	10	50	8	40	10	50	10	50	50
Usability/ease of operation	5	8	40	6	30	8	40	8	40	50
Integration with tooling	5	10	50	10	50	10	50	10	50	50
Scalability	3	5	15	5	15	5	15	5	15	30
Changeover complexity	3	7	21	7	21	7	21	6	18	30
Total	21		176		156		176		173	210
Importance Factor	1.0									
Adjusted Score	21		176		156		176		173	210
Facility Integration										
Fit and Finish	5	10	50	8	40	10	50	10	50	50
Database Interface	5	10	50	10	50	10	50	10	50	50
Electrical requirements	1	10	10	10	10	10	10	10	10	10
Compressed air/nitrogen require.	3	10	30	10	30	10	30	10	30	30
Total	14		140		130		140		140	140
Importance Factor	0.6									
Adjusted Score	8.4		84		78		84		84	84
Environmental										
Pneumatic Exhausting	3	10	30	8	24	10	30	10	30	30
Heat Dissipation	3	9	27	9	27	9	27	9	27	30
Air Disruption (fans, etc.)	3	8	24	8	24	6	18	8	24	30
Shedding/corrosion resistant	5	10	50	7	35	10	50	10	50	50
Portability	1	1	1	1	1	1	1	1	1	10
Total	15		132		111		126		132	150
Importance Factor	0.4									
Adjusted Score	6		52.8		44.4		50.4		52.8	60
Economics										
Labor costs	5	10	50	10	50	10	50	10	50	50
Material costs	5	10	50	10	50	10	50	10	50	50
Compliance costs	5	10	50	10	50	10	50	10	50	50
Purchase cost	10	3	30	10	100	1	10	1	10	100
Payment terms	3	10	30	10	30	10	30	10	30	30
Delivery/shipping/crating	1	3	3	10	10	3	3	4	4	10
Total	29		213		290		193		194	290
Importance Factor	2.0									
Adjusted Score	58		426		580		386		388	580
Performance										
Throughput	5	10	50	10	50	10	50	10	50	50
Setup and teardown time	5	7	35	7	35	7	35	8	40	50
Flexibility (ability to operation function independently)	5	8	40	8	40	8	40	7	35	50
Consistency/repeatability	5	10	50	8	40	10	50	10	50	50
Retrofitability	3	4	12	4	12	4	12	4	12	30
Total	23		187		177		187		187	230
Importance Factor	1.0									
Adjusted Score	23		187		177		187		187	230

Worker Safety / Ergonomics											
Changeover complexity	3	10	30	8	24	6	18	9	27	30
Safety features	5	10	50	10	50	10	50	9	45	50
Guarding	5	8	40	8	40	8	40	9	45	50
Burn potential	3	10	30	10	30	10	30	10	30	30
Sharps potential	3	7	21	7	21	7	21	5	15	30
Pinch points	3	5	15	7	21	5	15	7	21	30
Reach requirements	5	5	25	5	25	5	25	6	30	50
Lifting requirements	5	5	25	5	25	5	25	4	20	50
Total	32		236		236		224		233	320
Importance Factor	0.8									
Adjusted Score	25.6		188.8		188.8		179.2		186.4	256
Materials of Construction										
Clean ability	5	9	45	7	35	7	35	9	45	50
Assess ability	3	7	21	8	24	6	18	7	21	30
Compliance with cleaning agents	5	8	40	6	30	8	40	9	45	50
Surface exposure	3	5	15	5	15	5	15	5	15	30
Appearance	1	10	10	3	3	10	10	10	10	10
Total	17		131		107		118		136	170
Importance Factor	0.8									
Adjusted Score	13.6		104.8		85.6		94.4		108.8	136
Preventative Maintenance										
General requirements	3	10	30	10	30	10	30	10	30	30
Recommended frequency	1	8	8	10	10	8	8	10	10	10
Availability of procedures	3	5	15	10	30	7	21	5	15	30
Total	7		53		70		59		55	70
Importance Factor	0.2									
Adjusted Score	1.4		10.6		14		11.8		11	14
Calibration										
Ease of procedure	3	8	24	6	18	6	18	6	18	30
Availability of plug-in ports	3	7	21	7	21	7	21	6	18	30
Assess ability	1	8	8	8	8	8	8	7	7	10
Total	7		53		47		47		43	70
Importance Factor	0.3									
Adjusted Score	2.1		15.9		14.1		14.1		12.9	21
Warranty										
Coverage	5	10	50	10	50	10	50	10	50	50
Duration	5	5	25	5	25	5	25	5	25	50
Total	10		75		75		75		75	100
Importance Factor	0.4									
Adjusted Score	4		30		30		30		30	40
Availability										
Lead-time	5	1	5	3	15	10	50	1	5	50
Payment options	3	10	30	10	30	8	24	5	15	30
Short-term lease availability	1	1	1	1	1	10	10	1	1	10
Total	9		36		46		84		21	90
Importance Factor	0.3									
Adjusted Score	2.7		10.8		13.8		25.2		6.3	27
Software										
PLC options	3	10	30	10	30	10	30	10	30	30
Software options	3	8	24	4	12	8	24	10	30	30
Software security	5	10	50	10	50	10	50	10	50	50
Support	5	9	45	9	45	5	25	7	35	50
Validity/License	5	5	25	5	25	5	25	5	25	50
Total	21		174		162		154		170	210
Importance Factor	0.3									
Adjusted Score	6.3		52.2		48.6		46.2		51	63
TOTALS	206		1660.5		1604		1476		1594.7	2060

Appendix J: Current Process Flow



Appendix K: Projected Process Flow