Insulin Cartridge Alternate Source Initiative

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Abstract — This paper addresses a supply chain problem related to a molded component that is externally manufactured in a company in Singapore. It details the current situation, reason for undertaking the project and its goals and objectives. A structure problem solving approach was followed to establish product requirements, indentifying potential suppliers that developed project proposals and making the final supplier selection. The analysis resulted in the selection of Tessy Plastics from Shaghai as the partner to move forward in the project. Preliminaries scope of work and project plan were completed. Analyzed project financials showed very favorable. The project can now move to the Capital Appropriation Approval phase.

Key Terms — *DMAIC methodology*, *Product requirements*, *Request for Quote*, *Supplier selection process*.

INTRODUCTION

Background for undertaken the project

Currently Animas, a member of the Johnson & Johnson Family of Companies, purchases insulin cartridges from Beyonics in Singapore. The insulin cartridge is used as an insulin reservoir on medical insulin pumps. Figure 1 shows the purchased device.



Figure 1 Insulin Cartridge

The Insulin Cartridge is purchased on the final packaged, and then shipped to Animas in West Chester, PA. Animas currently manages the sterilization supply chain through Steris (Sterilization company) in New Jersey plus final testing which adds complexity and cost. The product is shipped to the distribution centers after completion of successful all the testing requirements.

Some of the concerns with the incumbent supplier are the following:

- There is a history of technical issues since there are unique challenges with this cartridge.
 - High number of batches scrapped due to high force being out of specification.
 - Leaking Cartridge Recall in 2011.
 Beyonics accepted partial responsibility.
- The Singapore location is not state of the art. It is an older facility with generally older equipment. They are resource challenged and have occasional reluctance to take full ownership when issues arise.
- Their long term Financial Stability is in question since they were recently purchased. Their unit cost has been high where only incremental improvements have been proposed.
- Their response time has been very slow on pressured or difficult situations.

Project Goal and objectives

Identify and select an alternate source for the cartridge that will help achieve the following objectives:

• Simplify Supply Chain by having the cartridge supplier manage sterilization,

final testing and direct shipment to the distribution centers. The current end to end supply is 8 weeks. The goal is to reduce it to at least 6 weeks.

- Update packaging to reduce shipping and packaging costs.
- Optimize total cost by 30%
- If possible utilization of a Johnson & Johnson (J & J) Preferred supplier.

LITERATURE REVIEW

"Select the right vendor, and outsourcing can serve as a powerful strategy for achieving business objectives such as lowering costs or shortening time to market. Select the wrong vendor, and outsourcing can mire companies in sub-par business performance and regret" [1]. Vendor selection is not a process to be taken lightly or hurried. Organizations should stick to a wellestablished methodology that clearly defines each step of the journey. At the end of the process, the goal is to select the best service provider for delivering the desired outsourcing outcome.

Reference [1] lists seven critical steps involved in making a good choice when selecting a vendor:

- Step 1: Identify: Gather the Team and Requirements
- Step 2: Collect Vendor Information: Draft the RFI
- Step 3: Develop the RFP
- Step 4: Conduct Due Diligence
- Step 5: Visit the Vendor Site: Look for Showstoppers
- Step 6: Test: Launch a Pilot Project
- Step 7: Finalize Vendor Selection

Making the final selection is a very difficult task and many attributes from the competing suppliers need to be assessed.

"When evaluating suppliers, clients tend to focus on suppliers' resources because these are highly visible on site tours, balance sheets and resumes. But they should be more interested in suppliers' ability to turn these resources – its physical and human assets such as physical facilities, technologies, tools and workforce – into capabilities that, in turn, can be combined to create high-level customer-facing competencies" [2].

Reference [3] shows The Flawless Project Execution (FPX) Methodology. It applies Project Leadership best practices to delivering and integrating new products, processes and technologies into organizations. This allows flawless execution and the attainment of project and business objectives. It emphasizes where many projects tend to fail: Clear Scope, Sponsor support, team alignment/Structure, communication and change management process. It provides tools for project leaders, a common methodology that leads to more efficient teams. It also provides examples of what things to avoid on a project execution.

Finally several techniques for analyzing single or multiple projects will be used for the financial analysis and justification of the alternate supplier project. Reference [4] teaches several methods for this type of analysis. For the alternate supplier project Net Present Value (NPV) and Internal Rate of Return (IRR) computations will be used. Both analysis are important and will be used for analyzing the project financials.

DMAIC METHODOLOGY AND PROJECT EXECUTION

DMAIC (an abbreviation for Define, Measure, Analyze, Improve and Control) refers to a datadriven improvement cycle used for improving, optimizing and stabilizing business processes and designs. The DMAIC improvement cycle is the core tool used to drive Six Sigma projects. However, DMAIC is not exclusive to Six Sigma and can be used as the framework for other improvement applications like for selecting an alternate source.

Define

In this section, the project statement and objectives were defined. Both were stated in detail in the introduction section of this article.

One of the most important key tasks in executing a project is the people working in it. A Multi-departmental project team was created for the project to cover all aspects impacted by the project. The team was designed using FPx, Flawless Project Execution team design structure. As part of the Core team governance, bi-weekly meetings were agreed until the Capital Appropriation Request (CAR) is approved and weekly thereafter. Monthly updates to sponsors/stakeholders were established. Figure 2 shows the created team.

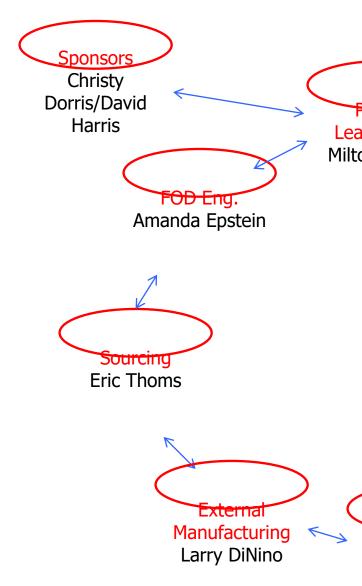


Figure 2 Cartridge Alternate Source Core Team

After the team was crated, roles and responsibilities were defined and agreed. A Responsible Accounted Consulted Informed (RACI) analysis was completed. A RACI sample is shown in Table 1.

 Table 1

 Sample of RACI (Responsible Accounted Consulted Informed)

RACI Chart												
Milestones	1											
t	Roles ->	FOD	EO	SQ	RA	PLAN	R&D	DQ	QA	SC	(Supplier)	Comments
Single Cavity												
Prototypes	Test plan development	с	R,A	с			с		с		с	WK Primary, LD
	Mold design requirements, review & approval	с	R,A								с	WK Primary, LD
	Test equipment development for sgl cavity tool	с	A	с			R	с	с			WK Primary, LD
	Mold acceptance		R,A								с	WK Primary, LD
	Product dimensional tolerance study & functional Verification	A	R				A	с			с	FOD Primary, WK, LD
	Parts for assembly machine development		R,A									LD primary
	Testing Summary Report		A	с			R	с	с		с	DS Primary

Also, in this phase the requirements package was prepared and sent to the suppliers for them to reply back with project proposals. The package included the following:

- Project Scope
 - Tooling build for injection molded components.
 - Hot stamping of molded components per specifications.
 - Assembly of molded and purchased components.
 - Packaging, Heat Sealing and Shipping of Finished Product.
 - Sterilization (EtO) and Final release testing.
- Project Estimated Volumes: Final cartridge assembly purchases in excess of 9,000,000 pieces on an annual basis. Monthly and/or weekly shipments of incremental volumes are expected.
- Specifications: Drawings, specifications, instructions, policies, engineering guides, etc., which are a part of this request, or disclosed during the selection process, are

the property of Animas Corporation, and shall not be duplicated nor disclosed.

- Timing: A three week response was requested for providing quotation information via electronic format to Animas Corporation.
- Expectations: Table 2 lists Animas Corporation expectations that will be conditions for the future award of the specified program, Insulin Cartridge Requirements business. Any exception to these terms need to be noted in the proposal.

Table 2 Animas Corporation Expectations

Payment Terms	Net 45 Days
FOB	Agreed upon destination
Lead time (repeat buy)	60 days, with 12 month rolling
	forecast and raw material
	authorization, 100%
	cancelable outside of 60 days
	lead-time, all exceptions must
	be noted.
Delivery	Delivery expectation is 100%
	on time, measured as 5 days

	early, 2days late for delivery
	to an Animas Corporation
	designated location.
Productivity	Goal of 6% year over year
	productivity improvement,
	achieved by process and
	material process
	improvements.
Pricing	Pricing to be quoted per the
	attached Excel spreadsheet,
	providing details down to the
	individual unit. Tiered price
	breaks are required at 5
	million units, 9 million units,
	11 million units, and 14
	million units on an annual
	basis. Alternative increments
	may be substituted.
Capital Requirements	Capital for tooling is to be
	quoted separately. Mold and
	tool building capabilities will
	be considered, including use
	of existing tooling.
	Alternative financing options,
	including adding to product
	pricing will be preferred.
Packaging	All material is to be stretch-
	wrapped and plastic banded to
	standard size plastic pallets.
	Existing unit packaging is to
	be quoted, but cost saving
	alternatives will be
	considered, including the use
	of existing tooling or lines
	currently in use.
Sterilization	Product is to be quoted as a
	delivered sterilized.
Quality	Quality documentation such as
	control plans, process maps,
	FMEA, first article, test data,
	to be provided upon request.
	1 1 1

RMA (Return Material	RMA to be provided within 48
Authorization)	hours of request. Corrective
	action report must be provided
	for all returned material upon
	request.
NRE (Non-recurring	All NRE, tooling
Engineering costs),	modifications, and fixtures
Tooling and Fixtures	must be listed separately from
	production pricing.

Measure

In this phase, a Request for Quote (RFQ) letter was completed. The package included all requirements established in the Define phase in addition to all product drawings and bill of materials. A total of eight packages were prepared and sent to eight different plastic molding suppliers.

The selection of the suppliers was based on experience from team members and benchmarking with sister companies from J&J. The following lists of suppliers were selected to compete on the bidding process:

- Beyonics current supplier
- Gerresheimer Germany
- Tessy Plastics Shanghai
- Flex Medical Gushu
- Schnipke USA
- Unomedical Mexico
- Techno-Plastics Puerto Rico
- Precision Concepts USA

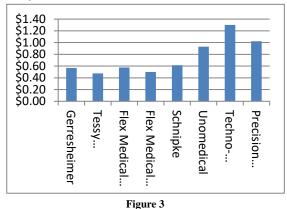
All expected proposals were received in the three week window and are summarize in Table 3.

Table 3Summary of supplier proposals

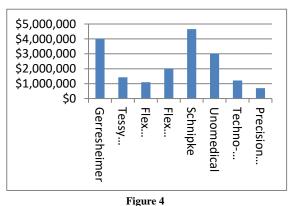
Cartridge RFQ Evaluation										
	/		Telsy heads by	anetall	siehul	6.6 mill			100°	p.
Supplies	Beyonic	Genesheimet	Tesh Pastic	Fred Medical	Longed Longed	Got red	Unomedica	Techno posito	Precision Concert	
Price each @ 9 mil./yr										
(includes sterilization)	\$0.7657	\$0.5678	\$0.4755	\$0.5760	\$0.5000	\$0.6144	\$0.9300	\$1.3000	\$1.0230	
% Difference to current	N/A	25.8%	0.378999608	24.8%	34.7%	19.8%	-21.5%	-69.8%	-0.336032389	
Capital Requirements										
(Production Tooling)	N/A	\$882,500	748413	\$1,091,500	\$2,009,400	\$1,463,598	\$3,000,000	\$1,209,900	452770.5	
Automation										
Requirements	N/A	\$3,119,000	680000	Incl. above	Incl. above	\$3,189,007	Incl. above	Incl. above	241680	
Total Capital Req'd	N/A	\$4,001,500	\$1,428,413	\$1,091,500	\$2,009,400	\$4,652,605	\$3,000,000	\$1,209,900	\$694,451	
Mfg. Location	N/A	GA, USA	China	China	China	OH, USA	MX	PR	Costa Rica	

Analyze

All eight responses from the suppliers were analyzed based on price per product and amount of capital expenditure by the supplier required fulfill the project. A comparison of both financial attributes is shown in Figures 3 and 4. Tessy Plastics (Shanghai) and Flex Medical (Gushu) have the lower price per part and also have a reasonable capital expenditure. Both were selected to move forward to the second round for a more in-depth analysis. Gerresheimer shows the best price per part, but has a capital expenditure of almost three times higher that of Tessy and Flex Medical. However, because of their technical competencies and good recommendations from other companies that have done business with them, it was determined to include them in the next round of analysis.







The next round of analysis was done using an Excel macro prepared by one of the team members. A print screen of the summary page is shown in Figure 5. It was used to facilitate the scoring process for the final selection of the supplier. The evaluation was done based on weighing different categories and sub categories and assigning a score of 1, 3 or 5 to the categories. Based on the research performed and using leanings from other similar projects, the final selection evaluation criteria will score the final competing suppliers the following competencies shown on Table 4.

Table 4	
aluation criteria	categorie

	Evaluation criteria categories					
Criteria Categories	Sub criteria Categories					
Design & Technology	Product/Process Protection					
	R&D Capability					
	Pilot/Prototype Capability					
	Core Manufacturing Capability					
	Analytical Capability					
	Core Service Capability					
	Cost Reduction Capability					
Quality	Quality Systems					
	Process Capability					
	Regulatory History					
	Quality Leadership					
Infrastructure	Personnel					
	Facilities & Equipment					
	Standards & Practices					
	Financial					
	Information Systems					
	Diversity					
Supply Chain	Business					
	Execution					
	Functional					
	Technical					
	Brand Protection					
	Sustainability					
Financial	Cash Flow Analysis					
	P&L Impact					

Capital for project by supplier

Date:	2-Oct-14	Sumr						il Scorir rce – Ins	•	llysis artridge					
Categories	-	Crite Weig		Beyo	nics	Tess Shang		100.00		nalyzed Gerresh	eimer	No s identi		No s identi	
Design & Technology	Product/Process Protection R&D Capability Pilot/Prototype Capability Core Manufacturing Capability Analytical Capability Core Service Capability Cost Reduction Capability	25%	0% 25% 10% 20% 10% 25%	0.75	0.00 1.25 0.30 0.60 0.10 0.50 0.25	1.13	0.00 1.25 0.50 1.00 0.50 0.50 0.75	0.85	0.00 0.75 0.30 1.00 0.30 0.30 0.75	0.85	0.00 0.75 0.30 0.60 0.50 0.50 0.75	0.00	0.00 0.00 0.00 0.00 0.00 0.00 0.00	0.00	0.00 0.00 0.00 0.00 0.00 0.00
Quality	Quality Systems Process Capability Regulatory History Quality Leadership	30%	25% 25% 25% 25%	0.75	0.75 0.75 0.25 0.75	1.20	0.75 1.25 0.75 1.25	0.90	0.75 0.75 0.75 0.75	1.05	0.75 1.25 0.75 0.75	0.00	0.00 0.00 0.00 0.00	0.00	0.0
Infrastructur ə	Personnel Facilities & Equipment Standards & Practices Financial Information Systems Diversity	10%	10% 20% 25% 15% 10%	0.30	0.30 0.60 0.75 0.45 0.30	0.45	0.50 1.00 1.25 0.45 0.30	0.37	0.50 0.60 1.25 0.45 0.30	0.41	0.50 1.00 0.60 1.25 0.45 0.30	0.00	0.00 0.00 0.00 0.00 0.00 0.00	0.00	0.0 0.0 0.0 0.0 0.0
Supply Chain	Business Execution Functional Technical Brand Protection Sustainability	10%	20% 50% 0% 30% 0%	0.40	0.60 2.50 0.00 0.90 0.00 0.00	0.50	1.00 2.50 0.00 1.50 0.00 0.00	0.40	0.60 2.50 0.00 0.90 0.00 0.00	0.46	0.60 2.50 0.00 1.50 0.00 0.00	0.00	0.00 0.00 0.00 0.00 0.00 0.00	0.00	0.0 0.0 0.0 0.0 0.0
	Cash Flow Analysis P&L Impact	25%	50% 50%	0.75 2.95	1.50 1.50	1.25 4.53	2.50 2.50	1.25 3.77	2.50 2.50	1.25 4.02	2.50 2.50	0.00	0.00	0.00	0.0

Figure 5 **Excel Macro for analyzing suppliers**

the alternate supplier for manufacturing of the Animas Insulin Cartridge. Tessy scored higher in all categories, shown on Figure 6.

They also demonstrated more engagement through the bidding process. During the discussion, something that favored Tessy is that they proposed developing the molding process in their Headquarters in Rochester, NY and then transfer the

Tessy Plastics from Shanghai was selected as molding cell to Shanghai for the final qualification and low cost manufacturing. This was very attractive, since Rochester is at 6 hours of driving distance from Animas. These will minimize traveling costs. Tessy also was willing to do some characterization activities using a single cavity mold to perform tolerance stack-up analysis and Design for manufacturability (DFM) experimentation.

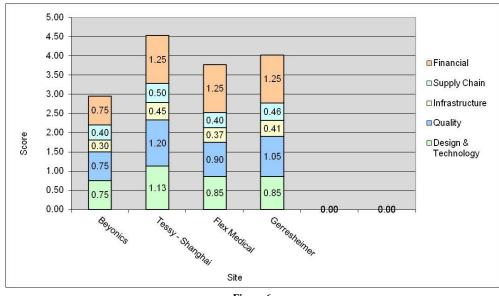


Figure 6 **Alternate Supplier Selection Analysis**

Improve

After the selecting process was completed, several working meetings were conducted with Tessy and a Statement of Work was developed between Animas and Tessy. The Statement of Work included the following sections:

- 1. Project Description and Scope
- 2. Cost layout
- 3. Specifications and drawings
- 4. Deliverables
 - 4.1. Prototype molds
 - 4.2. Verification of critical tolerances
- 5. Production tooling and assembly line
 - 5.1. Injection molds
 - 5.2. Mikron assembly line

- 5.3. Packaging line (Tessy asset)
- 5.4. Test equipment
- 5.5. Validation Master Plan
- 5.6. Project Management

The preliminary project plan, Table 5, developed by the supplier shows 13 month implementation duration. The plan is preliminary and needs improvement for accuracy. There are several key aspects of the project which are Animas responsibility that are not yet integrated into the project plan. For the purpose of moving to the next step, Capital Justification, the preliminary project plan is good enough.

Table 5
Preliminary Project Plan

	0	Task Name	Duration	% Complete	Start	Finish	Predecesso	Resour Name
1		Insulin Cartridge Plan	277.5 days	0%	Thu 1/2/14	Thu 2/5/15		
2		Whole Process Flow Chart Draft and Review	3 w ks	0%	Thu 1/2/14	Wed 1/22/14		Tessy
3		Prototype tool and assembly fixture	100 da ys	0%	Thu 1/2/14	Mon 6/2/14		
4		PO for 1 cavity Body and Plunger mold with sensor	0 wks	0%	Thu 1/2/14	Thu 1/2/14		Anim
5	-	Tool and assembly line supplier review	3 wks	0%	Thu 1/2/14	Wed 1/22/14	4	Tessy
6		tool design, review and approval	2 wks	0%	Thu 1/23/14	Mon 2/17/14		Tessy
7		Risk analysis, includes DFMEA, PFMEA, Flow chart, Control Plan	3 wks	0%	Thu 1/16/14	Mon 2/17/14		Tess
8		tool building	7 wks	0%	Tue 2/18/14	Mon 4/7/14		Tess
9		tool validation and product dimension study in Tessy (process include SIM study, GR&R, Cpk study, aging study, High/nominal/low tolerance	4 wks	0%	Tue 4/8/14	Mon 5/5/14		Tessy
10		Sample ship to Animas	1 wk	0%	Tue 5/6/14	Mon 5/12/14	0	Anim
11		Tolerance Challenge Sample testing in Animas	2 wks	0%	Tue 5/13/14	Mon 5/26/14		Anim
12	-	Assembly fixture and EFD spray system sourcing	2 wks	0%	Thu 1/23/14	Mon 3/31/14		Tess
13	-	documentation			Thu 1/23/14	Mon 6/2/14		ress
			85 days	0%				
14		Protocol for prototype tool and tolerance challenge test requirement draft, review and approval	2 wks	0%	Thu 1/23/14	Mon 2/17/14		Tessy
15		Validation report summary and approval	1 wk	0%	Tue 5/27/14	Mon 6/2/14	14,11	Tessy
16		Mass Production tool and line	272.5 days	0%	Thu 1/2/14	Thu 1/29/15		
17	\checkmark	PO for mass production tools and assembly line	0 wks	100%	Thu 1/2/14	Thu 1/2/14		Anim
18		Injection Tools	235 days	0%	Thu 1/2/14	Mon 12/8/14		
19		16 cavity production Tools pre-design (total 4 tools)	4 wks	0%	Thu 1/23/14	Mon 3/3/14	5	Tessy
20		Tool design update after challenge test on prototype tool done	1 wk	0%	Tue 5/27/14	Mon 6/2/14	11	Tessy
21		tool building	12 wks	0%	Tue 6/3/14	Mon 8/25/14	20,9	Tessy
22		tool trial and groom (includes SIM study, GR&R, Cpk study, Aging	6 wks	0%	Tue 8/26/14	Mon 10/6/14	21.28	Tessy
23		OQ Run and inspection	2 wks	0%	Tue 10/7/14	Mon 10/20/14		Tessy
24		OQ Sample review by Animas	2 wks	0%	Tue 10/21/14	Mon 11/3/14		Anim
25	-	PQ Run and inspection	2 wks	0%	Tue 11/4/14	Mon 11/17/14		
26	-	PQ Sample review by Animas	2 wks	0%	Tue 11/18/14	Mon 12/1/14		Tessy
27	-							Anim
		documentation	235 days	0%	Thu 1/2/14	Mon 12/8/14		-
28		Tool MVP (Master Validation Protocol) draft, review and approva	8 wks	0%	Thu 1/2/14	Mon 3/10/14		Tessy
29		Validation report summary and approval	1 wk	0%	Tue 12/2/14	Mon 12/8/14		Tessy
30		assembly line	257.5 days	0%	Thu 1/23/14	Thu 1/29/15		
31		Assembly line design, build and test in Mikron Singapore	175 da ys	0%	Thu 1/23/14	Mon 10/6/14		
32		Kick Off meeting, idea transfer, design review	3 wks	0%	Thu 1/23/14	Mon 2/24/14	17,5	Tessy
33		Assembly ling building	30 wks	0%	Tue 2/25/14	Mon 9/22/14	32	Tessy
34		FAT validation in Singapore factory (Tessy Team to be present	2 wks	0%	Tue 9/23/14	Mon 10/6/14	33	Tessy
35		Assembly line ship to Tessy	2 wks	0%	Tue 10/7/14	Mon 10/20/14	31	Tessy
36		Packaging line building	24 wks	0%	Tue 5/6/14	Mon 10/20/14	35 F F	Tess
37		Assembly and packaging Line install and run IQ gualification	3 wks	0%	Tue 10/21/14	Mon 11/10/14		Tessy
38		Assembly Line OQ qualification	1.5 wks	0%	Tue 11/11/14	Thu 11/20/14		
	-	OQ product Sterilization and bio-burden analysis	2 wks	0%	Thu 11/20/14	Thu 12/4/14		Tessy
39	_		1 wk	0%	Thu 12/4/14	Thu 12/11/14		Tess
						Thu 12/25/14		Anim
40		Assembly OQ sample to Animas	2					
40 41		OQ sample review in Animas	2 wks	0%	Thu 12/11/14			
42		OQ sample review in Animas Assembly line PQ run in Tessy	1 wk	0%	Thu 12/25/14	Thu 1/1/15	41,29	Tessy
40 41 42 43		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis	1 wk 2 wks	0% 0%	Thu 12/25/14 Thu 1/1/15	Thu 1/1/15 Thu 1/15/15	41,29 42,55	Tessy Tessy
40 41 42 43 44		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas	1 wk 2 wks 2 wks	0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15	Thu 1/1/15 Thu 1/15/15 Thu 1/29/15	41,29 42,55 43	Tessy Tessy
40 41 42 43 44 45		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis	1 wk 2 wks	0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15 Thu 1/2/14	Thu 1/1/15 Thu 1/15/15	41,29 42,55 43	Tessy Tessy
40 41 42 43 44 45		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas	1 wk 2 wks 2 wks	0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15	Thu 1/1/15 Thu 1/15/15 Thu 1/29/15	41,29 42,55 43	Tessy Tessy Anim
40 41 42 43 44 45 46		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas Outsource components	1 wk 2 wks 2 wks 110 days	0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15 Thu 1/2/14	Thu 1/1/15 Thu 1/15/15 Thu 1/29/15 Mon 6/16/14	41,29 42,55 43 17	Tessy Tessy Anim Tessy
40 41 42 43 44 45 46 47		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas Outsource components selection supplier (unit box, IFU, PETG Film, Tyvek, shipping box)	1 wk 2 wks 2 wks 110 da ys 10 wks	0% 0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15 Thu 1/2/14 Thu 1/2/14	Thu 1/1/15 Thu 1/15/15 Thu 1/29/15 Mon 6/16/14 Mon 3/24/14	41,29 42,55 43 17 46	Tessy Tessy Anim Tessy Tessy
40 41 42 43 44 45 46 47 48		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas Outsource components selection supplier (unit box, IFU, PETG Film, Tyvek, shipping box) sampling and qualification	1 wk 2 wks 2 wks 110 da ys 10 wks 12 wks	0% 0% 0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15 Thu 1/2/14 Thu 1/2/14 Tue 3/25/14	Thu 1/1/15 Thu 1/15/15 Thu 1/29/15 Mon 6/16/14 Mon 3/24/14 Mon 6/16/14	41,29 42,55 43 17 46 11SF-2 wl	Tessy Anim Tessy Tessy
40 41 42 43 44 45 46 47 48 49		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas Outsource components selection supplier (unit box, IFU, PETG Film, Tyvek, shipping box) sampling and qualification Purchasing Orings and needle from existing vendor	1 wk 2 wks 2 wks 110 da ys 10 wks 12 wks 8 wks	0% 0% 0% 0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15 Thu 1/2/14 Thu 1/2/14 Tue 3/25/14 Tue 3/4/14	Thu 1/1/15 Thu 1/15/15 Thu 1/29/15 Mon 6/16/14 Mon 3/24/14 Mon 6/16/14 Tue 4/29/14	41,29 42,55 43 17 46 11SF-2 wl	Tessy Anim Tessy Tessy Tessy
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		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas Outsource components selection supplier (unit box, IFU, PETG Film, Tyvek, shipping box) sampling and qualification Purchasing O'rings and needle from existing vendor Test Equipment Equipment Design and approval Equipment building	1 wk 2 wks 2 wks 110 days 10 wks 12 wks 8 wks 8 wks 8 wks 8 wks	0% 0% 0% 0% 0% 0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15 Thu 1/2/14 Thu 1/2/14 Tue 3/25/14 Tue 3/4/14 Thu 1/2/14 Thu 1/2/14 Thu 1/2/14	Thu 1/1/15 Thu 1/15/15 Thu 1/29/15 Mon 6/16/14 Mon 6/16/14 Tue 4/29/14 Mon 6/16/14 Mon 6/16/14 Mon 3/10/14 Mon 5/5/14	41,29 42,55 43 17 46 11SF-2 wl 17 50	Tess Anim Tess Tess Tess Tess Tess
40 41 42 43 44 45 46 47 48 49 50 51 52		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas Outsource components selection supplier (unit box, IFU, PETG Film, Tyvek, shipping box) sampling and qualification Purchasing Orings and needle from existing vendor Test Equipment Equipment Design and approval Equipment building Equipment calibration	1 wk 2 wks 2 wks 110 days 10 wks 12 wks 8 wks 110 days 8 wks 8 wks 6 wks	0% 0% 0% 0% 0% 0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/1/15 Thu 1/2/14 Thu 3/25/14 Tuu 3/4/14 Thu 3/4/14 Thu 1/2/14 Thu 1/2/14 Tuu 3/1/114 Tuu 5/6/14	Thu 1/1/15 Thu 1/15/15 Thu 1/29/15 Mon 6/16/14 Mon 3/24/14 Mon 6/16/14 Tue 4/29/14 Mon 6/16/14 Mon 5/5/14 Mon 6/16/14	41,29 42,55 43 17 46 11SF-2 wl 17 50	Tess Anim Tess Tess Tess Tess Tess
40 41 42 43 44 45 46 47 48 49 50 51 52 53		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas Outsource components selection supplier (unit box, IFU, PETG Film, Tyvek, shipping box) sampling and qualification Purchasing Orings and needle from existing vendor Test Equipment Equipment Design and approval Equipment calibration Sterilization	1 wk 2 wks 2 wks 110 days 10 wks 12 wks 8 wks 110 days 8 wks 8 wks 6 wks 170 days	0% 0% 0% 0% 0% 0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/1/15 Thu 1/15/15 Thu 1/2/14 Tuu 3/25/14 Tuu 3/25/14 Thu 1/2/14 Thu 1/2/14 Thu 1/2/14 Thu 1/2/14	Thu 1/1/15 Thu 1/15/15 Thu 1/29/15 Mon 6/16/14 Mon 6/16/14 Mon 6/16/14 Mon 6/16/14 Mon 3/10/14 Mon 5/5/14 Mon 6/16/14	41,29 42,55 43 17 46 11 SF-2 wl 17 50 51	Tess Anim Tess Tess Tess Tess Tess Tess
40 41 42 43 44 45 46 47 48 49 50 51 52 53 54		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas Outsource components selection supplier (unit box, IFU, PETG Film, Tyvek, shipping box) sampling and qualification Purchasing Orings and needle from existing vendor Test Equipment Equipment Design and approval Equipment building Equipment calibration Sterilization supplier selection	1 wk 2 wks 2 wks 110 days 12 wks 8 wks 110 days 8 wks 8 wks 6 wks 6 wks 6 wks	0% 0% 0% 0% 0% 0% 0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15 Thu 1/2/14 Thu 1/2/14 Tue 3/4/14 Thu 1/2/14 Thu 1/2/14 Tue 3/11/14 Tue 5/6/14 Thu 1/2/14	Thu 1/1/15 Thu 1/29/15 Thu 1/29/15 Mon 6/16/14 Mon 6/16/14 Tue 4/29/14 Mon 6/16/14 Mon 3/10/14 Mon 5/5/14 Mon 6/16/14 Mon 9/16/14 Mon 9/24/14	41,29 42,55 43 17 46 11 SF-2 wl 17 50 51 17	Tessy Anim Tessy Tessy Tessy Tessy Tessy Tessy Tessy
40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas Outsource components selection supplier (unit box, IFU, PETG Film, Tyvek, shipping box) sampling and qualification Purchasing Orings and needle from existing vendor Test Equipment Equipment Design and approval Equipment building Equipment calibration Sterilization supplier selection Dose validation (using prototype sample)	1 wk 2 wks 2 wks 110 da ys 10 wks 12 wks 8 wks 110 da ys 6 wks 170 da ys 6 wks 12 wks	0% 0% 0% 0% 0% 0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15 Thu 1/2/14 Thu 3/25/14 Tue 3/25/14 Thu 1/2/14 Thu 1/2/14 Thu 3/21/1/14 Tue 3/6/14 Thu 1/2/14 Thu 1/2/14 Thu 1/2/14	Thu 1/1/1/5 Thu 1/15/15 Thu 1/29/15 Mon 6/16/14 Mon 6/16/14 Mon 6/16/14 Mon 3/10/14 Mon 3/10/14 Mon 5/5/14 Mon 9/8/14 Mon 9/8/14	41,29 42,55 43 17 46 11 SF-2 wl 17 50 51 17 54,47	Tessy Anim Tessy Tessy Tessy Tessy Tessy Tessy Tessy
40 41 42 43 44 45 46 47 48 49 50 51		OQ sample review in Animas Assembly line PQ run in Tessy PQ product Sterilization and bio-burden analysis Assembly sample review by Animas Outsource components selection supplier (unit box, IFU, PETG Film, Tyvek, shipping box) sampling and qualification Purchasing Orings and needle from existing vendor Test Equipment Equipment Design and approval Equipment building Equipment calibration Sterilization supplier selection	1 wk 2 wks 2 wks 110 days 12 wks 8 wks 110 days 8 wks 8 wks 6 wks 6 wks 6 wks	0% 0% 0% 0% 0% 0% 0% 0% 0%	Thu 12/25/14 Thu 1/1/15 Thu 1/15/15 Thu 1/2/14 Thu 1/2/14 Tue 3/4/14 Thu 1/2/14 Thu 1/2/14 Tue 3/11/14 Tue 5/6/14 Thu 1/2/14	Thu 1/1/15 Thu 1/29/15 Thu 1/29/15 Mon 6/16/14 Mon 6/16/14 Tue 4/29/14 Mon 6/16/14 Mon 3/10/14 Mon 5/5/14 Mon 6/16/14 Mon 9/16/14 Mon 9/24/14	41,29 42,55 43 17 46 11 SF-2 wl 17 50 51 17 54,47	Tessy Tessy Anim Tessy Tessy

Tessy-Shanghai Financial Analysis

Based on the preliminary proposal purchased cartridges from the new supplier will cost approximately \$0.29 less that the current supplier. With this reduction the project will break even in approximately 9 months after full implementation. This is based on an annual volume of 9.2 millions cartridges per year. After breaking even, the initiative will have an annual savings of \$2.5 million every year.

Table 6 shows Net Present Value and Internal Rate of Return values calculated for the project with 5 year and 10 year project life. Based on the projected financial analysis the team is expecting a positive outcome in the capital money request approval process.

Table 6NPV and IRR Financial Indicators

NPV (5yrs)	\$3.56 M
IRR (5yrs)	95%
NPV (10yrs)	\$11.40 M
IRR (10yrs)	107%

CONCLUSIONS AND RECOMMENDATIONS

Conclusion

For the selection of the new Insulin Cartridge supplier, a structure process was followed using the DMAIC methodology. Project statement was created and clear objectives were identified. Project requirements were established by a multi disciplinary project core team. Potential suppliers were identified and all had the opportunity to compete in the bidding process replying to the RFQ packed prepared. A two step selection process was followed, first a pre-screening process based on cost was applied were three suppliers were selected to move forward. Finally a second analysis was conducted scoring and weighing several different categories.

Upon reviewing the project objectives from the beginning of the course:

- Simplification of the supply chain The new supply chain will be shorter by having the new cartridge supplier manage sterilization, final testing and direct shipment to the distribution centers.
- Optimization of cost by 30% the proposed price per part is 36.2% less expensive.
- If possible utilization of a J&J Preferred supplier – Tessy Shanghai is not a preferred Supplier but the Headquarters, Tessy Plastics in Rochester, NY is. Tessy NY will lead the project and Tessy Shanghai follows their Quality and Manufacturing systems. No issues are expected for Tessy, Shanghai in becoming a preferred vendor in the near future.

Recommendations and Next Steps

- 1. In-depth review of project with Tessy.
- 2. Re-quote if necessary.
- 3. Pre-Negotiation Activities.
- 4. Supply Agreement negotiation.
- 5. Review and approved Capital Appropriation Request (CAR).
- 6. Place initials orders.

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