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.

Introduction

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

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

1. Identify and select an alternate source for the cartridge that will help achieve the following objectives:
2. 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.
3. Update packaging to reduce shipping and packaging costs.
4. Optimize total cost by 30%
5. If possible utilization of a Johnson & Johnson (J & J) Preferred supplier.

DMAIC Methodology and Project Execution

DMAIC (an abbreviation for Define, Measure, Analyze, Improve and Control) refers to a data-driven improvement cycle used for improving, optimizing and stabilizing business processes and designs.

Define

In this section, the project statement and objectives were defined

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.

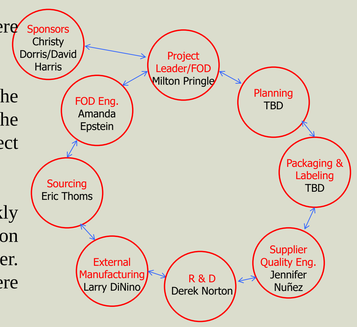

Figure 2
Cartridge Alternate Source Core Team

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	Roles ->	POD	EO	SQ	RA	PLAN	R&D	DQ	QA	SC	(Supplier)	Comments
Single Cavity Prototypes												
	Tool plan development	C	R,A	C			C		C		C	WK Primary, LD
	Mold design requirements, review & approval	C	R,A								C	WK Primary, LD
	Tool equipment development for sgl cavity tools	C	A	C			R	C	C		C	WK Primary, LD
	Mold acceptance		R,A								C	WK Primary, LD
	Product dimensional tolerance study & functional Verification	A	R				A	C			C	POD Primary, WK, LD
	Parts for assembly machine development		R,A								C	LD primary
	Tooling Summary Report		A	C			R	C	C		C	DS Primary

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:

A three week response was requested for providing quotation information via electronic format to Animas Corporation.

Measure

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; All expected proposals were received in the three week window and are summarize in Table 2.

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

Table 2
Summary of supplier proposals

Cartridge RFQ Evaluation / Supplier	Beyonics	Gerresheimer	Tessy Plastics (Shanghai)	Flex Medical (Gushu) Semiautomated	Flex Medical (Gushu) Fully Automated	Schnipke	Unomedical	Techno Plastics	Precision Concepts
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%	-33.6032389
Capital Requirements (Production Tooling)	N/A	$802,500	748413	$1,091,500	$2,009,400	$1,463,598	$1,000,000	$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	$1,000,000	$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.

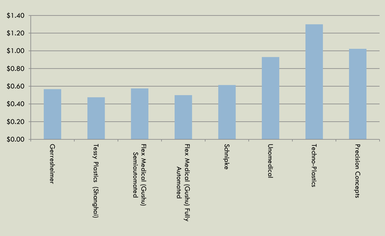

Figure 3
Price per Product

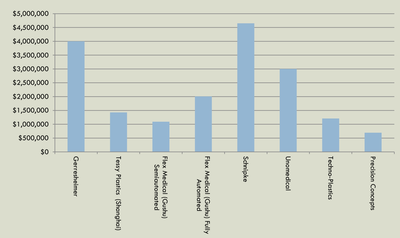

Figure 4
Capital for project by supplier

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 and the accumulative results are shown on Figure 6. 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.

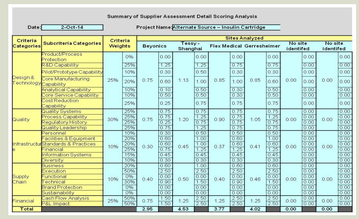

Figure 5
Alternate Supplier Selection Analysis

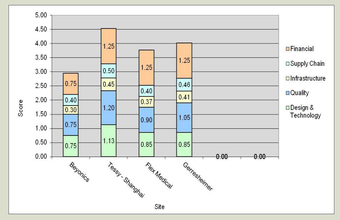

Figure 6
Macro for analyzing suppliers

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: Project Description and Scope, Cost, layout, Specifications and drawings, Deliverables, Prototype molds, Verification of critical tolerances, Production tooling and assembly line, Injection molds, Assembly line, Packaging line, Test equipment, Validation Master Plan, Project Management.

The preliminary project plan developed by the supplier showed 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.

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 3
NPV and IRR

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

Table 3 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.

Conclusions and recommendations

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 allowed to compete in the bidding process.
- A two step selection process was followed, first a pre-screening process based on cost and capital spending requirements. Finally a second analysis was conducted scoring and weighing several different categories.

Upon reviewing the project objectives:

- The new supply chain will be shorter by having the new cartridge supplier manage sterilization, final testing and direct shipment to the distribution centers.
- The proposed price per part is 36.2% less expensive.
- Tessy Shanghai is not a preferred Supplier but their Headquarters, Tessy Plastics in Rochester, NY is. Tessy NY will lead the project and Tessy Shanghai follows their Quality and Manufacturing systems.

Moving forward the team will:

- Have a review of project with Tessy.
- Start pre-Negotiation Activities, Supply Agreement negotiation.
- Review and approve Capital Appropriation Request (CAR).
- Place initial orders.