Flambeau®
MEDICAL MARKETS GROUP

Flambeau Buyer's Guide

Introduction

The Flambeau Buyer's Guide

The Flambeau Buyer's Guide is intended to be an interactive tool in the engagement and selection of a medical device contract manufacturer. This buyer's guide is *personalized* and meant to address **your** concerns and help **you**, our valued customer, make *intelligent buying decisions*. When selecting a medical device contract manufacturer it can be easy to skip a step or not ask the appropriate questions. This buyer's guide will assist in asking the pertinent questions as it relates to the critical aspects of choosing a medical device contract manufacturer. The checklist is not all inclusive, but rather a comprehensive guide to stimulate conversation and create meaningful dialogue.

Specific areas addressed include:

- Required certifications of a medical molder
- Capabilities in protocol writing and execution
- Validation activities and standard operating procedures
- Intelligent tooling selection and tooling requirements
- Understanding tooling class and how to apply to your project
- How to implement process improvements and re-capture margin

Who should use the Flambeau Buyers Guide?

- Seasoned medical device executives looking for a refresher on medical contract manufacturer selection
- Start-up firms who are searching for a trusted medical device contract manufacturer
- Engineering professionals who need a formula for evaluating medical device contract manufacturers
- Doctors or surgeons with a new and innovative idea

Typically customers of Flambeau come to us in two existing states:

Concept only. Still need product development and design assistance.	Existing product. Either in 510k or PMA phase. Need commercialization assistance.
⬇	⬇
Prototype may or may not exist. Require design for manufacturing, process development, and regulatory assistance.	Protype typically exists. Device components may or may not be made from actual production materials.
⬇	⬇
You do not know the appropriate questions to ask and need help selecting a supplier.	You **know** the appropriate questions to ask, but want to ensure you are *not missing* any during your supplier vetting process.

Supplier Selection

How to Choose Checklist

Initial Evaluation Phase

- ☐ Required certifications of a medical molder
- ☐ Is the company ISO 13485/ ISO 9001 certified?
- ☐ How long has the company managed contract manufacturing of medical devices?
- ☐ What are the company's core manufacturing processes?
- ☐ Will the company provide a copy of the table of contents of procedures?
- ☐ Will you provide a copy of the company's quality manual?
- ☐ Is the company FDA registered?

Product Development/Design Phase

- ☐ Does the company require 510k or FDA certification for products produced?
- ☐ Does the company offer clean room production/assembly? If yes, which class?
- ☐ How does the company manage medical grade materials?
- ☐ Does the company provide engineering/design for manufacturing support?
- ☐ Does the company have program management staff? If yes, years of experience and/or professional certifications?
- ☐ What type of CAD software is the company most comfortable with?
- ☐ How are files transferred between companies?
- ☐ How does the company control and manage design revisions?
- ☐ Who owns IP (intellectual property) after development is complete?
- ☐ Does the company produce patented products on a contract manufacturing basis?

Process Development Phase

- ☐ Does the company manage unit sterilization?
- ☐ Does the company manage sterilization dose mapping and dose audits?
- ☐ How does the company improve efficiencies over time?
- ☐ How does the company communicate process parameters?
- ☐ Does the company price to learning curve effect?
- ☐ How does the company manage line and tooling changeovers?
- ☐ How does the company report non-conformances?

Quality Control Phase

- ☐ How does the company handle corrective action and quality alerts?
- ☐ How does the company handle receiving/final inspection?
- ☐ Is the company flexible on print requirements?
- ☐ Does the company offer ongoing LAL or bioburden testing?
- ☐ What software does the company use for process validation?
- ☐ What type of measurement equipment does the company use (vision, touchpoint)?
- ☐ How does the company acquire gauges or fixtures? Are they medically certified?
- ☐ How does company handle statistical process control?

Commercial Launch Phase

- ☐ How does the company schedule ongoing production runs?
- ☐ Does the company have global program management capabilities?
- ☐ Who services business related issues after the sale?
- ☐ Does the company offer ongoing logistics support?
- ☐ Does the company engage in cost down activities?
- ☐ How are master supply-agreements developed and refined?

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Tooling Guide

SPI: Mold Classifications

- These classifications for injection molds only.
- 101 thru 104 - Classification of injection molds up to 400 tons
- 401 thru 403 - Classification of injection molds of 400 tons and up

The following contains a brief synopsis of the various mold classifications and the detailed descriptions of each mold class as interpreted by Flambeau. Part Design and or the part material will greatly influence the mold class choice. In addition these are basic guide lines. The details of each mold construction crosses classes in order to make a quality mold to make quality parts.

General Specifications

1. Detailed mold design required. Flambeau to approve mold design prior to start of construction.
2. Any hot half, hot runner, valve gate or heated manifold type systems to be approved by Flambeau.
3. All molds, with the exception of prototype, to have adequate channels for temperature control.
4. Wherever feasible, all details should be marked with steel type and Rockwell hardness approximately .005 deep.
5. Customer name, part number, and mold number should be steel stamped on mold. Air, hydraulic and water inlets and outlets to be labeled.
6. All molds should have eyebolt holes on the top side. There should be one above and one below the parting line to facilitate mold removal, if required, in halves.
7. SPI standard knock out pattern.
8. A Mold flow analysis is done if needed to determine gate location and vents.
9. The mold is to be sampled (T1 trial) with the specified material.
   a. Scientific injection molding practices will be used for the mold sample.
   b. During the sample each shot must release freely from the core or allow for robotic removal.
   c. After running, mold will be evaluated for abnormal wear.

Class 101 and 401 Mold

Cycles: Class 101 One million or more
Class 401 Over 500,000

Description: Built for extremely high production. This is the highest priced mold and is made with only the highest quality materials.

1. Mold base to be minimum hardness of 28 R/C.
2. Molding surfaces (cavities and cores) must be hardened to a minimum of 48 R/C range. All other details, such as sub-inserts, slides, heel blocks, gibs, wedge blocks, lifters, etc. should also be of hardened tool steels.
3. Ejection should be guided.
4. Slides must have wear plates.
5. Temperature control provisions to be in cavities, cores and slide cores wherever possible.
6. Over the life of a mold, corrosion in the cooling channels decreases cooling efficiency thus degrading part quality and increasing cycle time. It is therefore recommended that plates or inserts containing cooling channels be of a corrosive resistant material (i.e. Stainless steel plates/inserts) or treated to prevent corrosion (i.e. Nickel plated).
7. Parting line locks are required on all molds.

Class 102 Mold

Cycles: Not exceeding one million

Description: Medium to high production mold, good for abrasive materials and/or parts requiring close tolerances. This is a high quality, fairly high priced mold.

1. Mold base to be minimum hardness of 28 R/C.
2. Molding surfaces (cavities and cores) must be hardened to a minimum of 48 R/C range. All other details, such as sub-inserts, slides, heel blocks, gibs, wedge blocks, lifters, etc. should also be of hardened tool steels.

Tooling Guide

SPI: Mold Classifications Continued

3. Temperature control provisions to be directly in the cavities, cores, and slides wherever possible.
4. Parting line locks are recommended for all molds.
5. The following items may or may not be required depending on the ultimate production quantities anticipated It is recommended that those items desired be made a firm requirement for quoting purposes:
   a. Guided Ejection
   b. Slide Wear Plates
   c. Inserted Cavities

Class 103 and 402 Mold

Cycles: Under 500,000

Description: Medium production mold. This is a very popular mold for low to medium production needs. Most common price range.

1. Mold base must be minimum hardness of 8 R/C.
2. Cavity and cores must be 28 R/C or higher.
3. Class 402 only - Parting line locks required
6. All other extras are optional. The following items may or may not be required depending on the ultimate production quantities anticipated. It is recommended that those items desired be made a firm requirement for quoting purposes:
   a. Temperature control provisions to be directly in the cavities, cores, and slides.
   b. Parting line locks
   c. Guided Ejection
   d. Slide Wear Plates
   e. Inserted Cavities

Class 104 and 403 Mold

Cycles: Under 100,000

Description: Low production mold. Used only for limited production preferably with non-abrasive materials. Low to moderate price range.

1. Mold base can be of mild steel or aluminum.
2. Cavities can be of aluminum, mild steel or any other agreed upon metal.

SPI Mold Classification		101	102	103	104	401	402	403
Shot life		>1mm	>1mm	>500k	>100k	>500k	>500k	>100k
Cost Impact to Standard Price		$$$$	$$$	$$	$	$$$	$$	$
Molds for 400 ton and up						♦	♦	♦
Stainless Steel Core and Cavity or Nickel Plated cooling lines		♦	?			♦		
Cavity and Core	H13, (Rockwell C > 48)	♦	♦			♦		
	P20, (Rockwell C > 28)			♦			♦	
	Aluminum, Mid Steel, Other				♦			♦
Mold Base	P20, (Rockwell C > 28)	♦	♦	?		♦		
	Steel, (Rockwell C > 8)			♦			♦	
	Mild Steel, Aluminum				♦			♦
Inserted Cavities		♦	?			♦		
Wear Surfaces - Hard (Rockwell C > 48)		♦	♦	?		♦	?	
Ejection Guided		♦	?	?		♦	?	
Wear Plates		♦	?	?		♦	?	
Parting line locks		♦	♦	?		♦	♦	
Water cooled cavity, core & slide		♦	♦	♦	?	♦	♦	?

Process Improvement

Improving Customer's Critical Components

Introduction:

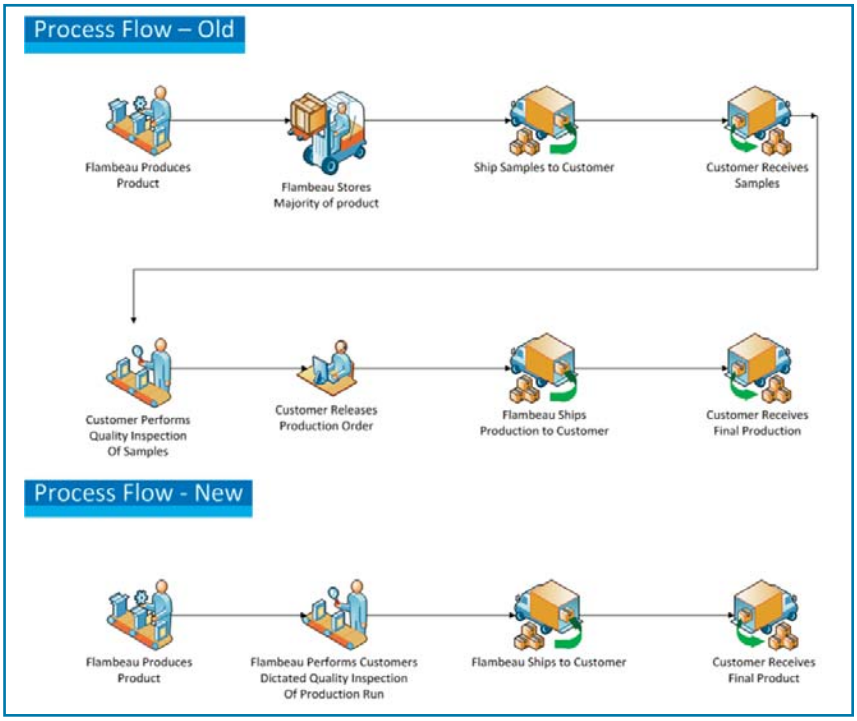
Flambeau Medical Markets Group is a premier medical device contract manufacturer company producing injection molded components in Phoenix, AZ. for Company X (name kept confidential), a global pharmaceutical and medical device company.

Background:

In 2015, Flambeau's relationship with Company X was challenged. Quality concerns, delivery misses, and responsiveness were all part of the concern between the two companies with Company X's IV infusion pump. Decisions were made and processes were implemented to turn the situation around.

Solution:

Flambeau began the process of classifying and categorizing critical and non-critical components. Flambeau implemented the PPAP process (Production Part Approval Process) on existing tools that now were considered critical. Flambeau underwent technical reviews, capability studies, and quality checks with engineering, quality assurance, plant managers, supervisors, and press operators; the whole team. Flambeau also upgraded their measuring system to more accurately produce products to exact specifications where actual measurements were taken of each part and used to complete various test sheets. A process was defined, documented, established, monitored, analyzed, and improved based on data.



Establishing confidence in the production process, Flambeau also implemented SWI's (Standardized Work Instructions) at each press for the operators to visually see the final output of the product. Before this process, press operators did not have visual aids to properly assemble the parts, remove flash, take parts off the mold, package the products, and count the correct amount into the cartons. A control document was implemented where if the output changed, then each part had to be signed off with approval. Eliminating inconsistency, each product mold was also assigned a press.

Continuously communicating and testing parts until they passed inspection, Flambeau received PPAP approval on 11 critical components in 2015 and 10 more critical components in 2016. With the next set of parts to update, Flambeau already created a template with records maintained and retained to execute items faster and more efficiently. Through extensive quality implementation efforts and having the attitude of being "change agents", the Flambeau team was able to improve part quality, produce usable product, and help Company X's resulting in the continuation of sales of Company X's flagship IV infusion pump.

Conclusion:

In September 2016, Flambeau was granted with the Supplier of the Year Award from Company X for the great achievement level attained. Company X has approximately 1,500 total suppliers (globally), and fifty-five of those suppliers provide critical components for their IV pumps; out of those suppliers, only 4 were chosen to receive "certified" status. Flambeau was also the only injection mold supplier to be chosen. This achievement parallels the outstanding performance in quality and customer service the Flambeau team achieved by implementing the PPAP and SWI process.

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