

## How to Select a Contract Manufacturer for your Medical Device

Selecting a contract manufacturer for your medical device can be a daunting task. Your decision of who you use, what services they provide and changes they make can have either positive or negative long term implications for your company. The first step is NOT to call back the last salesperson that just called you. The first thing is to define the product you want built, what services do you want the contract manufacturer to perform, determine a cost range for the piece part and how much non-recurrent engineering (NRE) costs are budgeted. You need to go through a process where you select possible candidates, assemble a bid package, receive initial quotes, assess their quotes, select/visit the top candidates and then requote with final requirements defined. This methodology gives you a comprehensive analysis, but expect this project to take three to six months.

The biggest issue when going to a contract manufacturer is your undefined product requirements. This is a common issue for the medical device industry and it also occurs in your personal life. When you go to a home builder and tell them you have a lot and you want them to build a three-bedroom rambler for \$200,000 what is the house going to look like? Are there blueprints? Do you have a list of features and appliances you want in the house? Do you have a list of materials you want used in the house? Are you going to do any of the work yourself? Answers to these questions will determine if you will want to live in the house that you just asked to be built. The same concept of having complete product requirements applies when you have someone else build your product; will you want to sell it?

Let's determine if you have the documentation needed to give to a contract manufacturer. Are your Design Inputs/Requirements for the medical device documented? This document does not have to be given to a contract manufacturer, but by having one, you can go back to it when your contract manufacturer has questions on your product Device Master Record (DMR). Hopefully your design outputs are in your released DMR (all the information needed to build the product). Your contract manufacturer will want to know as much as possible to give you the best quote possible. Specifically, do you have any of the following information/documents?

- Product Specification
- Bill of Materials
- Packaging Design
- Labeling and Instructions for Use (IFU)
- Suppliers for the parts/subassemblies
- Manufacturing Build Procedures (you may want the contract manufacturer to create these)
- Inspection Procedures (with pass/fail criteria)
- Testing Procedures
- Software (product or test, as applicable)

On the Risk Management side, do you have a Design Failure Modes Effects and Criticality Analysis (DFMECA) and/or a Process Failure Modes Effects and Criticality Analysis (PFMECA). These risk management analyses documents provide guidance to help build and test the product. These are documents that the FDA and your EU Notified Body will want to get the product approved. You may think that these documents are only paperwork required for a submission, but they are a knowledge transfer tool that can reduce the costs to build and test your medical device.

Other key requirements needed are the estimated build quantities (engineering test, sterility test parts, bioburden parts, marketing demos and production) for at least two years out, and hopefully by quarter. Also, you need to define your product selling price, the subcontract purchase price range, and then ensure there is enough margin leftover to make a profit. Other questions that are needed to be answered include:

- How much engineering support are you going to provide?
- How willing are you to make changes to the design?
- How many of the manufacturing processes produce product specifications that cannot be verified by inspection or test (e.g. bonds, welds, package sealing, and sterilization). These used to be called special processes, but they are your manufacturing processes that will require process validation.
- One last thing, once the product has been built, how are you going to get it to the next step in the product lifecycle?
- How do you want it packaged and labeled, do you need a certificate of compliance, do you want copies of the Device History Record (DHR)?

Now that you have the product and build requirements defined, you determine your supplier selection criteria. A medical device contract manufacturer is considered a critical supplier in any medical device quality system. Make sure to follow the requirements are defined in your own Quality System to select this new supplier. If your procedural requirements are not too prescriptive, you may want to rank your supplier assessments using the following seven categories.

1. Quality System Certification: ISO 9001, 13485, FDA Registered/GMP Compliant
2. Medical Devices Specialty, what kind of products do they build? How does it fit your needs?
  - a. Box Build/Assembly
  - b. Part Assembly
  - c. Converting (sheet and rolled goods)
  - d. Catheter Assembly
  - e. Cable assembly
  - f. Printed Circuit Board Assembly (PCBA)
  - g. Software
  - h. Packaging/Sterile Prep
3. What kind of manufacturing services do they provide (do they match what you need?)
  - a. Process Validation
  - b. Statistical Process Monitoring and Controls
  - c. Equipment Management: If you are giving them your equipment to build the product, can they maintain it and control the equipment software?
  - d. Automation needed for high volume builds
  - e. Testing (Electrical, Mechanical, Functional, Optical)
  - f. Software Delivery to the field
  - g. Sterile Release Management
  - h. Inventory Management
  - i. Stocking Ability (Depot/Manufacturing Kanban)
  - j. Shipping to Customers

- k. Repair/Rework
4. Product Development Support Services
  - a. Design Change Management/Records Management
  - b. Expertise/Project experience Match
  - c. Project Management (run the project on budget and on schedule)
  - d. Availability Meet Project Schedule, ability to meet your timeline
5. Part Costs
  - a. Tooling
  - b. Prototype
  - c. Pilot startup
  - d. Production quantities
  - e. Inventory purchases for optimized costs
  - f. How much customer furnished materials will be used
  - g. Payment terms
6. Location and Support Costs
  - a. How far are they from your support people? The farther away they are from your team, there will be more travel costs
  - b. Up front retainer needed
  - c. Time needed (define hourly rates for project manager, engineer, technician, operator)
  - d. Travel Costs
  - e. Shipping costs
  - f. International shipments/Tariffs and Agent fees/FDA import controls
7. Business Fit
  - a. Size: How big is the contract organization, how big is your organization
  - b. Manufacturing Capacity at the site/Do your volumes align with their capabilities
  - c. People in the organization/project member review (who they assign needs to be acceptable to you)
  - d. Communication/build status (e.g. website for tracking, weekly meetings, video conference calls)
  - e. Client References
  - f. Contract Manufacturer one location (need to verify their business continuity plan)

These seven categories provide a balanced approach when looking at a contract manufacturer. The piece part cost should not be your only criteria for selecting a supplier. There may be upfront engineering and validation costs that are required for medical devices, which includes:

- How are these costs going to be covered?
- Will they be charged as separate costs or amortized into the piece part costs?
- Will your contract manufacturer be readily available to answer questions?
- Will they be able to design your unique manufacturing processes?

I suggest putting these seven categories into a spreadsheet and then rank the candidate contract manufacturer in each of the categories. I always try to use smaller ranges when doing rankings, because it becomes harder when looking at a scale of 1-10. Also, I like to have a zero, to show they are not even in the ballpark. Let's use zero to four ranking method with the following definitions.

- 4 - Very strong match, meets all criteria, costs extremely competitive
- 3 - Strong match, meets some criteria, costs competitive
- 2 - Average match, meets couple of the criteria, costs average
- 1 - Weak match, meets one criteria, costs high
- 0 - No match, does not meet the any criteria, costs too high

Let me show you an example to use these criteria. Let's say you need to find someone to assemble a small electrocautery device that includes a small PCBA. The following four contract manufacturers are going to be ranked:

- A. Medical device electronics assembler in the same state
- B. Medical device packaging assembler in the same city
- C. Medical device catheter assembler in a different state, but they are low bidding to get into new types of assembly
- D. Commercial circuit board house in the same state that does some support, but they are the cheapest.

Which one would you chose? From this exercise, Subcontractor A and B would be looked at the next round.

Criteria	A	B	C	D
1 Quality System	4	4	3	0
2 Specialty	3	2	1	3
3 Manufacturing Services	3	4	3	2
4 Development Services	3	4	2	1
5 Part Costs	2	3	4	4
6 Location/Support	3	4	2	3
7 Business Fit	4	2	2	3
Total	22	23	17	15

With your DMR and your assessment criteria in hand, you can start searching for your candidate contract manufacturers to bid your project. There are many places to come up with a list of potential candidates. You can search the following websites:

- Qmed-Canon Communications – ([www.qmed.com](http://www.qmed.com))
- Media Brains ([www.medicaldevicedirectory.com](http://www.medicaldevicedirectory.com))
- Medicaldevice-network - Kable ([www.medicaldevice-network.com](http://www.medicaldevice-network.com))
- Medical Alley ([www.medicalalley.org](http://www.medicalalley.org))
- Thomas Registry ([www.thomasnet.com](http://www.thomasnet.com))
- Dun and Bradstreet ([www.dnb.com](http://www.dnb.com))
- Through your personal network

The next step is to visit their websites and contact them to see if they will bid your project. Then you will need to get Nondisclosure Agreement (NDA) signed with all the organizations that you chose to send a bid package. Never tell your candidate contract manufacturers what you are willing to spend, but rule of thumb is 1/3 of the cost is raw materials, 1/3 will be direct labor and scrap, and 1/3 will be

the overhead (purchasing, incoming/materials control, engineering, documentation, records, project management and profit).

You now need to put together an initial bid package. This package should have a cover letter that tells them exactly what you want quoted (include the requirements that were discussed earlier). There should also be a list of the documents with revisions that are included in the package. The biggest headache you will have is analyzing the inconsistency of what each subcontractor bids. By providing a consistent bid package and build quantity requirements with all the information defined above, you will be able to better assess your candidate contract manufacturers. Make sure to set a deadline for all responses, if they cannot bid the project in a timely manner (i.e. two weeks), you probably do not want to go with them.

One headache with the bid package is get all the files out to the candidate contract manufacturers. If your documents are small you can attach them to an email. But with bigger bid packages, you may either setup an FTP site that all of your candidates can access or setup an account in the cloud through one of the many service providers available (e.g. Dropbox, Google folders).

Now you can take all your bid responses and then assess them per the method defined earlier. You should get your list down to two or three candidates, but do not select with the top one even though they look the best from the rankings. At a minimum, you should visit the top two or three and do cursory audit. These visits will allow you and the candidate manufacturers to clarify requirements and to discuss possible solutions on how to build the product. You will learn about new manufacturing options and maybe even modify your product requirements. You will see how your budget matches against the bids. You may need to reassess your budget and discuss with the appropriate management.

Now you can finalize the bid package with your learnings from the candidate visits. This second round allows the candidate contract manufacturers to refine their bids based on their discussions with you. The final selection will be based as much on the cost as with the cultural fit between you and them. Once you select your contractor manufacturer, you will need to get the lawyers involved to finalize the contract and the deliverables. You may include a supply/manufacturing agreement, a quality plan and a schedule with milestones for payments.

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Hopefully, this provides you with a roadmap for your selection.

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Mark has 30 years of expertise in the medical device industry. He has managed all areas of product development, quality, regulatory, operations and information management activities for Class 1, 2 and 3 implantable and non-implantable medical devices. He has built and rebuilt online integrated corporate-wide quality systems in each of his positions. He has a Bachelor of Electrical Engineering from the University of Minnesota, a Masters of Applied Liberal Studies from Hamline University, Kellogg Executive Scholar, Professional Engineering and CMII Certificates. He has been with Innovize since 2013. He has served as the industry representative on the FDA ENT panel and has previously worked for Monteris Medical, St Jude Medical, AGA Medcial, Cardiac Science, St Croix Medical (Envoy Medical) and Guidant (Cardiac Pacemakers Inc).

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