# How To Avoid Compliance & Timeline Risks When Selecting A Medical Device Supplier

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Is there any more critical factor than predictable quality when choosing a medical device supplier?

Considering the severe consequences of noncompliance, it's hard to imagine anything more important. First and foremost, the health and well-being of patients is at risk. A product intended to improve health must be safe, reliable, and accurate. From a business standpoint, noncompliance can result in costly approval and product launch delays, customer returns, and potential field corrective actions or recalls. Perhaps even more damaging is the reputational harm that can result in loss of current customers and future business opportunities with new customers.

Medical device manufacturers today are challenged with several opposing priorities. Payers are pushing for lower costs and better value. A crowded market adds more cost pressure and requires speed. New ISO standards place more rigor on legal manufacturers for supplier controls. One doesn't want to end up with a supplier that does not offer comprehensive processes for managing and controlling risk.

Therefore, when considering suppliers, those who make the first cut must be the suppliers with the minimum procedures necessary to meet your compliance requirements and timeline. Suppliers that meet your threshold for quality are typically not going to be your lowest cost suppliers. There is a reason for that. Predictable quality requires a very high level of diverse engineering expertise, electronic integration of quality and business systems, and proven experience in the medical device sector. That is what keeps you in compliance. Predictable quality enables the precision to meet compliance requirements and the speed to meet your deadlines.

Predictable quality does not happen by accident or luck. It comes from a supplier with the culture, knowledge, experience, and track record of performance to produce products and provide services that meet customer requirements every time. What elements are required for a supplier to achieve predictable quality?

## 9 Elements Of A Predictable Quality System

### 1. Quality System Robustness

When evaluating prospective suppliers for your medical device, it is critical their quality management system is compliant to the ISO 13485 Medical Device Standard.

Have they converted to the recently released 2016 edition or do they have a methodical plan to do so by the conversion deadline? Suppliers who have a quality system that was "just getting by" the 2003 edition may have some significant work to do to bring themselves into compliance with the new standard.

Ask questions about their compliance history. How frequently are they audited by customers, ISO, FDA, or other Notified Bodies? Do they have a comprehensive internal auditing process? How can you be sure they truly do what they say they do?

### 2. Design for Manufacturability

You want to partner with a supplier that can be an extension of your development team. Will you provide final designs to the suppliers who are ready to tool up and manufacture, or will it require part design refinement? You'll want to ensure they have in-house prototyping and quick-turn molding capabilities so you are not forced to wait for multiple sub-tier suppliers to support frequent revisions and design changes during development.

You want to evaluate how mature their Design for Manufacturing (DFM) and Design for Supplier (DFS) processes are. This can be a make or break factor for a new program.

If you and your supplier are able to engineer out the bulk of the potential issues during DFM, you can be confident your product will be robust and predictable in serial production.

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**3. Process Validation Expertise**
Is your critical medical device project in good hands? You'll need to ensure your supplier has adequate skilled resources in the necessary disciplines to design, develop, qualify, and release to production a robust process meeting all requirements. Typically, a strong project team includes engineers with diverse backgrounds in mechanical, manufacturing, chemical, process, and quality engineering, to name some key areas of expertise.

If you are engaging on a finished, sterilized medical device program, you need to ensure the supplier has experience in sterile barrier packaging systems, sterilization validation, and ongoing sterilization monitoring methods.

If automated processes are involved, have you considered the supplier's software validation practices? How do they ensure the data being generated is valid for your submissions and lot acceptance purposes?

**4. Management of Outsourced Processes/Purchased Components**
Regulatory attention is increasingly focused on ensuring sufficient supplier controls throughout the supply chain. Will your supplier employ a risk-based approach to supplier classification, qualification, and ongoing monitoring processes? Pay attention to how they manage their supplier base because that is a good indication of their overall maturity. If they are simply transactional in nature, there is risk they have not taken the necessary deep dive into supplier capabilities and risks to your supply chain.

**5. Controlled Environment Monitoring and Certification**
Manufacturing medical devices in controlled environments is a critical element within a supplier's Quality Management System. You are going to review their monitoring program for particulate, surface, and airborne bioburden. Are they performing documented monitoring on a regular frequency or is it only done annually during certification time?

When you are at their facility for a tour or audit, watch the practice of employees entering and exiting the cleanrooms. Are they performing best practice gowning procedures or are there obvious gaps? Ask about their cleanroom practices training. Is it a one-time event or an ongoing awareness process?

**6. Sampling Plans and Process Control Strategies**
Ask how the supplier plans to ensure their sampling plans are based on valid statistical rationale. Are they using a one-size-fits-all approach or will they have data to back up their decision? A more robust supplier will plan for their production monitoring levels based on the performance observed during process validation at the limits of the qualified process.

Once you have a validated process, how are they going to ensure it continues to perform at the levels observed during qualification? Ask about common control strategies they use in production. Do they utilize process control plans/inspections that are part-specific or do they have generalized strategies? How do they ensure the dimensional outputs meet key capability requirements?

Ask how they monitor their critical processes. Is it separate from the product monitoring or do they take an integrated approach where the process inputs and outputs can easily be correlated? This aids in rapid root-cause analysis and correction/corrective action should issues arise.

**7. Inspection, Testing, and Process Monitoring Data**
If there is no record for a supplier's critical activity, then it did not happen. How does the supplier manage their data and records? Do they use manual, paper-based systems that can't be easily queried or do they utilize electronic records and SPC data that can be filtered, exported, and provided to you on a moment's notice to support a regulatory inspection or unannounced audit? Time is critical in those cases. Accuracy of data is also critical. Don't leave it up to chance the supplier will be able to come up with what you need.

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You'll want to evaluate their inspection equipment and inspection software validation processes. This is another critical element and you will likely find not all suppliers go through the same level of rigor. Also, it's important to evaluate their calibration program, as well as interim verification processes, to ensure critical equipment is within tolerance between formal calibration intervals. Is this interim verification data loaded into their SPC software and monitored for trends?

**8. Component History and Device History Records**
Most companies understand complete and accurate Device History Records (DHRs) are necessary to ensure compliance and all Device Master Record (DMR) requirements have been satisfactorily met. Have you given thought to sub-components used in the finished assemblies? Have their records been methodically reviewed to ensure there will be no issues detected, or worse yet, not detected until downstream after they have been consumed into critical medical devices?

A thorough Component History Record (CHR) review process is essential to prevent such unpleasant surprises. We find all too often the sub-components don't garner the same attention as the finished device, despite the sub-components' criticality.

Are those CHRs and DHRs paper-based or electronic? Hopefully you have confidence and have assessed the supplier's ability to provide real-time access to manufacturing records. Your state of compliance could depend on it. Regulators expect records within minutes, not the days it may take if you have to call an external provider to bring bankers boxes of records to your facility.

**9. Certificate of Compliance (CofC), Supplied Data, and Dock-To-Stock**
One make-or-break item for outsourcing of manufacturing is the documentation packet you receive with the shipment. Does your supplier have the ability to create customizable CofC to suit your company's specific requirements or are you going to receive a one-size-fits-all document?

Hopefully your supplier doesn't have to create a handwritten CofC for each shipment. Will they use a validated, system-generated CofC with the ability to integrate supplied data tables, data summary documents, and/or raw data?

Do you need that data electronically, before the shipment arrives? This should be no problem if your supplier has experience uploading raw data via web portals or FTP sites.

Now that you have packaged, sterilized medical devices on your dock, are you going to have to perform a receiving inspection? Hopefully not, as this can be a very expensive endeavor as the product would typically have to be scrapped out. You should be able to rely on your supplier to provide not only product that meets all specifications/requirements, but also a data package that allows you to have confidence to go dock-to-stock on your critical finished medical device.

## Summary

Evaluating prospective suppliers for quality is not easy — but it is far easier than the alternative of selecting the wrong supplier. You are looking for evidence of predictable quality. This doesn't happen by chance. When work is done with predictable quality, the following is true:

- Timelines are met
- Quality targets are met
- Systems are structured to meet or exceed customer requirements
- Compliance history is solid
- Enterprise resource planning system is a fully integrated electronic system

By selecting a mature supplier with a robust quality management system and a track record of successful new product launches, you can shorten your time to market, your business risk, and ultimately reduce the risk to the patient. Doing your homework up front avoids painful and costly compliance issues and pays big dividends in the long run.

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## About the author

Matt Knutson leads Donatelle's Quality Services Group. He is responsible for internal, external, and supplier Quality Management; and overall implementation of Donatelle's Quality Management System. As a key member of Donatelle's Leadership Team, Matt is responsible for helping set the strategic direction of the organization via quality objectives, system-related continuous improvement projects, internally developed QMS software applications, providing quality and regulatory oversight for new design and development programs, and for ensuring regulatory compliance with FDA, ISO, and other applicable regulatory requirements. Matt's background includes over 20 years in manufacturing and quality engineering/management with a strong emphasis in problem solving using structured methodologies. Matt holds a B.S. and M.S. in Manufacturing Engineering.

## About Donatelle Plastics Inc.

At Donatelle, we make products that enhance – and save – lives. We manufacture complex medical devices and components for low- and high-volume needs. That's all we do. And we do it with the utmost precision, consistency, and rigor, because for you – and your customers – **quality is essential. Reliability is a must. And delivering on what's promised is vital.**

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