

Quality System Development in Medical Device Start-ups

a report by

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The medical device industry, with its broad spectrum of product technologies and medical applications, is characterised by innovation from small, often start-up, companies. Medical device start-ups are challenged by limited resources, yet they must develop their technology, product and business strategy and simultaneously develop a quality system that is compliant with medical device regulations. Start-up quality systems can be developed efficiently in a way that supports, not stifles, creative development.

The US Food and Drug Administration (FDA) requires most medical devices to be developed under design controls¹ within a quality system.² Depending on product classification, European Union medical device directives may require a full quality assurance system (with design controls) or a production quality assurance system. Other countries, such as Canada, require compliance with the international standard for medical device quality systems, International Organization for Standardization (ISO) Standard 13485.

If quality system implementation is left too late, regulatory approvals may be delayed because product development was not performed under design controls. Sophisticated venture capital sources are reluctant to invest in a medical device start-up that lacks a plan for quality system development and regulatory approval.

The question is therefore how start-ups can develop a quality system that supports creative development but does not consume excess resources. Keys to successful quality system development are as follows:

- Have one way of doing business.
- Know when quality system components are needed – Develop components as necessary.

- Understand the ‘structure’ of a quality system – Build the foundation first.
- Start simple – Let the quality system evolve to meet the needs of the company.

Have one way of doing business.

No company works efficiently with two different modes of operation. Resist the temptation to have one mode for medical-device-regulated matters and another for ‘business’ matters. Quality systems are used to improve business processes in all industries. Use quality system processes to support business operations. For example, both business practice and quality systems need information control, personnel and purchasing practices. Flexible quality system processes can support these business needs as well as ensure regulatory compliance. In fact, compliance is enhanced when employees only need to learn and follow one system.

Know when quality system components are needed – Develop components as necessary.

The need for quality system components depends on both regulatory and business criteria.

The important regulatory criterion is the start of design. Regulatory agencies focus on design and development of the product to be sold. Activities that only develop technology are not regulated, with one important exception. Experiments involving human subjects are subject to human studies regulation,³ but not quality system regulation. Written protocols for human experiments, regulatory correspondence and monitoring to ensure that protocols and related responsibilities are followed may be a start-up’s first encounter with activities similar to quality systems.

1. Regulation: 21 CFR 820.30 Design Controls.

2. Regulation: 21 CFR 820 Quality System Regulation.

3. For example, human studies regulation includes FDA’s 21 CFR 812 Investigational Device Exemptions and the EU’s Clinical Trials Directive, 2001/20/EC.



Table 1: Quality System Structure

Product Realization			
Design Controls	Production and Process Controls		Post-market
Design Planning	Identification	Nonconforming	Servicing
Design Input	Traceability	product	Complaint files
Design Output	Labeling	Handling and storage	Vigilance (and other post-market surveillance)
Design Review	Packaging	Distribution	Recalls
Design Verification	Acceptance (testing)	Installation	
Design Validation	Acceptance status		
Design Transfer			
Supporting Functions			
Inspection, measuring and test equipment	Purchasing	Automated systems and process validation	
Human experiments (if applicable)	Statistical techniques		
	Good Laboratory Practice (if applicable)		
Leadership		Improvements	
Quality system		Quality audit	
Management responsibility		Management review	
Personnel		Corrective and preventive action	
Information Control			
Document control	Control of records	Training	
	Data		

Apart from human experiments, the first activity regulated is design and development planning. When the start-up begins planning how it will develop the product to be sold, applicable quality system components must be in place.

Design planning identifies when phases of product development will occur. The plan should ensure that quality system processes needed for each phase are implemented just in time.

Understand the 'structure' of a quality system – Build the foundation first.

The fundamental process for a company and a quality system is product realisation. Product realisation processes rely on a foundation of quality system components.

Medical device quality systems are documented. A company starts with how to control its documents (policies, processes, procedures and design documents) and records (test results and minutes of reviews). As processes are developed, they are communicated through training. Data systems must be effective, secure and backed up. These information controls are useful early in a business start-up. A start-up benefits by introducing non-rigorous information procedures well before rigorous procedures are required by regulation. In addition to supporting business needs, the procedures start to build the quality culture.

Once the start-up is handling documents, it develops and documents leadership and improvement processes. Management responsibility, qualified personnel, management review and improvement projects (corrective and preventive actions) benefit a start-up from its earliest activities. While a quality system helps a company do things right, management selects the right things to do.

In a start-up, these processes should be simple. Communication and rapid decision-making come naturally in a small organisation. They can be built on and just enough formality added to develop and maintain a strategic outlook.

Supporting functions come next. They are needed for good technology research. Well before product development, a start-up usually has informal methods for instrument calibration and maintenance, purchasing, statistical analysis and validation (confirming that systems and processes work). Again, by developing these processes early, a company can start simple while developing the quality culture.

As the innovative technology proves to be feasible, a company begins planning development of the product it will sell. This is when design controls officially begin. During design and development planning, the company plans when design phases will occur. A parallel schedule ensures that design control processes, and ultimately production and

post-market processes, are implemented just as they are needed.

Start simple – Let the quality system evolve to meet the needs of the company.

Small start-ups do not need elaborate processes. Communication among a small number of people is usually quick and effective. Documenting and retaining information often is not as successful, but it is something a quality system does well.

Benefits of early information control include protection of intellectual property and lowered dependence on a few key personnel.

Start-ups should avoid the temptation to copy a quality system from another company, especially a much larger company. Complex quality systems stifle a small company. A start-up is better served with a simple quality system. As the need for flexibility or rigour arises, the quality system can be revised. The system then evolves to meet the needs of the start-up company, not vice versa. Managers and key professionals participate more and take more responsibility when the quality system is something they can control positively.

At some point, the question arises as to when to move to specialised quality system software systems, such as electronic document and record control. The initial cost of the software is a hurdle. The optimal answer is to move earlier rather than later. Specially designed systems can greatly increase efficiency and ensure compliance.

Eventually, a company will need a system. It is much easier to implement when the company's procedures and organisation are young and flexible and when the amount of information to be converted is small. By moving early, a company reaps the benefits much sooner and at a lower ultimate cost.

Conclusion

A medical device start-up must develop a quality system to design a product and bring it to market. A quality system can be developed so that it grows with the company, supports business activities as well as product realisation, and develops a quality culture.

Successful development of a quality system requires management commitment to using the quality system, starting simple and letting the system grow and evolve as needed. ■