US

Managing Medical Device Supplier & Purchasing Controls

Best practices for complying with QSR purchasing controls plus top 10 FDA observations



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Why Do Manufacturers Need Supplier and Purchasing Controls?

Medical device manufacturers are responsible for every step of their global supply chain. As global and outsourced supply chains become more complex, manufacturers should implement an effective life-cycle management approach. The Food and Drug Administration (FDA) increased its scrutiny of manufacturers' supplier purchasing controls in response to recent medical device recalls in the United States due critical components and services failures from suppliers.

The United States Quality System Regulation (QSR) requires finished device manufacturers to evaluate the capability of their suppliers, contractors, and consultants to provide quality products pursuant to 21 CFR Part 820.50 - Purchasing Controls. From a practical perspective, the requirements of the Quality System Regulation link the ISO 13485 medical device quality management standard, the ISO 14971 risk management standard, and the applicable Global Harmonization Task Force guidance.

Overview of FDA medical device Quality System Regulation

In October 1996, FDA published a final rule for the QSR. In June 1997, revisions to 21 CFR Part 820 covering Good Manufacturing Practice took effect. The QSR includes requirements related to the methods, facilities, and controls used for designing, manufacturing, packaging, labeling, storing, installing, and servicing medical devices intended for human use.

The QSR established a framework for device manufacturers to follow and gave firms greater flexibility in achieving quality requirements. This action was necessary to add preproduction design controls and achieve consistency with quality system requirements worldwide. In support of the FDA Transparency Initiative, the Center for Device and Radiological Health (CDRH) provides data on how inspection observations and warning letter citations connect to the various subsystem requirements contained in the QSR.[1]

The top three FDA inspectional observations

Very little changed from 2014 to 2016 with respect to the most frequent inspectional observations. The top three inspectional observations were also the most frequent reasons for FDA Warning Letter citations in 2016. FDA citations are issued in the Production and Process Controls, Corrective and Preventive Actions, Management Controls, Design Controls, and Document Control Quality System Regulation Subsystems.

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Table 1: Top 10 Device Observations Used in Turbo EIR as of - 10/1/2015 through 9/30/2016				
Turbo EIR Cite ID	**Reference**	**Frequency**	**Short Description**	**Citation Text**
3130	21 CFR 820.100(a)	344	Lack of or inadequate procedures	"Procedures for corrective and preventive action have not been [adequately] established. Specifically, …"
14713	21 CFR 820.198(a)	264	Lack of or inadequate complaint procedures	"Procedures for receiving, reviewing and evaluating complaints by a formally designated unit have not been [adequately] established. Specifically, …"
630	21 CFR 803.17	146	Lack of Written MDR Procedures	"Written MDR procedures have not been [developed] [maintained] [implemented]. Specifically, …"
3282	21 CFR 820.90(a)	135	Nonconforming product, Lack of or inadequate procedures	"Procedures have not been [adequately] established to control product that does not conform to specified requirements. Specifically, …"
479	21 CFR 820.50	122	Purchasing controls, Lack of or inadequate procedures	"Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been [adequately] established. Specifically, …"
546	21 CFR 820.75(a)	119	Lack of or inadequate process validation	"A process whose results cannot be fully verified by subsequent inspection and test has not been [adequately] validated according to established procedures. Specifically, …"
3696	21 CFR 820.100(b)	99	Documentation	"Corrective and preventive action activities and/or results have not been [adequately] documented. Specifically, …"
3103	21 CFR 820.30(i)	78	Design changes - Lack of or Inadequate Procedures	"Procedures for design change have not been [adequately] established. Specifically, …"
2327	21 CFR 820.22	76	Quality audits - Lack of or inadequate procedures	"Procedures for quality audits have not been [adequately] established. Specifically, …"
3331	21 CFR 820.181	65	DMR - not or inadequately maintained	"A device master record has not been [adequately] maintained. Specifically, …"

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Although not among the top three cited observations, purchasing controls and supplier issues are frequent enough to warrant careful attention and vigilance on the part of manufacturers. The FDA issues a warning letter to the firm if the response concerning the investigator's observations is noted on the Form FDA 483s (FDA 483) List of Inspectional Observations. The following table shows the top three medical device warning letter citations.

Table 2: Top Ten Medical Device Warning Letter Citations 2014 and 2015

Number	Quality System Subsystem	FY'15	FY'14
No. 1 Cite	Corrective & Preventive Actions	CAPA - 21 CFR 820.100(a)	CAPA - 21 CFR 820.100(a)
No. 2 Cite	Corrective & Preventive Actions	Complaints - 21 CFR 820.198(a)	Complaints - 21 CFR 820.198(a)
No. 3 Cite	Productions & Process Controls	Process Validation - 21 CFR 820.75(a)	Process Validation - 21 CFR 820.75(a)
No. 4 Cite	Design Controls	Quality Audit - 21 CFR 820.22	Design Validation - 21 CFR 820.30(g)
No. 5 Cite	Corrective & Preventive Actions	Purchasing Controls - 21 CFR 820.50	Nonconforming Product - 21 CFR 820.90(a)
No. 6 Cite	Management	Nonconforming Product - 21 CFR 820.90(a)	Quality Audit - 21 CFR 820.22
No. 7 Cite	Productions & Process Controls	Design History Record - 21 CFR 820.184	Purchasing Controls - 21 CFR 820.50
No. 8 Cite	Design Controls	Design Validation - 21 CFR 820.30(g)	Design Changes - 21 CFR 820.30(i)
No. 9 Cite	Design Controls	Design Changes - 21 CFR 820.30(i)	Design History Record - 21 CFR 820.184
No. 10 Cite	Productions & Process Controls	Device Master Record - 21 CFR 820.181	General Production & Process Controls - 21 CFR 820.70(a)

Challenges Associated with Purchasing Controls Compliance

Based on the increased outsourcing of critical components and manufacturing of finished devices, as well as the number of recalls and manufacturing problems tied to Supplier and Purchasing Control issues, the FDA increased its scrutiny of manufacturers. The quality of a finished device depends on the quality of the raw materials, components, and services that went into it. Poor medical device quality can cause customer dissatisfaction, injuries, and recalls.

The FDA defines **Product** in § 820.3(r) as including components, manufacturing materials, in-process devices, finished devices and returned devices. A **Component** is defined in § 820.3(c) as any raw material, substance, piece, part, software, firmware, labeling, or assembly included as part of the finished, packaged, and labeled device. **Service** means parts of the manufacturing or quality system that are contracted to others, for example, plating of metals, testing, and sterilizing[.]

Common issues identified by the Agency's Quality System data involve the inadequate control of components purchased from other suppliers, as well as design and manufacturing controls. Purchasing Controls are of particular interest based on the growth in the worldwide supply chain. The requirements for Purchasing Controls are set forth in § 820.50. Firms must establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

According to FDA, the most commonly identified inadequacies for Purchasing Controls are:

- Inappropriate evaluation of suppliers
- Changes to the components without notification to the manufacturer
- Problems with the manufacturing of a component, subassembly, etc.
- Inadequate incoming acceptance activities to detect nonconformities
- Inadequate or lack of process validation activities at the supplier

Inspection and FDA authority often extend only to the finished device manufacturer. FDA does not perform a routine inspection of component manufacturers as summarized by the scope of the regulation.

- ... This regulation does not apply to manufacturers of components or parts of finished devices.... [820.1(a)(1)]
- "Finished device" means any device or accessory to any device that is suitable for use or capable of functioning whether or not it is packaged, labeled or sterilized. [820.3(l)]
- "Component" means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device [820.3(c)]

FDA has the authority to inspect component manufacturers but relies on the finished device manufacturer to ensure the purchased product meets specifications, and is safe and effective. The manufacturer must determine the adequacy and extent of required quality systems, with particular emphasis on change control and corrective and preventive action through auditing and other verification or assessment tools.

The degree of supplier control required to establish compliance may vary with the type and significance of the product or service purchased and the effect of that product or service on the quality of the finished device.[2]

Best Practices for Purchasing and Design Controls

The intent of 21 CFR Part 820.50 Purchasing Controls is to ensure device manufacturers select only those suppliers, contractors, and consultants who can provide quality products and services. As with finished devices, quality cannot be inspected or tested into products or services.[3]

Per the Food and Drug Administration Compliance Program Guidance Manual, CP 7382.845:

*"**The finished device manufacturer bears overall responsibility for the safety and effectiveness of the finished device** and must control all contractors under 21 CFR § 820.50 Purchasing Controls and 21 CFR § 820.80 Receiving, in-process and finished device acceptance. However, a **contract sterilizer/ contract manufacturer of finished devices and the finished device manufacturer are all legally responsible for compliance with the Quality System Regulation** and for assuring the safety and effectiveness of the finished device."*[3]

Each manufacturer shall establish and maintain procedures to ensure all purchased or otherwise received product and services conform to specified requirements. [21 CFR 820.50]

- Product includes components, manufacturing materials, in-process devices, finished devices, and returned devices. [21 CFR 820.3(r)]

Best Practices

1. **Purchasing Controls and Design Controls**
   Manufacturers should begin implementing purchasing controls, as well as supplier selection processes, in the design phase. Purchasing and supplier controls should be established during the design of a device component or service.[4] The process of selecting suppliers for materials, components, finished medical devices, or services is an integral part of delivering quality medical devices to the public.

   Design Controls - Product design and associated risks drives purchasing decision-making. [21 CFR 820.30]

   The planning for and selecting suppliers involve, quality assessment, supplier quality agreement, and supplier agreement.

   "... the quality of a product or service is established during the design of that product or service and achieved through proper control of the manufacturer of that product or the performance of that service Section 820.50 thus mandates that products be manufactured, and services are performed under appropriate quality assurance procedures."[3]

   The manufacturer should evaluate each supplier's capability and competency to fulfill the requirements of the purchased product and/or service.

2. **Risk-based Approach**
Critical components have more stringent controls and higher levels of evaluation than less critical components. Manufacturers should proactively reduce and control risks. Limited visibility translates to greater risk.

> *"…. the need for specifications should be based on the criticality of and risk associated with the use of a specific manufacturing material…. The extent of the specification detail necessary to ensure that the product or service purchased meets requirements will be related to the nature of the product or service purchased, taking into account the effect the product or service may have on the safety or effectiveness of the finished device …"*[3]

Statistical techniques, first article inspection, evaluation of prototypes or a first lot, an audit of the supplier, or any combination may be appropriate based on the degree of risk of the product and/or service. Manufacturers may also utilize self-administered questionnaires or surveys as part of their risk mitigation efforts.

3. **Supplier Audits**
Supplier audits (onsite or documentation review) should be well planned and thorough, focus on critical processes, and demonstrate conformance to specified requirements.

> *"The capability of the product or service suppliers should* ***be reviewed at intervals consistent with the significance of the product or service provided*** *and the review should demonstrate conformance to specified requirements."*[3]

Supplier audits provide objective evidence to demonstrate their ability to meet the acceptability criteria.

4. **Supplier Quality Requirements**
Organizations must establish specific supplier quality requirements based on the product/service provided, which demonstrates thorough objective evidence is fulfilled.

Acceptance Activities - Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities…. [21 CFR 820.80(a)]

Acceptance activities are defined as an inspection or test of materials for conformance to design specifications.

"Each manufacturer must establish an appropriate mix of assessment and receiving acceptance to ensure products and services are acceptable for their intended uses..."[3]

"... A finished device manufacturer may choose to provide greater in-house controls to ensure that products and service meet requirements, or may require the supplier to adopt measures necessary to ensure acceptability, as appropriate. FDA believes that appropriate mixes of supplier and manufacturer quality controls are necessary."[3]

The controls and responsibilities between the manufacturer and suppliers should be agreed upon by all parties. The manufacturer should determine the acceptance activities to be performed, either by the supplier and/or the manufacturer, based on the risk of the product/service provided.

5. **Supplier Contracts**

Supplier Contracts/Agreements should define all quality elements, responsibilities, requirements, and liabilities implemented by the supplier as an integral part of the supply of products or services. The Supplier Contract/Agreements ensure clearly defined responsibilities and promptly communicated change notifications.

This mutual commitment to quality is the foundation of a partnership.

6. **Establish Balance**
Parties should establish an appropriate balance of supplier controls, manufacturer quality controls, and acceptance activities. It is critical not to leave anything to assumptions, but parties should also take care not to let controls override communication and collaboration.

7. **Supplier Investigations and Corrective Actions**
Setting expectations for supplier investigations and corrective actions is integral to forming successful supplier controls. These controls are in turn crucial for ensuring products will not adversely affect safety and effectiveness, and that customer and regulatory requirements are met. The extent of corrective action is based on the risk and impact of the finding or cause. Based on the criticality of the supplier, it is important for an organization to provide support and assistance in remediation. The supplier should prepare a plan for correction, provide an analysis of the root cause, and perform the required corrective action quickly. Additional feedback and communication may be necessary, as well as the need to re-evaluate the continued suitability of the supplier.

Conclusion

Quality issues within the medical device supply chain concern every stakeholder. The quality, performance, and reliability of medical devices on the market, and in a company's effort to launch new products quickly, are more sophisticated due to worldwide supplier chains. Supplier qualification and assessment are required in both US QSR regulation and ISO standards.

Manufacturers can ensure their medical products meet the needs and expectations of their customers by implementing purchasing and supplier quality controls to ensure the safety and effectiveness of the medical devices brought to commerce. This involves identifying and defining the device specifications, sourcing and purchasing the product or service, and covers all activities from identifying potential suppliers to the delivery of quality product or services to the end user. Select suppliers based on their capabilities and your manufacturing requirements, establish adequate supplier controls, and maintain good documentation regarding purchases, data, and reviews. Following purchasing control requirements is good for your business and for the public health.

Learn more about FDA QSR compliance and audits?

If you enjoyed this white paper, we know you will like our video explaining how to prepare for an FDA inspection. We discuss how to prepare your facility, who should interact with the inspector, when to present and prepare documentation, expert tips for a successful audit, and much more.

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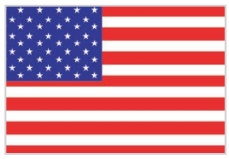

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About the Author

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References:

1 2016 FDA Update, CAPT Thomas R. Berry, BSPharm, PharmD Director, Compliance Branch FDA / OGROP / ORA / SW-FO / DEN-DO

2 FDA, Medical Devices: Current Good Manufacturing Practice (cGMP) Final Rule; QSR, Federal Register, 61 (195), Supplementary Information, Section V. Response to Comments and Rationale for Changes, comments no. 7, 99, 106, 107, and 111, October 7, 1996

3 Preamble to the 1996 QS regulation: comments 99, 103, 106 and 115.