



OEM and CM: The Often Unexpected Division of Regulatory Responsibilities

By Lianne Coppinger

Medical device original equipment manufacturers (OEMs) preparing to commercialize innovative technologies sometimes mistakenly assume that outsourcing product manufacturing frees them from certain regulatory requirements. In reality, however, a contract manufacturer (CM) cannot offload these compulsory duties from the OEM.

In the eyes of the US Food and Drug Administration (FDA), the OEM is ultimately responsible for the quality, compliance, safety and efficacy of its medical device. As such, the agency expects the OEM to ensure its outsourcing partner is in compliance with 21 CFR Part 820, the Quality System Regulation (QSR) and current Good Manufacturing Practice (CGMP) when manufacturing and distributing finished medical devices on its behalf.

Understanding the Roles and Responsibilities of the OEM and CM to Ensure Compliance

Whether a medical device OEM outsources its manufacturing or not, it must comply with certain quality systems standards and FDA regulations. FDA requires OEMs to develop a quality system that addresses the sections of the QSR applicable to their specific products and operations.

These sections include design controls, purchasing controls, corrective and preventative action (CAPA), change control, medical device reporting/complaint handling and others. For example, FDA requires OEMs to have a procedure for the collection and analysis of customer feedback to ensure that the company identifies and addresses any quality problems with the device in a timely manner. Regardless of where the quality problem originates, the OEM is responsible for implementing and managing any necessary remedial action. While the CM must also comply with all applicable quality systems standards and FDA regulations, the OEM is ultimately responsible for ensuring that its medical device is safe, effective and manufactured through compliant production.

FDA considers OEMs to be manufacturers even if they do not perform any of the actual production. As the “manufacturer,” the OEM must maintain compliance with the applicable QSR/CGMPs. If an OEM outsources its medical device manufacturing to a CM, both the OEM (the company that develops the specifications for the finished medical device) and the CM (the company manufacturing the finished medical device for the OEM) must comply with the applicable requirements of the QSR.

FDA requires OEMs to maintain quality systems commensurate with the level of risk their medical devices present, the functions they perform and the size of their organizations.

The following outline of a few QSR section requirements illustrates the OEM’s quality system responsibilities in further detail.

Design Controls

As the manufacturer, the OEM is the owner of its design, and thus must design and develop its device using the applicable QSR design controls. If the OEM outsources design activities to a CM, it must ensure the CM is compliant with the QSR design controls section 820.30. If an OEM outsources only the manufacturing of a finished medical device, it—and not the CM—is responsible for design control compliance. The OEM is also responsible for the creation of all relevant manufacturing documentation, such as the bill of materials (BOM), work instructions, assembly prints and test procedures/records that the CM needs to manufacture the medical device.

Purchasing Controls

FDA requires OEMs to ensure that all components, materials and services used in manufacturing their medical devices are acceptable for their intended use. When outsourcing the manufacture of a medical device, the OEM is responsible for assessing, selecting and documenting its evaluation of a qualified CM. The OEM must demonstrate to FDA that it has the appropriate level of control over the CM by qualifying the company as an approved supplier, establishing written agreements that clearly define roles and responsibilities and monitoring

the product and data for quality and compliance. To prove that its level of control is effective, the OEM needs to monitor and audit the CM and follow through with and document any required corrective action.

Device History Record

The OEM defines the requirements for building its specific medical device, such as the test and inspection criteria, in the Device History Record (DHR). It is the CM's responsibility, however, to perform these functions and collect the objective evidence in a DHR format. The OEM also defines the retention time for the DHR and the CM maintains the record in accordance with these requirements, making it readily available to the OEM.

Device Master Record

The Device Master Record (DMR)—a compilation of records documenting the procedures and specifications for a finished medical device—is the OEM's responsibility. When OEMs outsource manufacturing, the CM must execute these procedures and specifications in strict accordance with the DMR. The CM cannot add, change or

delete any information in the DMR without verification, validation and approval from the OEM.

Complaint Handling and CAPA

OEMs must also implement and maintain a complaint handling and CAPA system/process. If, during postmarket surveillance activities, the OEM identifies a problem with the medical device, it must have appropriate systems and processes in place to capture and investigate the reported issue to determine the root cause and best corrective action. Even if the problem originated with the CM, the OEM is still ultimately responsible for correcting the reported issue and documenting all related actions. The OEM must also ensure that the CM has the appropriate systems in place to correct the issue at its facility.

ISO 13485 vs. 21 CFR Part 820

Companies that are new to medical device manufacturing often find it extremely difficult to navigate the various industry standards and regulations: which are applicable to a given device, which are required in the US or abroad, who is responsible for compliance, etc. For example, in addition to compliance with the QSR, some



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countries require OEMs to be ISO 13485-certified to gain medical device marketing approval. The QSR and ISO 13485 are harmonized, but compliance with one does not guarantee compliance with the other.

Many medical device companies perform clinical trials and obtain clearance to export to countries outside the US before obtaining FDA approval for marketing within the US. With most companies seeking worldwide commercialization and distribution, however, quality management systems designed to comply with both the QSR and ISO 13485 are much more versatile and poised for any transition or change.

Working with an Experienced Contract Manufacturer

Partnering with a trustworthy, experienced CM that is compliant with the ISO 13485 standard and 21 CFR Part 820 is essential for the compliant manufacture of any medical device. FDA will hold both the OEM and CM responsible for any CGMP violations if it determines that the OEM failed to do an adequate job of controlling and auditing the CM. OEMs should thoroughly understand the regulatory requirements of both

parties to ensure their adherence to all relevant regulatory requirements for medical device manufacturing.

Conclusion

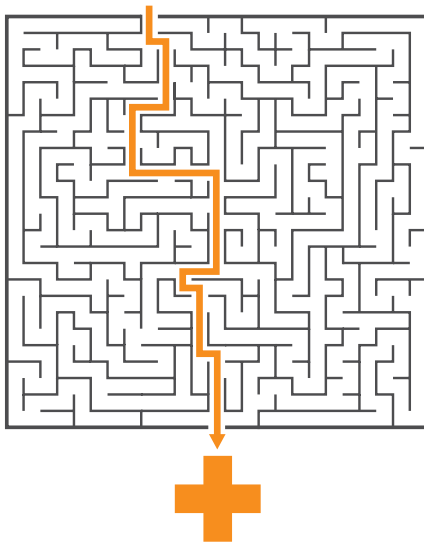
An OEM (the company whose name will appear on the medical device) will always have some level of regulatory responsibility that cannot be relinquished or contracted away to a CM under any circumstances.

The earlier companies identify their responsibilities and implement a plan for compliance, the easier their road to market will be. Choosing the right partner will ensure a smooth transition into manufacturing and reduced time to market.

Author

Lianne Coppinger has more than 17 years experience with quality system implementation, medical device manufacturing and post-market surveillance. Her accomplishments include developing, implementing and overseeing an ISO 13485:2003-certified and FDA-compliant quality management system, establishing and maintaining a production monitoring system and corporate auditing system, training and supervising staff to FDA regulations, and successfully passing several audits from various Competent Authorities. Coppinger also gained experience with Six Sigma methodologies and has been a Green Belt since 2006.

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