MEDICAL DEVICE
Manufacturing Standards

If your company produces medical devices, contract manufacturers can provide flexibility, expertise, and experience. Choosing contract manufacturers who are certified can offer an array of benefits:

- Access to growing markets around the world
- Demonstrable commitment to efficient, safe processes
- Protection against audits and litigation
- Marketable dedication to quality

The question? Which standards are relevant, and what certifications to look for.

Read on to discover the requirements and applications of the medical device industry's manufacturing standards.

CGMP

FDA

The current Good Manufacturing Practice regulations are the FDA's standard for the manufacture of medical products. Manufacturers failing to comply with cGMPs are consistently the target of regulatory actions. ■

ISO 9001:2008

This standard describes 10 quality management principles including a process-centered approach, factual decision-making, and continual improvement. After a 3-year grace period following the introduction of ISO 9001:2015, ISO 9001:2008 will become obsolete in September of 2018.

Manufacturers certified by registrars have been independently verified in their adherence to ISO standards. A certified manufacturer has been extensively audited and meets all requirements. ■

CFR 820 and ISO 13485

FDA 21 CFR 820 and ISO 13485 are the key standards for medical device manufacturers in the US and Europe, respectively. These standards form the basis for compliance to regulatory requirements such as cGMPs.

These extensive standards provide guidelines for a range of activities, including the design, production, traceability, labeling, and servicing of medical devices. While compliance may be costly, these standards open up markets around the world and are the best way for medical device manufacturers to protect against any potential litigation. ■
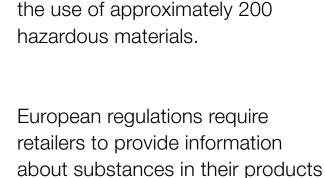
ISO 14971

This 9-part standard helps manufacturers reduce liability by describing best practices for risk management. ISO 14971 outlines correct processes for evaluating risks, hazards, and product performance requirements. Required for products to be sold in Europe if they are Class 2 or higher (has to do with invasiveness) ■

IEC 60601

This standard applies to the electrical compatibility and safety of medical equipment. IEC 60601 certification requires careful documentation of the design and manufacture process. ■

RoHS

The RoHS directive restricts the use of Lead, Cadmium, Mercury, Hexavalent Chromium, PBB, and PBDE in electronic equipment.

All electrical medical devices sold in Europe must comply with RoHS. Failure to comply can lead to fines and restrictions in the region. ■

REACH

REACH describes over 140,000 chemical substances for sale and distribution in the EU, and restricts the use of approximately 200 hazardous materials.

European regulations require retailers to provide information about substances in their products within 45 days of a request. REACH-compliant manufacturers help retailers doing business in the EU avoid costly penalties. ■

FCC and CE Marking

CE FC

While not strictly standards, FCC and CE marking processes are worth understanding. When placed on products, these marks constitute a manufacturer's assertion that they meet all applicable safety requirements.

Manufacturers using the FCC or CE marks must carry out self-assessments and submit signed declarations of conformity to the relevant legislative bodies.

If you are developing medical devices and want to take advantage of the efficiency and expertise of a contract manufacturer, choosing a partner compliant with the appropriate standards can increase your products' marketability and protect you from the difficulty of an audit.

"The FDA expects that the spec developer will make sure the contract manufacturer is QSR/cGMP compliant."

Alan Schwartz, FDA Veteran

Humphrey®

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