ControlTek

Electronic Manufacturing Services Provider

MEDICAL DEVICE MANUFACTURING: DON'T GET CAUGHT IN THE FDA HOT SEAT

REQUIREMENTS EVOLVE. DON'T LET YOUR PRODUCTS GET CAUGHT IN THE FDA HOT SEAT.

Please note: The following article is intended to be a reference for all audiences and includes general content relating to preparing products to comply with FDA requirements. More specific information related to individual FDA requirements is included at the end of the article for additional guidance.

PICTURE THIS.

The new product you're developing for the medical device market is almost ready for release. Even though you know FDA regulations can be tough, you've traveled this road before and you feel prepared to bring your product to market on-time and within budget.

What a surprise, then, to find your product's launch date unceremoniously set back three months when its packaging fails to comply with your medical device shipping and packaging validation process. You've just found yourself face to face with a painful medical device development truth that's flat-lined its fair share of new products long before they ever make it to market:

REQUIREMENTS EVOLVE.

When that happens (and it does, a lot. In 2015 alone the FDA will publish more than 20 new Guidance Documents to help users navigate their way through complex FDA regulations), you could find your product exposed to gaps you weren't even aware existed.

If success is 1% inspiration and 99% perspiration, preparation is the cool breeze that fans the brow of the Medical Device OEM.

The following are just a few of the requirements[1] you and your manufacturer will need to address to comply with FDA Good Manufacturing Practices for Medical Devices.

- Shipping and packaging requirements and validation
- A customer-approved, formal manufacturing control plan
- Test planning, development, and validation
- Vendor qualification, monitoring and management
- Manufacturing documentation
- Production controls[2]
- Purchasing requirements
- Acceptance activities[3]

Here's the good news. Ensuring a successful product launch doesn't have to be a nightmare because a little thoughtful planning and preparation early on can go a long way towards helping you reach the finish line successfully.

"Medical device manufacturing is not just a highly regulated industry," says ControlTek President Andy LaFrazia. "It is also prone to change."

"The regulations you adhered to during your last product launch may have changed dramatically by the time you're ready to introduce a new product. Even if you're familiar with the medical manufacturing industry, it can be a struggle to stay up to date on new or changing regulations."

When it comes to these regulations, a manufacturer's trouble spots can be broken into three categories: those directly related to manufacturing processes, issues stemming from incorrect or incomplete product documentation, or gaps in test design and development. All three are areas of new product development the FDA takes a great interest in.

MANUFACTURING PROCESSES

Many of the challenges that lie ahead for product developers can easily be avoided by partnering with a manufacturer with medical device manufacturing experience. That is, of course, as long as the medical device contract manufacturer follows FDA Current Good Manufacturing Processes. If they also follow ISO 13485, which relates directly to the manufacturer's quality management system, even better.

"Many medical device companies may not be aware of all of the requirements in one or more of these areas," LaFrazia adds. "Their manufacturing partner can take over that responsibility as long as it's documented as part of their manufacturing contract. Once that happens, the manufacturer's quality system can then add value to the medical device company's internal systems."

What that means is by working closely with their manufacturer, medical device product developers have the opportunity to take advantage of systems and processes the manufacturer already has in place to meet medical device requirements. At ControlTek, that can include validation of in-house tools, processes, or even vendor and supply chain management for any custom materials required for a new product.

"If a product requires any kind of special assembly or other manufacturing process, we'll ensure the new process is also validated to meet medical device requirements," says LaFrazia.

PRODUCT DOCUMENTATION

Product documentation is a crucial component of FDA compliance for medical devices. A DMR, or Device Master Record, is required by the FDA for all medical devices. Similarly, a DHF (Design History File) that includes the documented design history for any new medical device is also a requirement.

Many of these requirements can be completed by product designers in parallel to product development. When possible, device designers should also consider manufacturing and standard requirements as part of their product development. By doing so, they may be able to save considerable time and money throughout the new product introduction process.

TEST DESIGN AND DEVELOPMENT

Medical device testing is serious business. The earlier you begin your preparation for testing, the more prepared you'll be when it really matters. As you develop your testing strategy, it's important to remember to include test fixtures and testing protocols, too.

"The bottom line is that medical device requirements are more stringent than ever," says Mr. LaFrazia, "and the FDA is looking closely to make sure your products are meeting those requirements."

WHAT YOU NEED TO GET STARTED

While medical device manufacturing is certainly complex, there are several steps you can take to make the process easier.

The medical device manufacturing checklist on the next page can help as you start planning your next product launch.

Notes:

1) Per 21CFR, Part 820 Quality System Regulation Good Manufacturing for Medical Devices

2) Includes Process failure mode and effects analysis (PFMEA)

3) Includes inspection of incoming raw materials, in-process and finished device acceptance. Additional requirements include nonconforming product handling processes as well as both corrective and preventive action processes, and handling and storage requirements.

4) Per 21CFR Part 820

5) More Info at: http://www.controltek.com/medical-electronic-device-manufacturing

Device Master Records for medical products include information specific to[4]:

- Device specifications
- Production process specifications
- Quality assurance procedures
- Packaging and labeling instructions
- Installations, maintenance, and servicing procedures and methods

- Mastering and Managing the FDA Maze, Second Edition: Medical Device Overview
  - An excellent resource for anyone trying to navigate their way through FDA Regulations, this book is helpful for regulatory professionals, product designers, and executives.
- FDA Website
  - Find Quality System Regulations/Medical Device Good Manufacturing Practices for medical devices as well as any other FDA requirement information at the FDA website.
- ControlTek Medical Device Manufacturing Process
  - View ControlTek's own internal Medical Device Manufacturing process and see how we take products from initial feasibility through Production, Delivery, and even Life Cycle Maintenance.

Medical Device Manufacturing Checklist

Below you will find a short checklist to use as you prepare to bring your medical device products to market. This list should be used as a general guide; your contract manufacturer will work with you to ensure all of your specific medical device requirements are completed.

- I have a stable and complete design which has been verified and validated to meet device specifications and documented in an approved Design History File.
- My trusted manufacturer has in-house regulatory experience.
- A full risk assessment and analysis of the product's benefit/risk balance has been completed and documented.
- My manufacturer and I have agreed on a Formal Manufacturing Control Plan that includes a PFMEA.
- My manufacturer has ensured all tools and processes used in manufacturing have been identified, documented, and validated where required.
- All vendors have been qualified and documented via an Approved Vendor and Procedure List. Critical components have been identified and incoming inspection criteria identified and documented.
- My test development and documentation includes test fixture software validation. All test system design has been completed with formal medical device development procedures that are QSR compliant.
- My manufacturer's packaging and shipping has been documented and validated to ensure medical device products will not be damaged during shipment.
- I have a robust corrective action and preventive action process.
- I have a plan for ongoing monitoring and data collection for finished products.
- I have a plan for collecting field information that includes warranty and field return information.
- I am prepared for an FDA inspection at my facility or at my contract manufacturer's FDA registered facility.