Navigating FDA Approval for Battery Powered Medical Devices

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Introduction

For a medical device, the U.S Food and Drug Administration (FDA) approval process can take as little as one week to eight months or more. Studies have shown the entire process from concept to approval can take three to seven years. Launching a medical device into the market is not a fast process and having the wrong information or partner can cause delay and extra expense.

EaglePicher's 25 years of experience in medical device battery development and production has taught us the deliverables critical to a successful experience in working with the FDA. EaglePicher partners with numerous medical device manufacturers to design and build implantable cells and external battery packs to power life changing medical devices. Our experience includes medical devices implanted in the body such as stimulators, neuromodulators or cardiac monitors and batteries powering external devices like surgical tools and ventilators.

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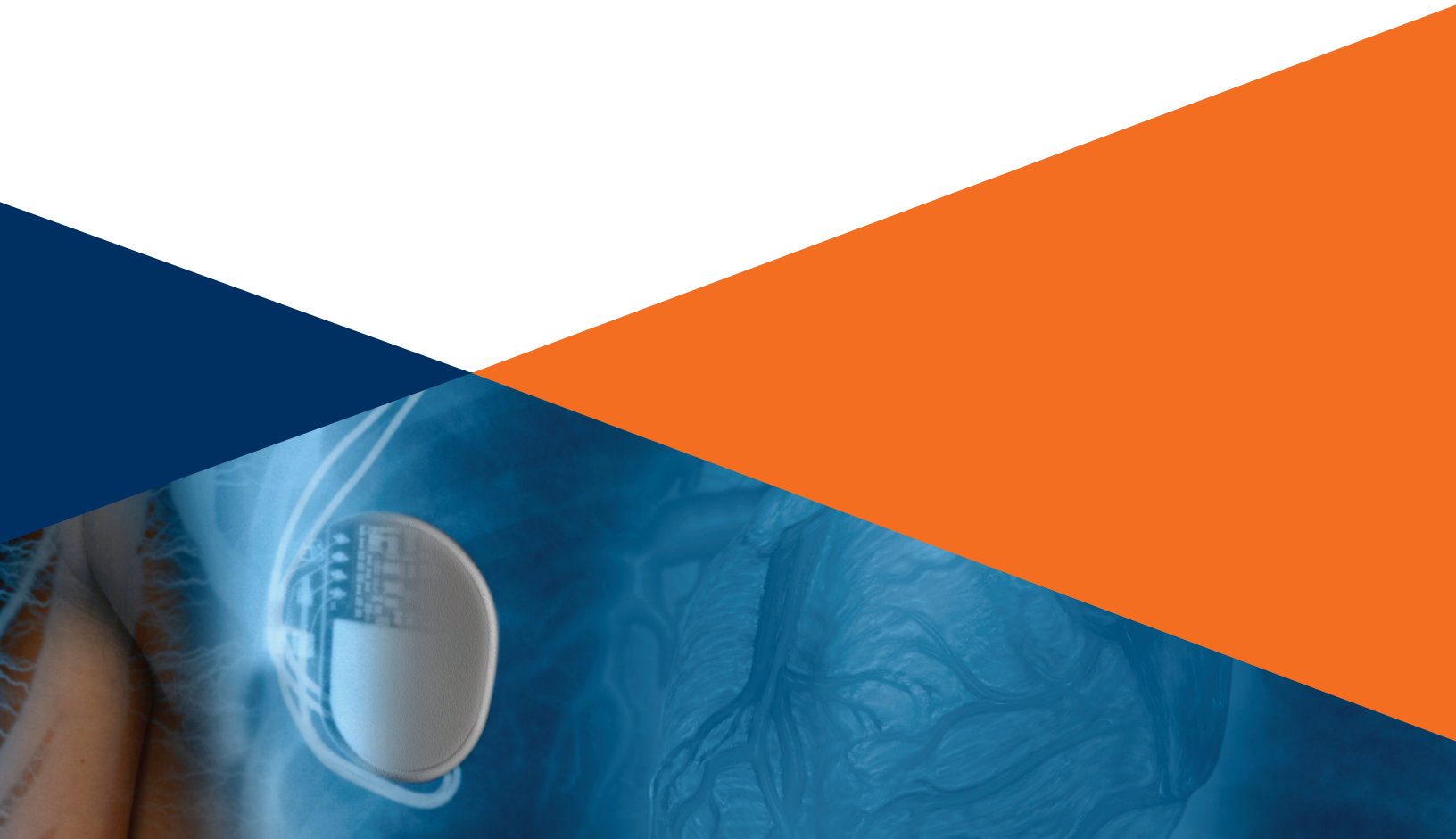
Getting Started

FDA requirements cover both primary (non-rechargeable) and secondary (rechargeable) batteries. These batteries can contain various chemistries and may consist of single cells or multiple cells connected in series, parallel or both. The batteries overall role is to convert chemical energy into electrical energy by a chemical reaction while reducing the risk of injury to the person using the device and the patient.

The design steps for building an implantable or external medical device can be very different and uniquely complex based upon the application; however, the battery design steps are similar in both scenarios. Starting with the assumptions that either product requires a full FDA approval, the battery/power source becomes a key component and possibly the critical path to approval. The FDA's 21 CFR sets the requirements for device approval and includes quality system regulations, testing requirements, labeling and device reporting to name a few.

The FDA employs specific power supply experts throughout their various units. The type of device will determine which FDA unit will work with the manufacture or designer during the approval process. Besides the FDA, EaglePicher's experience includes supporting other test agency suppliers such as TUV, UL, etc.

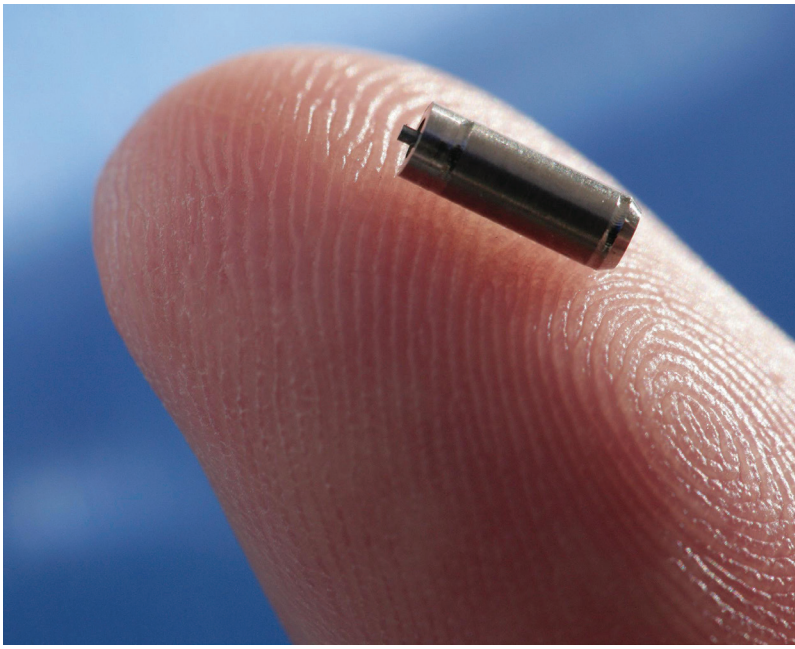


Navigating the Process

First, the FDA will need to understand the device's power cell at the most basic level. This includes the cell chemistry, history of the chemistry, previous products using the chemistry, cell modeling data, among other things. With EaglePicher's proven experience in battery development we can easily provide this type of data.

Second, as you move to the product side, you will need to provide product design efficacy materials. This will vary greatly based upon the type of device, therapy provided, as well as Class of device (I,II, or III). You will need to work close with the FDA to ensure proper data and testing is completed on the device, including design traceability. The host device (implantable or external) will have significant testing required in order to obtain FDA approval. The cell or battery pack is key to demonstrating to the FDA that all safety, design tolerances, and back up or shut down methods are carefully and thoroughly designed and tested.

Last, data modeling on the cell is particularly critical. In some cases, the FDA may ask for up to three years of actual cell testing data. This can be problematic when dealing with a new custom cell. EaglePicher can bridge this gap by leveraging our years of experience and proven track record. Another potential bridge is cell data modeling. This modeling has proven to be very accurate when based on real-time data that is extrapolated to future years. Once again leveraging a partner with this experience can expedite your process.



Summary

To help build compliance with the FDA and other regulatory requirements, EaglePicher maintains ISO 13485 certification and quality management system. EaglePicher understands the needs of the medical device market and our commitment to quality ensures our products exceed the high standards of the FDA. Our mission is to support our customers in their interfacing with the FDA. We built our processes and procedures in support of that mission.

About the Author

Trent Keeney, Business Development Manager for EaglePicher Medical Power, serves the worldwide primary and rechargeable battery medical device market. Trent has over 20 years as an experienced business leader with proven sales and marketing management experience. Working with both start-ups and leading OEMs, Trent has a successful track record of serving customer needs to facilitate growth.

About EaglePicher Medical Power

EaglePicher® Medical Power is a global leader of implantable power sources for medical devices. For more than 25 years, the company has focused on developing mission-critical, life-sustaining applications. Today as a top supplier of implantable-grade batteries, the company's extensive list of solutions includes both off-the-shelf primary and rechargeable batteries, proprietary customizable solutions, and external battery packs. EaglePicher developed and manufactured the first human implantable lithium-ion battery and the industry's smallest implantable medical battery. The company conducts research and development in its East Greenwich, Rhode Island office and has manufacturing facilities in Vancouver, British Columbia and Joplin, Missouri. As part of the EaglePicher commitment to patient safety, the company maintains ISO 13485 certification. Learn more about EaglePicher Medical Power's products and services at www.eaglepicher.com.