Medical & Life Sciences Case Studies

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LVAD Controller and Monitor

Commercialization of product in less than 18 months

The Situation

Left Ventricular Assist Device manufacturer that is CE approved and sold in Europe wants to enter the U.S. market. The device needs Class III device approval and the company was up against a tight 18-month plan to commercialize the product.

Challenges

- To remain competitive, must release a product to U.S. market quickly
- Availability of key staff to focus on commercialization efforts is limited due to clinical trial work
- Lack of systems knowledge with Class III medical devices

Solution

- Established a phased development plan to ensure product release within 18-month window
- Systems engineering support met product launch time frame
- Reduced regulatory risk by identifying verification and validation criteria

Proven Results

- Achieved commercialization of product in 17 months
- Product received FDA Class III approval
- Established processes and procedures for future regulated product development

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Radiation Therapy Control System

Delivery of real-time control system for radiation oncology

The Situation

Venture-funded medical device company focused on developing advanced radiation therapy technology struggling with development effort of a combined real-time imaging and radiation therapy system for cancer treatment.

Challenges

- Development effort late and over budget – threatening cancellation of entire program
- Needed assessment of current control system design effort to determine what, if anything, could be saved

Solution

- Designed and built new control system including software, programmable logic, printed circuit boards and mechanical enclosures
- Provided on-site integration and performance testing support
- Provided on-site verification

Proven Results

- New radiation therapy control system delivered in time for performance demonstration
- Additional Beta test sites arranged
- Enabled the start of 510(k) submission to FDA

Regulated Mobile Adherence

To support a disposable auto-injector syringe and smart label - Class III Medical Device

The Situation

An American multinational pharmaceutical company needed help creating a smart phone application to work in conjunction with its auto-injected medication. The company wanted the app to be able to assist patients by recording injections, maintaining injection history, delivering reminders for upcoming injections and securely transmitting and protecting injection data.

Challenges

- All development will be under Company's QMS.
- The application has ~300 software requirements.
- Application must be developed under Class III medical device specifications.
- Application to be created for use in iPhone and Android phones.
- Application must work when there is no server connection available.

Solution

- Initial test strategy and planning
- Review verification test case to identify opportunities for automation
- Create an automated system verification platform and tools
- Identify extensibility needs based on stakeholder input
- Define & document the automated verification strategy – including potential approach to additional test coverage

Proven Results

- New pumps allow connectivity through Bluetooth
- New pumps offer advanced therapies and provide potential advanced uses for extracted data
- Reduced system verification cycles
- New opportunities for regression testing to find quality issues earlier in the design/ revision cycles
- Increased automation capabilities for the future

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