



Case Study - Smartpill

Overview

Applied Sciences Group, Inc. has been under contract since 2005 to develop the software for an ingestible, wireless capsule that measures pressure, pH and temperature as it traverses the gastrointestinal tract. The information is used to provide gastric emptying time, combined small and large bowel transit time, total transit time, pressure contraction patterns from the antrum and duodenum, and motility indices. This capsule will aid in the diagnosis of Crone's Disease, gastroparesis and irritable bowel syndrome and other chronic gastrointestinal ailments.

The single-use wireless capsule is swallowed by the patient. The pill then periodically transmits data to a receiver worn by the patient while the pill is moving through the GI tract. After the capsule has passed, the data from the receiver is downloaded into a program at the clinicians' office, and the test results can be displayed and analyzed in both graphical and report formats at that time.

Software Development – Platforms and Languages

ASG has been involved in all development aspects of this project as well as product test development as it is manufactured. This project has been ongoing since 2005 and has utilized several ASG engineers at multiple levels:

- Risk Assessment
- Design
- Code
- Test
- Integration
- Quality Measures and Support for FDA Audits
- Analysis
- Report Generation
- Manufacturing Test Development

The capsule and receiver software was written in embedded C, based on the embedded nature of these two devices. The extensive analysis portion of this project, developed for use under the Windows operating system, was written entirely in the Microsoft Windows .net framework using Visual Basic.net and C#.net. Additional simulation and modeling was developed using Matlab and C#, utilizing the National Instruments signal processing library.

This project required that engineers learn and understand basic human anatomy and physiology, learn the appropriate terminology, and work with client staff to move this project through the FDA regulatory process for eventual approval. The first version of the capsule system was approved for clinical use in 2009.

This project continues to evolve as more versions of the capsule and additional analysis programs are being written and submitted to the FDA.

User graphics development and training documentation was critical in nature, as the clinicians utilizing the system had to be able to clearly monitor gastrointestinal data in order to provide accurate assessment of patients' conditions.

Project Management

Virtually all of the initial development work required that ASG employees be sited at the client's offices, in order to interact closely with the client's staff. For those ASG staff, client management provided direct oversight of ASG employees; with regular (weekly) status meetings attended by the ASG project manager. The design and implementation of much of the analysis software took place at ASG, with direct staff oversight by the ASG project manager and status reporting to the client. Generally, ASG and client project

managers met regularly during the entire product development phase regardless of where ASG staff actually performed the work.

FDA Guidance – Requirements, Design, Testing and Validation

For medical device development, ASG strictly follows FDA guidelines for software development. ASG staff helped develop the documents associated with the initial FDA submittal; staff met regularly with the client during requirements development and were intimately involved in risk assessment, design, verification testing (and reporting) and validation testing (and reporting). Software was documented and managed, with strict adherence to version controls.

Other ASG Resource Involvement

ASG was the go-to company that the client would approach when the client did not have the internal resources needed to address technical software and analysis issues. Supplemental ASG resources focused into several major areas:

- **Capsule Communications:** Capsule battery size, and therefore power, was a limiting factor into the rate at which data could be transmitted to the receiver. ASG developed the capsule data buffering logic, sleep algorithm and transmission protocols to conserve battery power while reliably moving the data from capsule to receiver.
- **Receiver Communications:** ASG utilized its USB driver development expertise to design, code and test the USB driver that the receiver used to deliver data to the PC.
- **Signal Analysis:** Post collection, the data is exceptionally noisy and – if simply displayed as raw data – any relevant patterns are hard to discern. ASG was asked to provide signal processing expertise to convolve, filter and integrate the data in order to improve signal to noise ratios.
- **Graphical User Interface:** ASG provide much of the design guidance for a clean graphical interface used by the various analysis programs.

Outcomes

Two versions of the capsule have been submitted and approved by the FDA. The manufacturing facility has also received FDA approval, and the capsule is now on the market.

Three ASG engineers have been included on several of the client's patent submissions.