KATHLEEN H. SELOVER

Kathy Selover's services are available through Clinical Device Group.

Professional Summary

A regulatory professional with extensive background and hands on experience in both quality and manufacturing environments within FDA regulated and ISO certified industries. Known for problem solving skills with the ability to comprehend and interpret the complex interrelationships between customers, quality, regulations, processes, operations and technologies. Experienced as a leader of cross-functional product development and problem solving teams. Combines excellent communication skills with strong organizational and analytic abilities.

Professional Abilities and Accomplishments

Regulatory:

- Managed various regulatory submissions for medical devices, biologic products and clinical studies and acted as primary liaison with Food and Drug Administration reviewers.
- Established quality systems, including the preparation of policies and procedures to meet US FDA regulatory and ISO 9000 and 13485 requirements.
- Planned and executed numerous quality system audits to assure continued compliance to FDA and ISO requirements.
- Developed training programs to support quality systems and various quality initiatives including quality system installation, change control, employee safety, new employee orientation, and document control.
- Interpreted, assessed, and communicated current and new FDA regulations to ensure client quality system compliance.
- Developed protocol models for process validation, design verification, design validation and software validation efforts.
- Managed and directed domestic and international product recall efforts.
- Coordinated clinical trial documentation for multi-site clinical studies in support of FDA marketing applications.

Manufacturing

- Managed various operational functions including Quality, Purchasing, Inventory Control, and Manufacturing.
- Led process improvement initiative that resulted in a 25% decrease in direct labor costs.
- Initiated statistical process control (SPC) in manufacturing and statistical sampling plans for raw material and finished product testing.
- Created and maintained a document tracking system for controlling manufacturing documents.
- Designed, implemented, and managed various OSHA mandated employee training and monitoring programs.
- Initiated an inventory control program that eliminated the stock out of essential supplies.

Product Development/Design Control

- FDA medical device Design Control expert
- Develop regulatory strategy for product development projects and regulatory submissions.
- Interpret and integrate FDA design control requirements into design development, change, and transfer activities.
- Regulatory core team member on product development teams.
- Able to coordinate and manage process validation and design transfer for medical devices.
- Develop design validation protocols and manage execution of validation activities.
- Perform data analysis for constructing strong and effective regulatory submissions and rationales.

Client Listing

Quality Regulatory Solutions, a Quality Systems and FDA-Regulatory Resource Provider, Principle/Owner

- *Bristol Myers-Squibb*, Buffalo, NY – Operational responsibility for the assembly, collation and submission of a European Marketing Approval Application (MAA) for a new drug; July-November 1999 (Consultant)
- *Cognigen Corporation*, Williamsville, NY – Installation and primary author of policies and procedures for a company wide quality system; led team responsible for developing IT disaster recovery plan July 2000 – October 2001; September 2003-June 2004. (Consultant)
- *Appro Healthcare*, Buffalo, NY – Solutions oriented, medical device FDA regulatory and quality systems resource provider for a start up medical device company. Hands on involvement facilitating the installation of team-based product development compliant with design controls as well as providing general regulatory services. December 2000 to 2003. (Consultant)
- *Innovative Biotechnology International*, Grand Island, NY – Led regulatory effort to assess and develop regulatory plan for FDA release of assay system for biological warfare agent detection. April –December 2002.
- *Curbell*, Orchard Park, NY – Provide FDA regulatory consultation for both manufactured and distributed products. June 2002 – December 2005.
- *InRange Systems* – Regulatory consultant to a start-up medical device company located in Pittsburgh, PA. Interface with design team on regulatory issues, provide consultation on quality system development, interfaced with FDA on regulatory submission strategy.
- *Rheonix* – Regulatory consultant to start up medical device company located in Ithaca, NY. Leading design control implementation for the development of new in-vitro diagnostic medical device with both integrated instrumentation and assay reagents. With company's vice president of scientific development, formulating regulatory and clinical study strategies. 2010
- *SmartPill Corporation, Inc.* – Vice-President, Regulatory Affairs and Quality in a start-up medical device company. Established regulatory policy, quality system, interfaced with contract manufacturers, and clinical trial sites. Prepared and submitted 510(k) for marketing approval in December of 2005 and received 510(k) release in July of 2006 for a complex active device incorporating an ingestible capsule, external data receiver, and analysis software. Led efforts to obtain ISO 13485 certification in 2007. Submitted and obtained clearance for second indication for use in 2009.

Education and Professional Development

AAS, Medical Technology — Alfred State College, Alfred, NY
BS, Management — Houghton College, W. Seneca, NY
MS, Creativity and Change Leadership — Buffalo State College, Buffalo, NY
Government (FDA and Health Canada), Industry and Professional Org. sponsored seminars and training.

Professional Affiliations

- Member – Regulatory Affairs Professional Society (RAPS)
- Member - American Society for Quality (ASQ),
- Member - Association for the Advancement of Medical Instrumentation (AAMI)
- Member - CLSI