Atlanta, Georgia USA
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# Joseph J. Schwoebel

## Summary

**Medical Device Clinical and Regulatory Expert**: Strategic planning and tactical execution of PMAs, 510(k)s and IDEs. Complete twelve (12) multi-site clinical studies and obtain PMA approval/510(k) clearance of 150+ products. Setup and monitor compliance programs: QSRs (ISO 13485), Post Market Surveillance, and Medical Device Reporting.

**Quality Systems Engineer** for medical device firms to assure compliance with 21 CFR 820 and ISO-13485. Coordinate registration and listing of products and quality surveillance programs, including Notified Body and FDA facility audits. Serve as company management representative.

## Employment

**2013 – Present** **Coweta Medtech Partners, LLC** **Newnan, GA**

Chief Executive Officer

- Provide Clinical and Regulatory consulting guidance during the early stage growth of innovative medical device firms. Establish and optimize the client's clinical and regulatory programs to meet commercialization objectives throughout the product development lifecycle. Setup and conduct clinical investigational studies that demonstrate safety, effectiveness and performance of new products.
- Develop comprehensive strategies to obtain clinical and regulatory goals; develop, launch and monitor clinical studies; prepare global submissions (PMAs, PMA Supplements, 510(k)s and CE Marks); and maintain relationships with investors, investigators, development partners, and regulatory agencies.
- Prepare design dossiers that facilitate release of European MDD Certificates. Manage relationships and interactions with Notified Bodies or Regulatory Authorities during the review process. Serve as "manufacturer representative" during Notified Body audits resulting in successful outcomes. Establish and maintain quality management systems to reduce the possibility of adverse findings during audit.
- Resolve medical device design control issues impacting FDA PMA approval of new products. Implement improvements to allow firms to successfully complete audits by the FDA and Notified Body with no serious deficiencies. Identify obstacles delaying the successful completion of design validation testing.
- Product experience includes implantable cardiac pacemakers, implantable neurostimulators, advanced ECGs, electrophysiology catheters, cochlear implants, implantable electrodes, disposable introducers, vessel dilators and accessories for interventional procedures.

**2012 – 2013** **Neuros Medical, Inc.** **Cleveland, OH**

Vice President, Clinical and Regulatory

- Neuros Medical is a Cleveland, Ohio neurostimulation company, which is developing a new treatment for patients afflicted with chronic, intractable pain.
- Obtain FDA approval of critical IDEs: (1) feasibility study to evaluate implantable Altius™ Generator electrical nerve block device, and (2) pivotal multisite study for commercial release of Altius™ Generator.
- Build and maintain an infrastructure to implement quality management systems and sustain regulatory compliance during early-stage operations.
- Establish procedures for the Quality Management System. Assure compliance with 21 CFR 820, ISO-13485:2011 and IS0-14155:2011. Review clinical study data and prepare clinical reports to present the results of clinical evaluations. Provide strategic leadership of the firm's quality management systems.

## Employment

**2011 - 2012** **PPD, Inc.** **Atlanta, GA**

Executive Consultant, Global Regulatory Affairs

- Develop Global Regulatory Affairs (GRA) strategies for large multi-national Clinical Research Organization (CRO). During my tenure, the GRA organization increased its billable revenues by 1215%, surpassing the goal of 200% growth.
- Manage PMA and 510(k) submissions of key clients, including *Merck, Medac, Novartis, Roche, Baxter, Shionogi, Delcath, and BiO2.* Focus on transitioning PPD's "pure CRO services" to comprehensive "product life-cycle services," per client expectations and the FDA's requirements. Expertise includes ISO-13485 and 21 CFR 820.
- During my tenure, client satisfaction rating of PPD's CRO services rose from industry position # 2 → # 1. The company transitioned from public to private ownership in 2011.

**2006 - 2010** **Celonova Biosciences** **Atlanta, GA**

Vice President, Regulatory Affairs

- Incubator company supported by a large wound-care company. Celonova Biosciences aimed to develop and release biomimetic surface coatings which reduce inflammation and improve wound healing.
- Develop a strategic plan for product line expansions into new therapeutic areas, such as drug delivery, coronary and peripheral stents. Identify opportunities for a new thromboresistant polymer coating. Leveraged existing regulatory assets into expansion plans to assure the effective use of resources.
- Prepare and submit PMAs, 510(k)s and IDEs for new implantable cardiovascular medical devices. Develop overall regulatory strategies for a global product launch, including the United States, Europe, and the Middle East. Establish a Quality System to comply with 21 CFR 820 and ISO-13485, including complaint management, supplier audits, post-market surveillance, and field performance reporting.
- Coordinate the ISO-13485 certification process, including the selection of Notified Body. Obtain ISO-13485 certification and guide surveillance audits conducted by Notified Bodies. Implement corrective actions recommended by the Notified Body and initiate preventative actions to prevent observations. Coordinate effective design control program with particular focus on design transfer to production.

**2006 - 2010** **Inset Technology** **Mt. Olive, NJ**

Vice President, Regulatory Affairs

- Secure CE Mark and ISO 13485 Certifications for new implantable medical devices through two (2) different Notified Bodies. Select notified bodies and developed relationships with product reviewers. Conducted validation studies under GLP and various international standards.
- Achieve successful FDA inspections of clinical study operations (BIMO) and quality system regulation (FDA Division of Compliance) with no significant inspectional observations. Implement an overall strategy to effectively manage the company's compliance requirements.
- Optimize the Quality Management System (QMS) for guiding research, development, manufacturing, and distribution of products. Prepare safety and effectiveness summaries and clinical evaluation reports under new European Medical Device Directives.
- Review the regulatory status of acquisition candidates to assist business development in an evaluation of new growth opportunities. Conduct due diligence of the submission portfolio and design dossier of target acquisition companies to minimize regulatory risks to investors

## Employment

**2001 – 2006** **Allegheny Intermediate Unit** **Pittsburgh, PA**

Chief Technology Officer

- This is the largest educational services organization in Pennsylvania. Responsible for technology services for 3,500 employees and instructional support for 41 school districts in Allegheny County.
- Obtain $10,000,000 of funding for regional gigabit Internet network. I have led a construction project to install 1800 miles of fiber optic cable and developed a program to sustain the operation of services.
- Organize clinical and regulatory support of Haan Foundation Power4Kids research, which used fMRI to show how reading remediation programs affect the functional performance of the brain.

**2000 – 2001** **CardiacAssist** **Pittsburgh, PA**

Vice President, Regulatory Affairs

- Obtain IDE approval and 510(k) clearance of FDA (CDRH) for novel percutaneous ventricular assist device (PVAD) to treat heart failure. Start-up company environment.
- Establish a complete QSR compliance program (including design control) to enable the start-up company to successfully complete its first FDA inspection with no observations
- Obtain CE Mark and ISO-13485 Certification to permit European sales launch of the medical device.

**1998 – 2000** **Health Hero Network** **Mountain View, CA**

Director, Regulatory and Clinical Affairs

- Obtain 510(k) clearance of Health Buddy device to connect diabetic patients to their disease management team to achieve better glycemic control. Start-up company environment.
- Establish a complete QSR compliance program (including design control) to enable the start-up company to successfully complete its first FDA inspection with no observations.

**1991 - 1998** **Biotronik, Inc.** **Portland, OR**

Director, Regulatory Affairs

- This is the largest cardiac defibrillator and pacing company outside the United States. It's based in Berlin, Germany. The company has 2,800 employees and conducts its research primarily in Europe.
- Obtain twenty-five (25) PMA, 510(k) and IDE approvals of Class III cardiovascular implants (pacers, electrodes, programmers) through new leadership and effective regulatory strategies.
- Improve complaint handling process and medical device reports (MDRs) to meet FDA's expanding expectations. I have resolved pre-existing issues with obtaining FDA release of a compliance hold placed on company's pre-market approvals. Repaired company's overall relationship with the FDA.

**1988 - 1991** **Cardiomedics, Inc.** **Irvine, CA**

President

- This was a subsidiary of Trimedyne, a medium-sized interventional cardiology company in Southern California. Launch Sequential External Counter-Pulsation (SECP) System for the treatment of chronic stable angina.
- Secure 510(k) clearance of the company's Sequential External Counter-Pulsation System. This required software validation, comprehensive pre-clinical testing, demonstration of IEC-60601 compliance and a formal clinical study to validate labeling claims. Setup the company's GMP compliance program and completed the initial FDA inspection of the facility with no inspectional observations.
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## Employment

**1984 – 1988** **Pacesetter Systems, Inc.** **Sylmar, CA**

Director, Regulatory Affairs

- Secure PMA approval of Genisis AFP (programmable, dual chamber, rate adaptive cardiac pacer). This included the implantable pulse generator, programmer and software, as well as family of endocardial electrodes with silicone insulation. Successfully completed multi-site clinical study of product.
- Obtain 510(k) clearance of Phoenix and Programmalith III single-chamber cardiac pacer families. Successfully completed three (3) GMP facility inspections of the company's manufacturing facilities.

## Education

**University of Miami** **Miami, FL**

Master of Business Administration

- Emphasis on health care operations and management. Executive MBA program.

**Penn State University** **University Park, PA**

Bachelor of Science in Electrical Engineering

- Biomedical engineering, *cum laude*, electrical engineering honors society.

## Professional

Regulatory Affairs Professional Society (*Regulatory Affairs Certified*)
Southeast Medical Device Association (SEMDA)
Georgia Bio (*regional trade organization*)
AdvaMed Committees

## References

Available on request.