

## **PERRY DE FAZIO**

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### **EDUCATION**

Rensselaer Polytechnic Institute, Troy, New York

B.S., Biomedical Engineering, Minor, Materials Engineering - May 1995

Clemson University, Clemson, South Carolina

August 1995-February 1998, Research: *Hydrophilic materials to prevent biofilm formation in biliary stents.*

### **PROFESSIONAL EXPERIENCE**

*Analyst, Medical Devices, Nerac, Inc. (04/07 – 11/10)*

- Industry analyst with a focus on technical assessments, market research, regulatory landscaping and intellectual property analysis for the purpose of indentifying and assessing emerging medical device technologies. My reports advised clients of a technology's market potential and provided strategies for next steps, e.g. organic growth, license or acquisition.
- Responsible for closing and managing \$1.5M in project revenue, including proposal generation, client management, budgeting, timelines, resource allocation and approval of final work product
- Primary client relationship stakeholder from initial sales presentation through completion, culminating with on-site presentation of final deliverables, often to executive-level groups
- Managed a team comprising a dozen engineering and scientific specialists within the medical device and life science industries
- Project lead and sole contributor for a technical and intellectual property research program pertaining to a novel orthopaedic biologic compound. The IP and market due diligence was the basis for a \$35M acquisition
- Project lead and sole contributor for a comprehensive strategic planning program that shaped the yearly R&D budget for a Fortune 500 medical device company. This included technology assessments, market landscapes, intellectual property analysis and clinical literature reviews for six technologies and disease states.
- Project leader for a reimbursement-driven meta-analysis for intra-aortic balloon pump therapy. This covered several hundred articles and 15 disease states
- Project leader and primary author on over 50 clinical literature reviews for regulatory compliance with MedDev 2.7.1
- Project leader and primary contributor for a program identifying companies and technologies for acquisition by a major orthopedic device manufacturer as well as providing patentability and clearance research for the company's internal prototype designs. In addition to identifying several targets, high-risk patents were uncovered that could have led the client into lost development dollars or costly litigation.
- Primary technical contributor for a project identifying technologies and manufacturing processes to be applied to diabetes care for a multi-billion dollar organization

*Senior Research Engineer, Covidien (12/03 – 03/07)*

- Leader of several multi-disciplinary product development teams in the design and development of new surgical products for areas including surgical fluid management, surgical site infection, correct site surgery, post-operative pain management and lost article detection. This included authoring detailed business plans for each program, overseeing design and testing of prototypes, presenting milestone updates at the executive level and coordinating activities of internal stakeholders and external vendors.
- Provided competitive intelligence and intellectual property analysis for innovation teams investigating emerging technologies for possible distribution, license, or acquisition. Additional responsibilities on these teams included *in vitro* and *ex vivo* technology evaluation, clinical literature reviews, and networking with clinical thought leaders.
- Utilized primary research and Design for Six Sigma methodologies such as Voice of the Customer (VOC) interviews, Kano Surveys, and Pugh Analysis in the evaluation of new product concepts
- Arranged and conducted customer interviews towards developing customer requirements for new product development endeavors
- Developed a base of key clinical contacts and relationships for the identification and evaluation of new product opportunities
- Team leader on a project coordinating the re-qualification of nearly 100 product codes representing nearly \$10M in sales at an off-site manufacturing facility
- Participated in value analyses for cost savings at off-site manufacturing facilities

#### *Senior Design Engineer, Ortheon Medical (4/02 – 09/03)*

- Project leader for the development of a knotless arthroscopic rotator cuff repair system utilizing a unique orthopaedic soft tissue anchoring technology. This included authoring and conducting tests protocols for the laboratory environment as well as cadaveric and *in vivo* animal models
- Authored and conducted an animal study protocol utilizing an ovine model to examine the efficacy and wound healing characteristics of a prototype system
- Authored the company's clinical risk assessment for the device which became the basis for a clinical trial protocol
- Conducted several failure analysis studies at in-house manufacturing sites as well as at off-site vendors
- Created and maintained a clinical and intellectual property database and provided detailed monthly reviews of the findings to the CEO and VP of R&D
- Established competitive benchmarks of an array of third-party products to be used in conjunction with the soft tissue repair system *via* laboratory tests
- Collaborated with clinical thought leaders during device development and evaluation, including off-site cadaver and animal labs as well as observation of a host of surgical procedures
- Created, implemented, and analyzed primary market research surveys used for strategic product positioning
- Trained distributors in the field and accompanied their initial sales calls. Also attended first-use cases to provide technical assistance to physicians
- Attended conferences for competitive technological assessments as well as to gather physician feedback on the current state and future of rotator cuff repair

#### *R&D Engineer, Salient Surgical Technologies (04/00 – 02/02)*

- Project leader for the development of a novel RF / energy-based thermal ablation and energy delivery system from concept phase to product launch. Responsibilities included authoring and conducting 510(k) and verification/validation protocols, leading activities with off-site manufacturing vendors and working with clinicians for device optimization.
- Developed proper device techniques through extensive laboratory and animal testing. I subsequently demonstrated these open and minimally invasive techniques for clinicians in product training sessions. I also created a program pertaining to technical fundamentals, device setup and proper use for company-wide sales training.
- Performed extensive *in vivo* animal research, including chronic wound healing studies that were presented at SAGES 2002. The focus of the work included the electrical, thermal, and hemostatic properties of hard and soft tissues.
- Conducted root cause and failure mode analysis for product complaints
- Worked with in-house legal counsel in conducting intellectual property research and assessing the freedom-to-operate and patentability of new product concepts
- Traveled to initial clinical use sites to provide technical assistance during procedures. This included pre-op briefing as well as O.R. setup and device monitoring throughout the procedure.
- Analyzed competitive intelligence through patent and journal reviews as well as industry trade shows for use in new product development strategies
- Through market research and engineering tests, constructed a recommended capital equipment list (e.g., RF generators, infusion pumps) to be used with the company's products. This research was implemented into the instructions for use as well as company-wide sales training material.
- Conducted product demonstrations and answered physician inquiries about the technology and its applications to prospective customers at conferences

#### *Project Engineer, Boston Scientific Corporation (02/98 – 04/00)*

- Project leader for the development and launch of a new biliary catheter product line and also for a line of polypectomy snares. This included authoring and conducting 510(k) and verification/validation protocols, providing regular updates to V-level management and extensive travel between the R&D and manufacturing facilities to work with team members at both sites.
- Researched new technologies for the next generation of flexible endoscopic devices. This involved extensive patent and clinical literature searches as well as gathering competitive intelligence through primary means. This information was analyzed and presented to the executive committee as a basis for go / no go decisions.
- Leader of a post-market troubleshooting team to address performance issues with a newly launched product. This included authoring and conducting test protocols and gathering physician feedback data to formulate recommendations for a corrective course of action.

### **PATENT APPLICATIONS AND OTHER PUBLICATIONS**

- US7611521 / US2010049320 – *APPARATUS AND METHODS FOR TENDON OR LIGAMENT REPAIR*
- US20080125696 / EP1894585 / JP200849162 – *ADJUSTABLE ASPIRATION DEVICE AND METHOD OF MAKING*
- *September '07* – Interviewed for and quoted within a *Cincinnati Business Courier* article on a novel aortic valve procedure
- *February '08* – Interviewed for and quoted within an *Investor's Business Daily* article on state of the medical device industry. This article was also picked up by *CNN Money* online.

- *March '08* – Interviewed for and quoted within an Investor's Business Daily post-mortem retrospective on medical pioneer James Sorenson. This article was also picked up by *CNN Money* online.
- *August '08* – Co-authored a *Medical Device and Diagnostic Industry (MD&DI)* article about reimbursement issues in Europe
- *October '08* – Authored and conducted an industry-wide webinar for Canon Communications on emerging technologies within the medical device arena, including wireless technologies, nanotechnology, and natural orifice surgery
- *October '08* – Interviewed for and quoted within an *FDANews* article on the next generation of medical device innovations
- *December '08* – Interviewed for and quoted within a *Genetic Engineering and Biotechnology News* article on the adoption rate of RFID technology within the pharmaceutical and biotech industries

#### **OTHER EXPERIENCE**

- Expert trial witness, *I-Flow v. Apex Medical Technologies*. This was an intellectual property dispute about items relating to the design, manufacture, sale and marketing of disposable infusion pumps

#### **REFERENCES**

Available upon request