

LYNN A. PAWELSKI

SUMMARY

Regulatory executive with over 30 years of experience across the life sciences industry: medical device, pharmaceuticals and consumer products. Demonstrated ability to lead in complex situations, to utilize creativity and flexibility in surmounting regulatory and product development obstacles and to maximize the potential of opportunities to drive growth. Energetic and pragmatic, creates an environment that facilitates open and honest dialogue and accelerates decision making.

BUSINESS EXPERIENCE

Vice President, Corporate Regulatory Affairs and Country Quality and Regulatory (4/23-present)
Vice President, Global Regulatory Affairs (3/18-4/23)
BAXTER HEALTHCARE Deerfield, IL

- Responsible for Global Regulatory Affairs function and associated resources including talent development and retention. Develops and executes regulatory strategies in alignment with business strategy across all Segments and Divisions; ensures successful product development, registration and maintenance of BAXTER's global pharmaceutical and medical device businesses
- Responsible for Country Quality and Regulatory teams supporting NPD, on market products, distribution and technical services

Worldwide Vice President, Regulatory Affairs (9/12-3/18)
Johnson & Johnson Medical Devices, ETHICON, INC. Somerville, NJ

- Responsible for regulatory innovation and lifecycle management for ETHICON device and biologic/combination products globally
- Connected with key internal and external customers to gather insights, anticipate emerging needs and business challenges and align with operational priorities, strategies and tactics
- As member of the sectorwide Regulatory Affairs Leadership team, led global internal and external outreach as well as shaping and management of Regulatory talent globally across medical devices businesses

Vice President, Global Regulatory Affairs – OTC (1/10-9/12)
Vice President, Regulatory Affairs US (3/07 – 1/10)
Johnson & Johnson Consumer, MCNEIL CONSUMER HEALTHCARE Ft. Washington, PA

- Leadership and support for OTC businesses globally, including strategy development, proactive management of policy and ingredient issues
- Developed, implemented and executed product development and launch strategies with cross-functional partners (including Rx-to-OTC switch)
- Led strategy and development of several successful US FDA Advisory Committee meetings related to ingredient issues (Pediatric Cough/Cold, Nasal Decongestants, Acetaminophen)

Senior Director, Regulatory Affairs (4/03- 3/07)
Director, Regulatory Development (11/00 – 4/03)

Johnson & Johnson,

MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS

Ft. Washington, PA

- Led regulatory affairs function for consumer and prescription pharmaceutical company: significant resource expansion requiring strategic and efficient organizational design and recruitment
- Areas of responsibility included OTC and Rx Development (including potential switches, new Rx indications and licensing and acquisition candidates); OTC and Rx Marketed Products Support
- Provided regulatory expertise evaluation and integration of potential new product and other acquisition/licensing opportunities
- Johnson & Johnson Regulatory Affairs team lead for Pfizer Consumer Healthcare acquisition/integration

Director, Regulatory Affairs (4/00 – 11/00)

Associate Director, Regulatory Affairs (10/99 – 4/00)

Manager, Regulatory Affairs (7/97 - 10/99)

Johnson & Johnson, PERSONAL PRODUCTS COMPANY

Skillman, NJ

- Provided strategy for new initiatives as well as extensions to existing business
- Coached and ensured the development of all Regulatory and Information Services Associates
- Product line responsibilities included prescription and over-the-counter drugs, dietary supplements and medical devices

Manager, Regulatory Affairs (8/95 - 6/97)

Regulatory Associate (11/92 – 8/95)

WHITEHALL-ROBINS HEALTHCARE

Madison, NJ

- Oversight for several major over-the-counter brands including topical, anti-inflammatory, gastrointestinal, cough/cold, oral care, and dietary supplement products
- Managed the strategy, development and launch of Rx-to-OTC switch candidates

Regulatory Affairs Assistant (9/91 - 11/92)

ANAQUEST, BOC Healthcare

Liberty Corner, NJ

- Responsible for non-clinical aspects of NDA submissions for anesthesia products. Compiled preclinical, clinical and chemistry related responses to FDA questions and requests for information
- Assisted in preparing and planning for one of the first "NDA Days" for new prescription product – Suprane; received formal FDA recognition

Regulatory Affairs Assistant (Part-time) (6/89-8/91)

CONVATEC, Bristol Myers-Squibb

Skillman, NJ

- Assisted in preparing FDA submissions for devices related to burn care/wound healing
- Compiled and developed databases for competitive information
- Supported clinical development function in establishing records-retention system and practices

EDUCATION

Masters of Business Administration: Pharmaceutical/Chemical Studies
Fairleigh Dickinson University, Graduate School of Management

Madison, NJ

Bachelor of Arts, Economics
Northwestern University

Evanston, IL

REFERENCES Available upon request

APPOINTMENTS

Industry Representative, General and Plastic Surgery Devices Panel, FDA Medical Devices Advisory Committee (*Current and 12/16-9/20*)

Board Member, Secretary – SHAMROCK REINS (Non-profit 501(c)(3) Organization), Pipersville, PA (*2/14-4/18*)