LYNN A. PAWELSKI

SUMMARY

Regulatory professional with over 25 years of experience in the consumer products, pharmaceutical and medical device industry. Extensive managerial and mentoring experience. Demonstrated ability to lead in complex situations; strengths include strategic thinking and execution; building consensus and influencing decisions; creating mutually beneficial outcomes with business partners; and utilizing creativity and flexibility in surmounting regulatory and product development obstacles.

BUSINESS EXPERIENCE

BAXTER HEALTHCARE, INC.
Deerfield, IL

Vice President, Global Regulatory Affairs (4/18-present)

- Responsible for Global Regulatory Affairs function and associated resources including talent development and retention. Accountable for the development of regulatory strategies closely aligned with business strategy and ensuring successful registration and maintenance of BAXTER pharmaceutical and medical device products globally.
- Member of R&D Senior Leadership Team; Americas Extended Leadership Team

JOHNSON & JOHNSON

ETHICON, INC.
Somerville, NJ

Worldwide Vice President, Regulatory Affairs (9/12-3/18)

- Responsible for regulatory innovation and lifecycle management for ETHICON medical device and biologic/combination products globally
  - Global leadership on innovation strategy – shortened time to market in key emerging markets
  - Focused on efficient and effective life cycle management efforts with focus on compliance
- Member of Global Management Board – contributing to global business strategy
- Member of Medical Device Sector Regulatory Affairs Leadership team - focused on global external Regulatory outreach/shaping and Regulatory talent management across sector

McNeil CONSUMER HEALTHCARE, DIVISION OF MCNEIL-PPC, INC.
Fort Washington, PA

Vice President, Global Regulatory Affairs – OTC (1/10-9/12)

- Leadership and support for OTC businesses globally including strategy development, proactive management of policy and ingredient issues
  - Multiple interactions with China and Canadian Health Authorities (SFDA and HPB)

- Lead strategy and development of several successful US FDA Advisory Committee meetings related to ingredient issues (Pediatric Cough/Cold, Nasal Decongestants, Acetaminophen)
- Sponsored the development and implementation of Acetaminophen Risk Management program – first of its kind for OTC ingredient; integrated program across Rx and OTC

- Member of Management Board and responsible for US Regulatory Affairs function
- Corporate regulatory lead for US Consumer Trade Association, Consumer Healthcare Products Association (CHPA)

Vice President, Regulatory Affairs US (3/07- 1/10)

- Responsible for leading entire US regulatory affairs function including:
  - Life cycle management of existing brands and pipeline – commercial, development, manufacturing/compliance support
  - Develop, implement and execute product development and launch strategies with cross-functional partners (including Rx-to-OTC switch)
  - Responsible for all FDA and other US government agency interactions; additional interactions with foreign health authorities as required

McNeil CONSUMER & SPECIALTY PHARMACEUTICALS, DIV. OF MCNEIL- PPC, INC.
Fort Washington, PA

Senior Director, Regulatory Affairs (4/03- 3/07)

- Responsible for the leadership of regulatory affairs function for consumer and prescription pharmaceutical company. Lead significant resource expansion including organizational design and recruitment. Areas of responsibility included:
  - OTC and Rx Development (including potential switches, new Rx indications and licensing and acquisition candidates – Zyrtec switch, Concerta adolescent, adult and generic strategies); OTC and Rx Marketed Products Support; CMC Regulatory
- Johnson & Johnson team lead for Regulatory function during Pfizer Consumer Healthcare acquisition/integration

Director, Regulatory Development (11/00 – 4/03)

- Responsible for regulatory aspects of development of new products and claims including Rx-to-OTC switches, prescription drugs and other projects requiring clinical development
- Support major prescription and over-the-counter brands in post-approval regulatory requirements including labeling and advertising review
- Provide regulatory expertise evaluation and integration of potential new product and other acquisition/licensing opportunities including Alza acquisition.

PERSONAL PRODUCTS COMPANY, DIVISION OF MCNEIL-PPC, INC.
Skillman, NJ

Director, Regulatory Affairs (4/00 – 11/00)
Associate Director, Regulatory Affairs (10/99 – 4/00)

- Provide strategy for new initiatives as well as extensions to existing business as a Member of Senior Management team within Women's Health franchise
- Interact with FDA and corporate management
- Coach and ensure the development of all Regulatory and Information Services Associates
- Product line responsibilities include prescription and over-the-counter drugs, dietary supplements, medical devices and cosmetics including new business evaluations

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

- Interact with government agencies for Rx and OTC drug products
- Provide strategic guidance and support all regulatory aspects of marketed and developmental dietary supplement products
- Coach Research and Development scientists in the development of all technical reports and documents, including Chemistry, Manufacturing and Controls information, and providing strategic guidance in these areas
- Participate in trade association task forces and strategic working groups

WHITEHALL-ROBINS HEALTHCARE
Madison, NJ

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

- Oversight for several major brands including topical, respiratory, gastrointestinal and dietary supplement products including the review and approval of advertising; Lederle Laboratories integration
- Managed the compilation of submissions and FDA meetings related to development of Rx-to-OTC switch candidates
- Provided regulatory strategy/guidance to various interdisciplinary project teams
- Interfaced with federal and state agencies as well as industry associations on key initiatives

Regulatory Associate (11/92 - 8/95)

- Coordinated and assisted in strategic preparation for NDAC meeting for Rx-to-OTC switch
- Assisted in potential new product research and business development opportunities as well as trademark renewal filings
- Provided regulatory support of anti-inflammatory, cough/cold, hemorrhoidal, oral care, topical, vitamin and mineral products as well as international affiliates; AH Robins integration

ANAQUEST, A BOC HEALTHCARE COMPANY
Liberty Corner, NJ

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

- Responsible for non-clinical aspects of NDA submissions. Compiled preclinical, clinical and chemistry related responses to FDA questions and requests for information
- Assisted in preparing and planning for "NDA Day" for new prescription product
- Other duties included generating IND and NDA annual report submissions, IND protocol and information amendments, and reviewing clinical study reports and protocols. Assisted in international regulatory filings

CONVATEC, A BRISTOL-MYERS SQUIBB COMPANY
Skillman, NJ
Regulatory Affairs Assistant (Part-time) (6/89-8/91)

- Assisted in preparation of FDA submissions for burn care/wound healing and ostomy products
- Complied and developed databases for competitive information
- Developed export documentation for device products
- Supported clinical development function in establishment of records retention system and practices

EDUCATION

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

Northwestern University, Evanston, IL
Bachelor of Arts