KIMBERLY ROHN

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Deerfield, IL

BIOPHARMACEUTICAL QUALITY ASSURANCE LEADER

Accomplished Quality Leader, embedding quality into products, and monitoring and responding to unexpected shifts in performance or market expectations to assure customer delight and business success. Quality team management within commercial and clinical biopharmaceutical companies. Development and enhancement of processes and systems to avoid and mitigate patient and business risk. Deep compliance knowledge of US-FDA and global pharmaceutical, biotechnology and sterile product requirements and approaches.

PROFESSIONAL EXPERIENCE

TAKEDA PHARMACEUTICALS, DEERFIELD, IL **2008 - 2017**

Director, Global Quality Compliance & Systems (2015-2017)

Established global harmonized processes for critical Quality System elements through collaboration and engagement of multiple functions. Formed and led global teams from over 70 countries to establish harmonized critical processes within the global quality network.

- Drove implementation of processes for Recalls, management notification of critical events, Quality Councils/Management Review and metric reporting for global Takeda
- Harmonized quality complaint processes, resulting in optimized procedures and the basis for design of a new global technology platform to drive efficiency and reduce operating costs
- Established a global surveillance program to identify new regulatory and industry initiatives and trends
- Developed and implemented programs for significant global compliance initiatives, leading to efficient and aligned approach to meet timelines, including Data Integrity and ICH Q3D Elemental Impurity Risk Management
- Designed and implemented a Quality Culture orientation for new leadership and global workforce, driving compliance by communicating commitment and meaning of Quality at Takeda

Director, US Quality Management Systems (2008-2015)

Key leader of Commercial Quality Management System integration between TAP and Takeda. Ongoing management and improvement of quality process and associated technology for the US business and global supply chain. Partnered to optimize technology platforms for operational excellence.

- Led global teams to establish optimized processes for deviations, CAPA and Change Control for global and single market products.
- Integration of key quality processes during multiple mergers, acquisitions and with key business partners
- Subject matter expert and strategic decision maker for significant compliance issues to protect patients and mitigate risk to the business
- Established an international, multi-lingual procedural infrastructure to support global products and their supply chain
- Designed and implemented world class product complaint management processes and technology system for the US business, ensuring timely identification of emerging trends
- Established and managed a multi-level Management Review program, assuring effective governance of the Quality Management System (QMS) and response to internal and industry trends

TAP PHARMACEUTICAL PRODUCTS, INC., LAKE FOREST, IL 2005 - 2008
Director, Quality Management Systems
Led and improved core GxP Quality Systems for the commercial and R&D areas of the US business to drive quality, efficiency and to manage risk.

- Managed Quality Systems for Complaints, CAPA, Change Control and Management Review programs for commercial and clinical products, assuring effective risk management and continuous improvement
- Drove investigations and Health Authority interactions on high risk issues related to patient safety, product quality and operational compliance for commercial and investigational products to mitigate risk
- Led the Product Quality Complaint function to improve processes and technology to efficiently capture, investigate, resolve and monitor customer issues with sterile injectable and oral dosage form products
- Managed Policy/Procedure and training systems for the commercial and R&D operations, embedding best practices into the organization

PARADIGM QUALITY CONSULTING, INC., DEERFIELD, IL 2000 - 2005
Owner, Independent Consultant
Established an independent consulting company serving pharmaceutical, biotech and complex medical device clients in proactive quality management and compliance/risk mitigation. Interacted with Health Authorities on behalf of clients, garnering confidence and approvals.

- Developed mitigation plans for pharmaceutical and complex medical device manufacturers in response to health authority inspections, leading to resolution of issues and successful outcomes
- Authored Master Compliance and Validation plans and key protocols for developmental pharmaceutical and biotechnology organizations for investigational and commercial products
- Facilitated interactions with FDA in meetings and inspections to achieve compliance, product approvals
- Performed audits of client operations, regulatory submissions and suppliers for compliance with GLP, GCP and GMP requirements to improve processes and avoid/mitigate risk for patients and business

BAXTER INTERNATIONAL, ILLINOIS
Quality Assurance Vice President, Hemoglobin Therapeutics (1997-1999)
Quality Director, Blood Substitutes (1990 – 1997)
Established and led international Quality organization to bring a novel biological product from preclinical evaluation to commercial manufacturing. Led Supplier Quality Management program for human red blood cell raw material. Key player in the design and approval of a commercial biotech manufacturing facility.

Manger, Corporate Regulatory Affairs (1989-1990)
Research key initiatives and develop compliance strategies for the business for biocompatibility testing and practical Developed compliance strategies for mail order pharmacy business

QA/RA Director, Alternate Site Therapies (1984-1989)
Develop and manage Quality Assurance and Regulatory Compliance for new alternate site businesses within Baxter for Homecare Pharmacy, Chemotherapy Services and Regional Pharmacy Compounding operations. Extensive interaction with FDA and State Boards of Pharmacy for inspections and development of requirements for operations with unclear compliance expectations.

Research Associate/Manager/Senior Manager, Microbiology R&D/Sterility Assurance (1977 – 1984)
Optimization of Biological Indicators used for sterilization monitoring. Team member during key sterilization validation studies that led to elimination of sterility testing for devices and parenteral products.

EDUCATION

Illinois Institute of Technology
Microbiology Master's Program Coursework

University of Illinois, Chicago, IL
Bachelor of Science (B.S.), Biology; Chemistry, Education minors

AFFILIATIONS AND ACCOMPLISHMENTS

PDA, Northwestern University Biotech Masters Instructor, Big Brothers Big Sisters, Lake County YWCA Woman of Achievement in Business