Miranda A. Deverall, Ph.D.

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Expertise and Strengths

Regulatory Affairs leader with 15+ years of experience in device submissions, clinical data review, Good Promotional Practices and validation of medical diagnostic devices. Develops regulatory strategies with cross functional teams, drives completion of complex and business critical projects, and provides innovative solutions to problems. Expertise in clinical chemistry and toxicology.

Education

Ph.D. Biophysical Chemistry December 2005, Purdue University, Indianapolis, IN
Dissertation Advisor: Dr. Christoph A. Naumann
Dissertation Title: Obstructed Lateral Diffusion of Lipids and Membrane Proteins in Polymer-Tethered Bilayers
B.A. Chemistry May 2000, Hanover College, Hanover, IN

Professional Experience

BD, Sparks, Maryland
Director, Regulatory Affairs, January 2022-Present

- Leads a global Regulatory Affairs team with responsibility for global regulatory strategies and regulatory submissions in the US and EU.
- Provides regulatory leadership to the Microbiology business area that markets thousands of IVDs globally including reagents, instruments, and software.
- Educates and communicates on regulatory requirements to the business.
- Develops and supports a team of 16 regulatory professionals.

BioPorto Diagnostics, Hellerup, Denmark
Vice President of Regulatory Affairs, November 2019-January 2022

- Head of US Regulatory Affairs in the US with responsibility for US regulatory strategy, regulatory submissions to the FDA, and all communications with regulators.
- Developed and aligned with the FDA on the regulatory strategy and clinical study design for a novel IVD with Break Through Device designation.

- Created regulatory compliance policies and procedures including establishing a program for investigator-initiated studies and Good Promotional Practices to ensure compliance to global laws and regulations.
- Educates and communicates regulatory requirements to the business.

Roche Diagnostics, Indianapolis, IN
Regulatory Affairs Manager, 2016-October 2019

- Led the team responsible for Clinical Chemistry and Toxicology reagents for US submissions and achieved clearance for numerous reagents and two new clinical chemistry platforms. Applied the Reagent Replacement and Instrument Family Policy to apply numerous previous cleared reagents onto the new clinical chemistry platform.
- Developed regulatory strategies with global project teams with the goal of partnering with the business to ensure successful submissions. Current projects include new clinical chemistry reagents and new instrument platforms.
- Educated and communicated on regulatory requirements to the business by authoring and reviewing regulatory opinions, pre-submissions, and regulatory clearance plans.
- Partnered with the global regulatory team to assess the regulatory impact of device modifications for a portfolio of products that included hundreds of IVDs. This included implementation of procedures to assess cumulative changes over the lifecycle of each product.
- Created a culture of engagement with a focus on professional development for a team of 5 regulatory professionals.
- Actively engaged in creating an agile environment that can adapt to the business needs. This regulatory department project created development opportunities for regulatory professionals outside of the US to submit to the FDA and regulatory professionals in the US to develop global dossiers for global registrations.

Roche Women's Leadership Initiative, 2011- 2017, Programming Lead

- Held positions of increasing responsibility culminating with leading all WLI programing (mentoring program as well as all virtual and in person events). Actively participated in the program since its inception to prepare individuals to meet their definition of success. Since the program initiation, the number of women in key leadership roles increased significantly (~11%).

Roche Diagnostics, Indianapolis, IN
Regulatory Affairs Principal, 2014-2016

- Regulatory lead for the US 510(k) submissions for reagents which include developing the regulatory strategy, providing guidance to the regulatory team, reviewing the analytical and clinical data, and working with the FDA.

- Supported the US 510(k) submission for the cobas c 513 instrument submission with a new generation of the HbA1c assay.
- Authored regulatory opinions, pre-submissions, and regulatory clearance plans.
- Reviewed labeling changes for Therapeutic Drug Monitoring (TDM) products and other Clinical Chemistry and Toxicology products as necessary.

Roche Diagnostics, Indianapolis, IN
Quality Systems Lead, Commercial Compliance, Medical and Scientific Affairs, 2012-2014

- Served as the primary liaison for MSA, including Diabetes Care, to ensure compliance to quality and regulatory related processes and procedures. No escalated regulatory actions were deemed necessary during my tenure.
- Reviewed Investigator Initiated Studies, Roche Sponsored Studies, and customer facing educational materials. Reviewed promotional content as needed to support the Commercial Compliance team.

Roche Diagnostics Operations, Inc., Indianapolis, IN
Validation Consultant, Supply Chain Quality, 2011 – 2012

- Served as the Quality representative for Supply Chain and Site Services which included leading the Validation Review Board, advising on validation activities and process improvement opportunities, and partnering with engineers to manage deviations and ensure consistency and compliance with validation strategies.

Roche Women's Leadership Initiative, 2011- 2017, Programming Lead

- Held positions of increasing responsibility culminating with leading all WLI programing (mentoring program as well as all virtual and in person events). Actively participated in the program since its inception to prepare individuals to meet their definition of success. Since the program initiation, the number of women in key leadership roles increased significantly (~11%).

Roche Diagnostics Operations, Inc., Indianapolis, IN
Product Support Scientist, 2007 – 2010

- Main responsibilities included product transfer from R&D to manufacturing, product transfer between sites, process validation activities, and product support for TDM (therapeutic drug monitoring) and DATs (drugs of abuse testing) products.
- Participated in validation activities in response to deficiencies cited in a Warning Letter. The corrections were found to be adequate and ensured the right to operate.

Postdoctoral Research Associate, Purdue University, West Lafayette, IN
Research Advisor: Dr. Christine A. Hrycyna, 2006 – 2007

- Managed a collaborative project between a synthetic chemistry and a biochemistry laboratory to develop a supported membrane model for characterization of integral membrane protein function in planar sensor architectures.