ANN M. QUINN BSMT (ASCP), RAC
Rochester, NY 14612
585-764-6188

SUMMARY OF QUALIFICATIONS

World Wide Director of Regulatory Affairs with **20+ years** of proven experience **directing and coordinating regulatory affairs** and development of Regulatory strategies in support of successfully obtaining timely regulatory license approvals. . Oversee worldwide submissions of Clinical Chemistry and Immunodiagnostic product lines for an in vitro diagnostics company **generating $1.7B annually**. Adaptable and decisive **leader** with proven success directing up to 14 Regulatory and Quality Associates. Responsible for leading a team of Regulatory professionals in developing and executing a Worldwide Regulatory Strategy for licensing of 2 Ortho Clinical laboratory automated platforms, the largest developed program in the history of the company up to that time.

EDUCATION

Bachelor of Science
Medical Technology
State University College of Arts and Sciences
Geneseo, NY

Medical Technology Internship
The Memorial Hospital
Danville, VA

PROFESSIONAL CERTIFICATIONS

Regulatory Affairs Certified (RAC)

American Society of Clinical Pathologists (ASCP) Registered

MEMBERSHIPS

Regulatory Affairs Professional Society (RAPS)

American Association of Clinical Chemistry (AACC)

EXPERIENCE

ORTHO-CLINICAL DIAGNOSTICS, INC.
Worldwide Director of Regulatory Affairs
Rochester, NY 14612
2014-Present

ORTHO-CLINICAL DIAGNOSTICS, INC. (A JOHNSON & JOHNSON CO.)
Worldwide Director of Regulatory Affairs
Rochester, NY 14612
2007-2014

ORTHO-CLINICAL DIAGNOSTICS, INC. (A JOHNSON & JOHNSON CO.)

Manager Regulatory Affairs
Rochester, NY
1996 -2007

ORGANON TEKNIKA CORP.
Regulatory Affairs Administrator
Durham, NC
1989-1996

ORGANON TEKNIKA CORP
Quality Control Analyst
Durham, NC
1987-1989

BURROUGHS WELLCOME, CO
Research Assistant
Research Triangle Park, NC
1986-1987

University of N.C. Hospitals
Medical Technologist
Chapel Hill, NC
1984-1986

Accomplishments:

- Streamlined Product Delivery System (PDS) and represented QRC on a Management team responsible for oversight of the revision of the Product Develop Process Document to bring clearer focus to deliverables and better linkage to governing regulations and Design History File (DHF) document linkage to regulatory submissions.
- Secured a major customer contract for Immunodiagnostic infectious disease assays by establishing a strong working relationship with FDA reviewers and obtaining FDA correspondence used to demonstrate pending PMA approvals.
- Obtained PMA approval for the first HIV assay on a random-access analyzer in the US.
- Supported successful HIV PMA FDA pre-approval inspection of UK manufacturing facility (the first CBER inspection of this factory) resulting in no 483 observations, a first for these inspectors.
- Provided development opportunities for 5 direct reports and 3 indirect reports to ensure the ability to increase the breadth of experience and support the group motto of "one voice, one signature".
- Saved significant revenue by creating a strategy supporting the launch of Hepatitis B assay in Japan for use on two new instrument platforms without impacting current product requirements for existing instrument and developed a unique product configuration for Japan
- Developed and implemented a successful Modular PMA Process by which 5 Infectious Disease Products were PMA approved including the first hepatitis marker to be approved in the US for use on a random-access analyzer.
- Participated in development of a process for managing submission decisions for product modifications, including development of an in-house training program for more than 30 personnel.

Presentations:

- Delivered a presentation at China's first International Medical Device Regulatory Forum (CIMDR) on FDA guidance for Replacement Reagent and Instrument Family Policy and Guidance on Migration of Class III assays to new Model Analyzers. The information was regarded as the most

valuable and informative presentation of all those given during the 2.5 day IVD track of the meeting by China FDA representatives.

- Co-developed a "Road Show" presenting the new Product Innovations and Design Quality function along with roles and responsibilities, each tailored to the internal partner audience.
- Planned IVD Track at 2003 Annual Regulatory Affairs Professional Society meeting
- Prepared and delivered a presentation at QRC Site Quarterly review on the Journey to FDA approval of VITROS anti HIV 1+2 and its impact on OCD business in the U.S.
- Developed and delivered a presentation on FDA PMA requirements for medical devices to representatives of Chinese SFDA and J&J Medical China.
- Presented at 2004 Annual AMDM meeting on Tips for Successful Modular PMA submissions in conjunction with an FDA presenter
- Presented at April 2001 Association of Medical Diagnostic Manufacturers (AMDM) meeting on the topic of "Special 510(k)s"
- Presented at the first Annual OCD Process Excellence Conference on "Value Stream Mapping Regulatory Affairs."
- Co-chair of 2017 AMDM Annual meeting
- Co-chair of 2018 AMDM Annual meeting

Committees:

- Elected to Board of Directors for Association of Diagnostic Manufacturers (AMDM) for a 3-year term, and have been re-elected to two additional terms.
- Active Participant representing Ortho on AdvaMed IVD Task force and PMA Working Group.
- Represented QRC on the Clinical Laboratories Line-Of-Business (LOB) team responsible for making decisions on business priorities.
- Member of a 10-person multi-disciplinary due diligence team constructed to present the business to potential buyers; personally depicted the regulatory landscape including the number products and licensing status in key markets around the world.
- Supervised and managed regulatory activities associated with the Immunodiagnostic Products Franchise.
- Led a team of 7 Regulatory professionals and 7 design quality associates in developing and executing a Worldwide Regulatory Strategy for licensing of 2 Ortho Clinical laboratory automated platforms, the largest developed program in the history of the company up to that time.
- Developed a policy outlining requirements for running studies on unlicensed product in the US and EU (Performance evaluations, Market trials etc.) in partnership with External Evaluation Group Manager.
- Conceptualized acceleration plans for HIV combo project as a regulatory affairs core team member.