CAPABILITIES AND EXPERIENCE
DAVID PETRICH

WORK EXPERIENCE

Vice President of Quality and Regulatory: Landrich Group (2023 to Present)

- Provide Quality Management System (QMS) and Regulatory Affairs guidance for clients to achieve market authorization for Medical Device, In Vitro Diagnostics (IVD) and Biopharmaceutical products
- Perform QMS assessment and audits for clients to ensure readiness for design and development, performance evaluations/clinical studies, manufacturing and post-market activities in the U.S., EU and ROW

Quality Site Head and Senior Director of Design Quality Assurance: Roche Molecular Systems (2014 to 2022)

- Lead design and develop, manufacture, production and post-market support of Roche's molecular IVD systems
- Developed and implemented IVDR-compliant QMS processes and technical documentation for IVD products
- Ensured right to operate by managing FDA, BIMO, Competent Authority, and Notified Body audits and inspections
- Lead due diligence and QMS integration for Liat and GenMark Point of Care (POC) product lines

Director, Regulatory Affairs: Roche Molecular Systems, Inc. (2012 to 2014)

- Interacted with CBER and collaborated with other stakeholders obtain Biological License Applications (BLA) approvals for blood screening products and systems
- Effectively managed CBER, BIMO and other regulatory authority inspections and audits to ensure right to operate
- Received Recognition Award for role in obtaining approval from the Brazilian Ministry of Health after unsuccessful performance evaluations

Vice-President of Quality and Regulatory: AcroMetrix Corporation/ Life Technologies (2007 to 2012)

- Led Quality Control, Quality Assurance, and Regulatory Affairs functions at US and EU sites to develop metrologically traceable quality control materials, calibration standards and external quality assurance panels.
- Successfully managed FDA inspections, ISO 13485:2016, IVDR, and CE certificate audits.
- Submitted traditional/*de novo* 510(k)s, Design Dossiers for IVD/CE approvals in the U.S., E.U., and other countries.

Process Development and Pilot Plant Manager: Siemens Medical Diagnostic Solutions formerly (Bayer Diagnostics and Chiron Diagnostics) (1996 – 2007)

- Developed quantitative molecular HIV-1 viral load assay to obtain first PMA approval from FDA
- Lead team that developed and validated manufacturing processes and analytical methods for HIV-1, and HCV PMA submissions

EXPERIENCE HIGHLIGHTS

Quality and Regulatory executive with 20+ years of success in leading cross-functional teams to develop, manufacture, and commercialize In Vitro Diagnostics (IVD) and medical device products. Expert knowledge of Quality Management System (QMS) processes, specializing in Design & Development, Clinical Trials/Performance Evaluations, Manufacturing, and Post-Market support. Led several high-impact quality integration projects to ensure compliance and bring new high value products to create additional revenues. Executive MBA, Regulatory Affairs Certification (RAC), and Certified Lead Auditor for ISO Standard 13485 with highly effective leadership and interpersonal skills.

EDUCATION & ACCREDIATION

- Executive Master of Business Administration (MBA) - Saint Mary's College
- Bachelor of Science in Nutrition Science - University of California Davis
- Regulatory Affairs Certification (RAC)
- ISO 13485 Certified Lead Auditor
- Clinical Laboratory Standards Institute (CLSI) Subcommittee Member for Quantitative Molecular Methods and Laboratory Quality Management Systems
- Good Clinical Practice and ICH(GCP) Certification