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 access for Medical Device, In Vitro Diagnostics (IVD) and Biopharmaceutical products
- Perform clinical program and QMS assessment and audits for clients to ensure GxP readiness for design and development, performance evaluations/clinical studies, manufacturing and post-market activities in the US and ROW

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

- Provided strategic and tactical leadership to design and develop, manufacture and support novel medical device/IVD products
- Ensured right to operate by managing numerous FDA, BIMO, Competent Authority, and Notified Body audits and inspections
- Developed and implemented IVDR-compliant QMS processes and technical documentation for IVD products

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

- Collaborated with key stakeholders to design, develop and secure regulatory approvals to market novel blood screening products
- Effectively managed CBER, BIMO and other regulatory authority inspections and audits to ensure right to operate

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 & ACCREDITATIONS

- 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