Meet the Expert

Mark is an industry subject matter expert in FDA, EMA and global regulations governing design, construction, commissioning and qualification of cGMP facilities and equipment.

Mark has more than thirty years of experience in assuring Current Good Manufacturing (cGMP) compliance, commissioning and qualification of state-of-the-art global biopharmaceutical facilities. Mark has the unique experience of leading and implementing the latest Commissioning and Qualification (C&Q) methodologies in a large pharma company, as well as successfully completing complex capital projects in countries around the world. Mark is a registered professional engineer and has managed design, construction and qualification of projects covering vaccine and biotechnology manufacturing, oral solid dosage production and pharmaceutical research and development facilities. He has held various positions in project engineering, process engineering, and regulatory compliance. Mark's experience covers sterile products and aseptic processing, oral solid dosage facilities, critical utilities, HVAC, pharmaceutical and R&D facility design, commissioning, qualification and regulatory compliance. Mark is currently a Director of Compliance Consulting at IPS, where he is applying his broad experience to assist multiple clients in meeting their cGMP challenges through practical, compliant engineering solutions.

Throughout his career Mark has provided technical support for ongoing operations, including lean six sigma process improvements and responsibility for global quality management system and engineering compliance guidance. Some examples of Mark's accumulated expertise include:

- Led the harmonization of Merck and Schering Plough Quality Management System guidance on facilities, equipment and utilities post-merger.
- Performed numerous GMP design reviews, risk assessments and C&Q reviews on projects worldwide.
- Managed the successful fast track installation and start-up of a sterile syringe filling line in the Netherlands as Project Manager and Team Leader.

Mark contributes to the industry body of knowledge as the co-leader of ISPE's C&Q Community of Practice Steering Team. He has been a frequent presenter at association meetings, conferences and industry events on such topics as "Building Compliance into Facility Design and Construction" (PDA) and "Pharma Manufacturer's C&Q Risk Approach Task Team Forum" (ISPE). Mark has achieved Black Belt certification in Lean Six Sigma. Mark holds a Bachelor of Science degree in Civil Engineering and a Master of Business Administration from the University of Pittsburgh.

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Areas of Expertise

- FDA / EMA and Global Regulatory Compliance
- Lean Six Sigma, Black Belt
- Engineering Quality Management Systems
- cGMP Facility Design and Design Review
- Manufacturing Facility cGMP Assessments
- Product Quality Risk Assessments
- Commissioning, Qualification and Validation (CQV)
- Application of Quality by Design (QbD) to streamline CQV
- ASTM E2500 Execution
- Technical Consultancy
- Validation Master Planning