Meet the Expert

Michael is an experienced subject matter expert in CQV risk assessment and planning, project management and project team alignment.

Michael has over 15 years of experience providing project management, equipment, software, process validation, and quality/operational management in regulated industries. His industry experience, backed up with a strong educational background in biology, technical quality engineering and business, uniquely positions him to be successful in a wide variety of leadership roles in the biotech and pharma industry.

His primary responsibilities at IPS are to provide senior level management and direction to the IPS CQV group, leadership for large and technically complex projects, and facilitate successful relationships with clients based on service, trust and performance.

Michael's experience in the area of CQV project delivery includes: project management, master planning, and project cost/schedule development/tracking, risk assessment, FAT/SAT assistance, commissioning, qualification, validation, training, system turnover/documentation and interfacing with project team members. He has a passion for working with the IPS team to deliver the best possible solutions for clients while providing meaningful career opportunities and challenges for our most important resource – our talented team of compliance professionals.

Michael volunteers his time to various industry and non-industry organizations. He has a strong belief that giving back not only enhances others, it enhances yourself as well. Recently, Michael has been working with the ISPE PV Committee to draft guidance for PV Lifecycle Implementation at Contract Manufacturer's and PV Guidance for OSD Packaging.

Michael holds a Bachelor of Science in Biology from Pennsylvania State University and an MBA in Pharmaceutical Management from Drexel University.

Michael Westerman
Compliance Expert

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Areas of Expertise

- CQV Project Management
- Strategic CQV Program Development (ASTM, EU, FDA)
- Packaging Process Validation / Equipment CQV
- New Technology CQV Planning (Serialization / Single Use Systems)
- Compliant Facility Design (Global Requirements)
- Maintenance and Calibration Program Development
- CQV Risk Assessment and Mitigation from the "Factory to the Floor"