

# THE LEADER IN GLOBAL ENGINEERING AND CONSULTING SERVICES FOR THE LIFE SCIENCES INDUSTRIES

## CONTACT US



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## QUALIFICATIONS

- CQA • RAC
- CQE • Six Sigma
- ISO Certifications

## QUALITY ASSURANCE

PharmEng consultants will work alongside you to evaluate cGxP quality management systems, documentation, training programs, deviation & CAPA Investigations, risk management plans, protocol development, system implementations, validation as well as provide continuous support to your facility.

Our team includes staff at all levels with senior team members with 25 years of Quality & Compliance experience.

## SERVICES WE OFFER

- Quality System Audits
- Inspection Readiness/Mock Audit
- Remediation & Warning Letters
- Medical Device Audits
- Quality Oversight/Backfill
- Quality Agreements
- QMS Generation & Implementation
- Quality Control Laboratory
- SOP Development
- Project Management
- Tech Transfer Support
- Supplier Audits/Vendor Qualifications
- DQ/IQ/OQ/PQ Authoring/Execution
- Risk Management
- Training (e.g., GMP overview, Deviations and CAPAs)
- Gap Analysis
- Deviation/OOS/Nonconformance/CAPA Investigations
- Investigation Backlog Evaluation/Remediation
- Data Integrity (DI) Evaluation
- Complaints and Adverse Events
- Annual Product Quality Reviews
- Change Controls
- Batch Record Reviews
- Product Release
- Stability
- Environmental Monitoring

PharmEng Technology has been providing quality services to leading manufacturers of healthcare and pharmaceutical products since 1997. We have extensive experience in establishing and managing quality systems tailored to our client's operations.

PharmEng Technology's Quality Assurance Division offers comprehensive quality and regulatory solutions. Our Quality Assurance services include desktop evaluations and on-site gap assessments to extensive inspections and mock agency audits. Our team has extensive experience in US, Canadian and international quality and regulatory affairs and understands the impact continuous compliance oversight has on maintaining a quality management system.