BioPharma Quality Control and Compliance Consulting

QC and regulatory compliance for the development and production of drugs, biologics, and vaccine products.

Providing consulting services to the pharmaceutical, biologics, and diagnostics industry for Quality Control management and US and EU regulatory compliance of biologics, drugs, vaccines, and diagnostics through the development and commercial product life cycle.

Contact Info

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Services:

Quality Control:

- Laboratory operations management for efficiency, effectiveness, and regulatory (cGMP) compliance and regulatory inspection preparedness, for lot release, product stability program, and in process control.
- Qualification / verification / validation of analytical methods (biochemical, physical, microbiological, in vivo, in vitro) for product release and stability of drugs, biologics, and vaccine products.
- Environmental and utilities monitoring, qualification, and investigation of manufacture of biologics, drugs, and vaccine products

Regulatory and Quality

- Compliance to cGMP, 21CFR, USP/EP, and ICH regulations
- Preparation for CDER, CBER, EMEA inspection.
- Preparation and review of CMC sections of NDA, PLA, MAA filings

Technical Expertise

Extensive experience managing all aspects of analysis of product quality covering in process monitoring and bulk and finished product lot release and stability, environmental monitoring of aseptic processes and pharmaceutical utilities, applying a range of analytical methodologies; *in vivo* and *in vitro* biosafety, cell culture bioassays, immunochemistry, microbiological, chromatography, electrophoresis, and chemical/biochemical methods.

Representative Consulting Projects:

- Conduct cGMP and ICH compliance assessment of global pharmaceutical company commercial product drug product stability program and analytical procedure validation for global generic drug products, and then develop and execute remediation plan.
- Develop raw materials qualification program for combination device/biologic product
- Conduct cGMP and ICH compliance assessment of QC analytical method validation program for release and stability of biological diagnostics products.
- Conduct mock FDA PLI/PAI audit and inspection readiness assessments for drug substance and drug product biologic manufacturers.
- Develop a Dept. of Defense (DoD) RFP proposal for Quality Control operation and product release for recombinant vaccine and small molecule drug products for a vaccine and small molecule drug supplier.
- Interim QC Director for biotechnology company developing therapeutic live-virus vaccines.
- Create QC operations procedures such as conducting laboratory investigations (OOS), managing reference materials/standards, and reserve samples.
- Conduct supplier audits of contract testing laboratories.
- Oversight of clinical and commercial drug product and bulk drug substance (API) lot release and stability studies conducted at contract laboratory for client, including review for technical and GMP compliance and investigation of non-conformance and OOS events.
- Draft BLA Module 3 sections for biologic drug product and drug substance

Industry Experience Overview

Over 25 years Quality Control management experience in biopharmaceutical and diagnostic industries producing vaccines, recombinant monoclonal antibodies and proteins, and oligonucleotide biopharmaceutical drug substance, API, and drug products, and drug/device combination products, from the laboratory bench to department management.