William G. White

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Consultant

Quality Control and Regulatory compliance for the development and production of drugs, biologics, and vaccine products.

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.

Proprietor, BioPharma Quality Control & Compliance Consulting **2010 to Present**

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.

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 focused on development and commercialization of therapeutic live-virus vaccines.
- Create QC operations procedures such as conduct laboratory investigations, 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 biotech industry producing vaccines, recombinant monoclonal antibodies and proteins, and oligonucleotide biopharmaceuticals, and drug/device combination products, from the laboratory bench to department management.

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Overview

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MedImmune, LLC, Santa Clara, CA **2005-2010**

Director, Quality Control

- Managed QC laboratory operations performing cell culture-based bioassays, *in vivo* biosafety tests, microbiological, and biochemical tests for commercial and clinical live virus vaccine lot release and stability and raw materials.
- Supervised managers responsible for QC staff conducting testing and laboratory operations to meet lot release and project timelines, while maintaining laboratories and operations in compliance with cGMP, EMEA, ICH, and CFR requirements.
- Managed non-conformance and OOS investigations, change control for test methods and procedures, and implementation of corrective and preventative actions.
- Represented QC for CBER and EMEA/MHRA inspections, developed responses to 483 observations, CBE-30 and PAS supplements to BLA license for modification to approved QC methods
- Established and qualified cGMP *in vivo* testing laboratory for embryonated egg and animal based biosafety testing for live virus vaccines lot release testing and rapidly scaled up testing capacity meeting seasonal live influenza virus vaccine and novel H1N1 influenza virus vaccine production.
- Established environmental monitoring program utilizing a risk-based analysis approach which assured efficient and effective control of environment of clinical and commercial live virus vaccine seed, bulk, and filling production facilities.

Corgentech Inc., South San Francisco, CA **2003-2005**

Associate Director, Quality Control

- Managed QC laboratory and contract laboratories performing testing for release, in-process, and stability studies of oligonucleotide drug product and bulk drug substance.
- Authored QC-related CMC sections of oligonucleotide drug product NDA.
- Coordinated with Analytical Development group and contract laboratories to create method validation protocols, managed/coordinated execution of validation studies, wrote, and reviewed/approved reports for chromatographic, mass spectrometry, biochemical, and physical analytical methods.
- Supervised QC laboratory staff performing method validation studies, drug/device compatibility studies (510K filing), and development of QC laboratory operations systems (sample management, instrument use and maintenance procedures, etc.)

MedImmune Vaccines, Inc. (Aviron, Inc.), Mountain View, CA **1999-2003**

Manager/ Associate Director, Quality Control Operations

- Managed QC analytical laboratories and operations support groups of over 30 technical and managerial/supervisory staff performing cell culture bioassays and other biological, chemical, and physical tests for release of live virus vaccine process intermediates, bulk drug substance, and sterile drug product; LIMS Operations group supporting multiple QC sites; and data and sample management group.
- Managed non-conformance investigations including OOS results, including root cause analysis and CAPA development and implementation.
- Expanded capacity of QC laboratories (from single laboratory to multiple laboratories operating 7 days/week on multiple shifts) to meet testing needs of scaled up bulk and final product production to multi-million dose commercial scale by efficient utilization of existing laboratory space, increased staff, streamlining QC procedures, and enhanced technical training program to maintain compliance standards and high quality of work.
- Prepare QC Operations for CBER pre-licensure inspection by resolution and closure of backlog of non-conformance event investigations, training QC staff for interactions with auditors, develop and implement CAPAs that improved QC Operations preparedness. Developed responses to 483 observations and BLA Complete Review Letter, resulting in approval of the first live virus influenza vaccine.

MedImmune Vaccines, Inc. (Aviron, Inc.), Mountain View, CA

- Continuous improvement of QC procedures and systems for robustness (e.g. implemented reagent/control qualification procedures) and lot release cycle time reduction
- Improved management of contract testing laboratories by enhancing communication between MedImmune and contract laboratory, by creating tools and established procedures to track samples submission, invoices, and budget forecasts.
- QC leader in joint QC/Analytical Development team to validate and implement automated cell culture bioassay for product release, including creating instrument FRS/URS, pre-validation and validation protocols, training, and technical transfer.
- Member LIMS team setting user/functional requirements, selection, prototype development and validation.

Genentech, Inc., South San Francisco, CA **1985- 1999**

Technical Manager, QC Microbiology

- Provide range of operational support to the QC Microbiology laboratory group including development, enhancement, and maintenance of internal databases, supervised Microbiologist and computer/systems support analyst, performed technical and compliance review of test records and led investigations of laboratory non-conformance events and anomalous test results.
- Represented QC Microbiology and other QC groups for major upgrade to CALS/Beckman LIMS and implementation of new electronic document system: establishing user/functional requirements, prototype testing, validation, user training and implementation.
- Led team validating in-process bioburden test method; protocol design, executing of validation studies, and writing report.

Supervisor / Senior Supervisor, QC Commercial and Clinical Product In-Process and Lot Release Laboratory

- Created and managed QC group responsible for in-process testing of commercial and clinical manufacturing processes, 7 day/24 hour support.
- Coordinated in-process testing across multiple shifts ensuring seamless transition between shifts and providing timely results to multiple manufacturing operations.
- Managed QC technical and supervisory staff including hiring, training, and annual performance evaluations.
- Managed laboratory operations and staff performing chromatographic, chemical/biochemical test methods for lot release, in-process, and cleaning/changeover testing for commercial product production
- Coordinated bulk and final product release testing to meet product release timelines
- Validated lot release test methods, including protocol development, coordination of testing, and writing report for BLA submission

Education

B.A. Biological Sciences, University of California, Santa Barbara,