

Compliance Consulting Activities

SUMMARY:

Joe Busfield has over 30 years experience in the food, pharmaceutical, and biopharmaceutical industries, the last ten years as an independent consultant. Prior to consulting he worked directly for manufacturing companies.

Consulting assignments have included equipment qualifications and utilities' validation and compliance programs, specializing in the areas of calibration, maintenance, and engineering programs in the regulated industry and operations programming, including document control and change control systems.

His responsibilities in owner's facilities have included project engineering, validation, instrumentation, calibration, maintenance, and utilities for oral dose, parenteral, and food manufacturing facilities. His experience includes operation, design, start up, and validation.

COMPLIANCE PROJECTS:

Serve as part of several teams providing auditing and remediation services in response to Consent Decrees, AIP's, VAI's, Warning Letters or "near-consent decree" situations for various locations of several clients. Areas of responsibility included: Maintenance Programs, Calibration Programs, Engineering Operations, Document Control and Change Control Systems, and Equipment Qualification/Validation. Activities included:

*Wyeth, Schering-Plough, Glaxo SmithKline*¹

Multiple sites of major pharmaceutical, biologics, and vaccine manufacturers under Consent Decree

- Developed or participated in the development of corporate guidelines (Level II'S) for engineering, maintenance, calibration, and validation.
- Assessed multiple sites for compliance with cGMPs in the Maintenance and Calibration operations, Engineering and Equipment Validation issues, Change Control and Documentation systems.
- Prepared remediation programs for the assessed areas via Program Development, SOP preparation, training and ongoing coaching.
- Assisted in development of responses to FDA observations.
- Assisted in developing specifications and selecting vendors for computerized maintenance and calibration management programs (CMMS and CCMS)

*Solvay*¹ - Oral Dose facility

- Developed Engineering Life Cycle approach for compliance in the engineering, commissioning, validation, maintenance and calibration areas in response to an AIP (Application Integrity Policy) decree of the FDA.

*Centeon*¹ & *American Red Cross* - Blood Collection and Processing Organizations

- Performed and assisted in mandated assessments under Consent Decrees in the areas of WFI systems, HVAC systems, maintenance, and calibration systems. Also assisted in the development of new facility plans to replace older, non-compliant facilities.

*Sanofi-Aventis*¹ - Vaccine Production Facility

- Assessed and developed Calibration Program for site after significant regulatory observations.
- Assisted in developing the URS and FRS (User and Functional Requirements Specifications) for a CCMS (Calibration Management Program).

SmithKline Beecham - Parenteral Production Facility

- Developed new maintenance program and installed new CMMS as part of a response to a FDA Warning Letter

Examples of Other Projects:

Aviron (Medimmune) – *Santa Clara, CA and Liverpool, U.K.*

- Conducted maintenance program audits and develop new maintenance management programs (manual and automated)
- Served as an independent interface with landlord to resolve GMP utility supply issues

Chiron Diagnostics (Bayer) - Walpole, MA

cGMP Audits and new facility and equipment qualification and validation.

Centocor - Malvern, PA

Audited and subsequently developed new Metrology Program and calibration SOP preparation

DuPont Merck - Wilmington, DE

Sterile Pilot Plant qualification/validation documentation and program audit

¹ As part of the Qantic Group, LLC

Compliance Consulting Activities

Musculoskeletal Transplant Foundation - Edison, NJ

Set up metrology and maintenance portions of Quality System for new tissue processing operation

OraPharma Corporation - Warminster, PA

- Audit and evaluation of facility and compliance status of potential contract manufacturing sites.
- Audit and evaluation of facility and compliance status of potential filling and packaging sites.

Ortho-Clinical Diagnostics - Raritan, NJ

Audited Calibration Program

Audited and remediated Maintenance Program at a biologic, diagnostic reagent and parenteral facility, including developing administrative and detailed procedures and training personnel.

Procter & Gamble - N. Norwich, NY

- GMP Systems compliance audit for a 350,000 square foot oral dosage form facility
- Oral dose production facility HVAC system study as part of a team of investigators

Ionics Water Systems - Montgomeryville, PA

- Preparation of qualification/validation documents and execution of protocols for Ionics client, Regeneration Technologies, Inc.
- Preparation of qualification/validation documents for Ionics client Aventis.
- Preparation of qualification/validation documents for Ionics client J&J

PHARMACEUTICAL COMPANY OPERATING EXPERIENCE:

SmithKline Beecham (Conshohocken, PA) - As Manager of Building Operations and Engineering, Mr. Busfield had responsibilities for all GMP maintenance, calibration, engineering, and operation of building systems in a 200,000 square foot sterile manufacturing facility. Duties included engineering, maintenance, and calibration for all building and process equipment (lyophilizers, washers, autoclaves, filling machines), operation of WFI and Pure Steam systems, preparing and managing capital budgets, and installation of facility and process equipment.

McNeil Pharmaceutical (Spring House, PA) - As Plant Engineering Manager, Mr. Busfield's duties included responsibilities for all GMP maintenance, calibration, engineering, and operation of building systems for 600,000 square foot facility, housing research laboratories, animal vivarium, oral dose manufacturing and corporate headquarters. Responsibilities included engineering, start-up and maintenance and calibration responsibilities for tablet presses, granulators, coating pans, packaging equipment, preparation of mechanical equipment validation documents, and instrumentation.

EDUCATION:

M.B.A., Management and Finance, *LaSalle University*, Philadelphia, PA

B.S., Mechanical Engineering, *Drexel University*, Philadelphia, PA

Served as adjunct faculty at several colleges teaching math and management courses.

PROFESSIONAL ACTIVITIES AND AFFILIATIONS:

International Society for Pharmaceutical Engineering (Member)

Speaker at various ISPE Seminars covering Validation, HVAC, Instrumentation, Documentation, Change Control, and Utilities for pharmaceutical and biotechnology companies.

Instrument Society of America (Senior Member)

Certified as Instrument Engineer (Philadelphia Section ISA)

Member, Education Committee - Philadelphia Section ISA

Directed, coordinated, or lectured at numerous courses for the ISA

SPEAKING/LECTURING

ASTM

Speaker on validation/change control/calibration topics for the E48 - Biotechnology Committee.

Blue Mountain Quality Resources

Presented seminars on Compliant Maintenance Programs and Facility Portion of the Quality System inspection initiative, both public and in-house.

Center for Professional Advancement -

Regularly lecture at two-day seminars on Compliant Calibration Programs, both public and in-house, U.S. and Europe

Various Seminar Organizations
(ISPE, Barnett, IVT, etc.)

Speaker on facilities' issues including engineering, validation, maintenance, and calibration programs in the US and Europe.