

**Compliance Consulting/Remediation/Training Activities**

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**SUMMARY:**

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

Consulting assignments have centered on 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, equipment qualifications and utilities' validation.

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: Engineering Operations, Maintenance Programs, Calibration Programs, Document Control and Change Control Systems, and Equipment Qualification/Validation.

Some examples of specific remediation activities include:

*Teva Animal Health*<sup>1</sup>

Led the effort to remediate facilities and equipment quality systems, including project engineering, maintenance, calibration, etc. Assisted in the remediation efforts for validation system and overall project management (developed Work Plan, Verification Protocols, Certification Protocols, and associated reports) for a liquids, solids, and parenterals manufacturing site.

*KV Pharmaceuticals*<sup>1</sup>

Worked with client team to remediate manufacturing systems for oral dose facility. Also participated in the remediation effort for engineering, calibration, maintenance, and pest control.

*Leiner Health Products*<sup>2</sup>

Developed Corporate and Local programs for Maintenance, Calibration, and Project Engineering for a dietary supplement company undergoing complete revision of operations as part of a regulatory compliance project.

*Wyeth*<sup>2</sup>, *Schering-Plough*<sup>2</sup>, and *Glaxo SmithKline*<sup>2</sup>

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*<sup>2</sup> - 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.

*Centex*<sup>2</sup> & *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*<sup>2</sup> - 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, Liverpool, U.K., and Philadelphia, PA*

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

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<sup>1</sup> As part of Lachman Consultants

<sup>2</sup> As part of the Quantic Group

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*Chiron Diagnostics (Bayer) - Walpole, MA*

cGMP Audits, assisted in 483 responses and new facility and equipment qualification and validation.

*Centocor - Malvern, PA*

Audited and subsequently developed new Metrology Program and calibration SOP preparation

*Ortho-Clinical Diagnostics - Raritan, NJ*

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

*Ionics Water Systems - Montgomeryville, PA*

- Preparation of qualification/validation documents and execution of protocols for Ionics clients, Regeneration Technologies, Inc., Aventis, and 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, *LaSalle University*, Philadelphia, PA

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

Served as adjunct faculty at Philadelphia University, Delaware Valley College, Chestnut Hill College, and St. Frances deSales University, 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 by the Philadelphia Section of the ISA

Member, Education Committee - Philadelphia Section ISA

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

**SPEAKING/LECTURING**

University of Wisconsin

Regularly present two-day seminars on Compliant Calibration Programs for the Engineering Continuing Education Program

Center for Professional Advancement

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

Blue Mountain Quality Resources

Presented seminars on Compliant Maintenance Programs and Facility Portion of the Quality System inspection initiative.

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

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

ASTM

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

In-house Seminars

Contracted regularly to present in-house seminars on the Facility and Equipment portion of the Quality System Inspection Guideline, Compliant Maintenance Programming, or Compliant Calibration Programming for organizations such as Pfizer, JHP Pharmaceuticals, Bioport, AVI Biopharm, and Teva/IVAX