

Compliance Consulting/Remediation/Training Activities

SUMMARY:

Thirty years experience in the pharmaceutical, biopharmaceutical, and device industries, working as an independent consultant to the health care industry since 1995. Consulting assignments have concentrated on compliance programs, specializing in the areas of manufacturing operations, facilities (water systems, HVAC, etc.), engineering, calibration, maintenance, and related programs in the regulated industry. These assignments include working as part of the Third Party cGMP Expert Team in companies under Consent Decree or other regulatory distress.

HIGHLIGHTS OF COMPLIANCE PROJECTS:

Worked as part of 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 multiple clients. Some examples of client companies where compliance activities were performed:

*Mylan Sterile Operations*¹, Hosur, India

Teva API Plant, Mexico, MO

*Novartis*¹, Suffern, NY

Impax Laboratories, Haywood, CA

*McNeil Consumer Healthcare*¹, Multiple Sites

*West-Ward Pharmaceuticals*¹, Eatontown, NJ

*Teva*², St. Joseph, MO

*Actavis*¹, Goa, India

*KV Pharmaceuticals*², St Louis, MO

*Caraco*², Detroit, MI

Leiner Health Products, Carson, CA¹

*Wyeth*¹, Multiple Sites

*Schering-Plough*¹, Multiple Sites

*Glaxo SmithKline*¹, Cidra, PR

*Centeon*¹, Kankakee, IL

American Red Cross, Multiple sites

PHARMACEUTICAL COMPANY OPERATING EXPERIENCE:

SmithKline Beecham (Conshohocken, PA), parenteral facility - Manager of Building Operations and Engineering

McNeil Pharmaceutical (Spring House, PA) Oral dosage forms - Plant Engineering Manager

EDUCATION:

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

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

Served as an adjunct faculty member at various Philadelphia area universities.

SPEAKING/LECTURING

University of Wisconsin

Presented two-day seminars on a Compliant Calibration Program for the Engineering Continuing Education Program

Center for Professional Advancement

Presented two-day seminars on a Compliant Calibration Program, both public and in-house, U.S. and Europe

In-house Seminars

Presented in-house seminars on the Facility and Equipment portion of the Quality System Inspection Guideline, Compliant Maintenance, or Compliant Calibration for organizations such as Alcon (Ciba Vision), AVI Biopharm, Bioport, Bio-Rad, JHP Pharmaceuticals, Pfizer, Sanquin (Netherlands), Terumo CVS, and Teva/IVAX

PUBLICATIONS

Monitoring and Controlling Energy Consumption in Plant Operations, Pharmaceutical Engineering, July-August, 1984

Staying in Control - Ongoing Change Control and Calibration Programs - ASTM E48 Proceedings (STP), April, 1995

"Equipment: Subpart D", 'Good Manufacturing Practices for Pharmaceuticals – Sixth Edition' Joseph D. Nally, editor, 2006

cGMP Maintenance Program Considerations, Journal of Validation Technology, Summer 2012.

cGMP Equipment, Instruments, and Calibration, Journal of GXP Compliance, February, 2013

¹ As part of the Quantic Group

² As part of Lachman Consultants