SUMMARY:

A recognized expert in compliant operations and facility programs in the pharmaceutical and related industries, Joe is the principal of Pharmaceutical Technical Services (PTS). He brings extensive experience in the healthcare industries and uses this experience to assess/audit client operations and, if required, develop remediation plans that include compliant and pragmatic programs in the facilities operation areas of a regulated client and organization design/development. Consulting assignments are usually concentrated in the areas of GMP facilities (water systems, HVAC, etc.), change control, documentation, engineering, calibration, maintenance, pest control, equipment qualification, and related programs. Assignments have also included working in FDA mandated Third-Party CGMP Expert teams in companies individually or as part of a team of SMEs within expert umbrella consulting companies. These assignments have included for example, Complaint Response evaluation, Deviation Response Evaluation, Due Diligence audits, Person-in=Plant oversight of specific operations, and Third-Party oversight of specific operation.

EXAMPLES OF COMPLIANCE PROJECTS:

Working independently, and as part of a SME team, providing auditing, assessment, and remediation services in response to Consent Decrees (at least 14 different sites), VAI's, OAI's, Warning Letters, 483's or other regulatory sanction situations for various locations of multiple clients, domestic and overseas. Programs have also been developed for start-up companies and organizations committed to avoiding compliance issues. Specific areas of responsibility have included:

- Engineering GMP Project Management Programs
- Maintenance Programs
- Calibration Programs
- Engineering Change Control Systems
- HVAC Programs (HEPA filter testing and Test and Balancing)
- Complaint Response Evaluation
- Person-in-Plant observation
- Purified Water and Water-for-Injection Systems Evaluation and Operation
- Pest Control Programs
- Replacement Parts Control
- Facility Service Providers' Qualification
- Equipment Qualification/Validation Programs and oversight
- Facility/Engineering Inspection Readiness
- Data Integrity assessments in Facility Programs
- Documentation Programs
- GMP Facility Cleaning
- Engineering/Maintenance Organizational Design
- Deviation Response Evaluation
- Due Diligence audits
- Third-Party oversight of operations

TRAINING SERVICES:

Seminars are presented that outline Compliant Calibration and Compliant Maintenance program considerations and the Facility Section of the *Quality Systems Approach to Pharmaceutical CGMP Regulations*. Seminars have been presented as public courses and specific client sessions. These seminars have been offered with the following organizations or at the listed clients:

Center for Professional Advancement (Public Courses at various locations in US and Europe)
University of Wisconsin (Public Courses at various locations in US)
Alcon Labs (TX)
Bio-Rad Labs (CA)
Bluebirdbio (MA)
Celgene (NJ)
Ciba Vision (GA)
JHP (MI)
Momenta (MA)
NIH (MD)
Sanquin (Netherlands)
Terumo (MI)

PHARMACEUTICAL COMPANY OPERATING EXPERIENCE:

SmithKline Beecham (Conshohocken, PA) - As Manager of Building Operations and Engineering, responsible for all GMP engineering, maintenance, calibration, and operation of building systems in a sterile cephalosporin 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, HVAC, and Critical Utilities systems, preparing and managing capital budgets, and installation of facility and process equipment.

McNeil Pharmaceutical (Spring House, PA) - As Plant Engineering Manager, duties included responsibilities for all GMP maintenance, calibration, facility project 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 qualification documents, and instrumentation.

EDUCATION:

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

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

Fundamentals of Biomanufacturing, *NC State University*, Remote Learning

Served as an adjunct faculty member teaching Mathematics, Management, Operations Management, and Organization Design courses at Philadelphia University, Delaware Valley University, Chestnut Hill College, and deSales University.

PROFESSIONAL ACTIVITIES AND AFFILIATIONS:

International Society for Pharmaceutical Engineering – ISPE (Member)
Past speaker at various ISPE Seminars covering Instrumentation, Documentation, Engineering Change Control, and Utilities

Instrument Society of Automation – ISA (Senior Member)
Completed certification program of the Philadelphia Section of the ISA
Past Member, Education Committee - Philadelphia Section ISA
Directed, coordinated, or lectured at numerous courses for the ISA

PUBLICATIONS:

Chapter 11: Equipment, Good Manufacturing Practices for Pharmaceuticals – Seventh Edition, Graham P. Bunn, editor, 2019

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

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

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

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