GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Stephen Brown

BSc, Biology
Independent Consultant

Recognised Areas of Expertise:

Accomplished regulatory professional with extensive experience in pharmaceutical and medical device compliance, including a distinguished tenure with the U.S. Ex-FDA. Specialized in CGMP inspections, audit readiness, and regulatory strategy for sterile, biological, and pharmaceutical manufacturing. Proven success in identifying compliance gaps, leading high-impact inspections (domestic and international), and supporting firms through regulatory remediation. Expertise spans aseptic processing, APIs, vaccines, 503A/503B pharmacies, medical devices, and data integrity. Recognized for clear, factual reporting and strong training, coaching, and collaboration skills.

- Consent Decree & Warning Letter Remediation
- Aseptic Processing & Sterile Manufacturing Oversight
- Regulatory Gap Assessments
- GMP / ICH Q-series Guidelines
- Technical Writing & Documentation
- Client Relationship Management
- Analytical Thinking & Problem Solving
- CGMP Compliance
- FDA Inspection Readiness & Mock PAIs
- Quality Systems Auditing
- Data Integrity (ALCOA+)
- Deviation & CAPA Management
- Root Cause Analysis
- Change Control & Risk Assessment

Professional accomplishments include;

- As a Drug Specialist between 1999-2021, conducted inspections related to biopharmaceuticals, vaccines, PET drugs, conventional (503A) and outsourcing (503B) pharmacies, active pharmaceutical ingredients, solid oral dose, and liquids.

- As a member of Team Biologics, conducted numerous inspections of manufacturers of therapeutic drug products, vaccines, allergenic extracts, fractionated products, and medical devices.
- An inspection of a manufacturer of parenteral drug products resulted in a Warning Letter based on GMP deficiencies. The firm voluntarily corrected all deficiencies.
- An inspection of an in vitro medical device manufacturer resulted in a Notice of Intent to Revoke letter. The firm voluntarily corrected all deficiencies.
- Participated in the inspections of multiple 503A pharmacies which in several cases resulted in the issuance of Warning Letters. A recent inspection of a 503A pharmacy in 2019 resulted in a Warning Letter and voluntary recall by the firm of sterile drug products.
- Served as the team lead for the inspection of a national outsourcing pharmacy, directly contributing to the corporate-wide permanent injunction of the firm which resulted in a Consent Decree.
- Inspected a manufacturer of unapproved drugs which resulted in the issuance of a Warning Letter and a subsequent permanent injunction the following year. As a result, the firm was prevented from distributing unapproved drugs that were potentially injurious to public health.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Independent Consultant working for SBrown GMP Consulting, LLC - Houston, TX

Career History:

- **2023 - Present: SBrown GMP Consulting, LLC - Houston, TX – Independent Consultant**
    - Delivered CGMP compliance consulting services to pharmaceutical, biological, and aseptic manufacturing clients, with emphasis on FDA and international regulatory standards.
    - Performed comprehensive compliance assessments, including CGMP inspection readiness and mock FDA Pre-Approval Inspections (PAIs).
    - Conducted audits of Quality Control (QC) laboratories, evaluating testing practices, data integrity, and adherence to regulatory requirements.
    - Reviewed and certified batch records to ensure completeness, accuracy, and compliance with regulatory and internal standards.
    - Investigated product complaints, deviations, and non-conformances; evaluated root cause and CAPA implementation for effectiveness.

- Prepared clients for FDA inspections by assessing systems, training personnel, and verifying procedural compliance.
- Interpreted and applied FDA and ICH regulations and guidance documents, providing actionable recommendations to ensure inspection readiness and data integrity.

- **2021 – 2023: Parexel International - Newton, MA – Principal Consultant**
  - Provided CGMP compliance consulting to pharmaceutical, biologic, and aseptic manufacturing clients across a range of product types and facility classifications.
  - Conducted vendor and supplier audits to assess regulatory compliance with FDA and ICH guidelines.
  - Led mock Pre-Approval Inspections (PAIs) to prepare clients for FDA inspections and ensure inspection readiness.
  - Identified compliance gaps and recommended corrective and preventive actions (CAPA) to strengthen quality systems.
  - Supported clients in remediation projects following regulatory enforcement actions such as Warning Letters or 483 observations.
  - Advised on quality agreements and vendor management strategies to enhance supply chain reliability and compliance.
  - Developed inspection readiness plans tailored to client operations, including aseptic processing and sterile product manufacturing.
  - Delivered actionable guidance on regulatory expectations and current industry trends to ensure ongoing compliance.

- **1989 – 2021: United States Food and Drug Administration (FDA) – Consumer Safety Officer**
  - Conducted complex GMP, GLP, and GCP inspections of biopharmaceutical, vaccine, PET drug, API, and compounding pharmacy facilities (503A and 503B) to assess regulatory compliance and ensure public health protection.
  - Evaluated root cause analyses and corrective and preventive actions (CAPA) for product complaints, in-process deviations, and non-conformances to verify adequacy and effectiveness.
  - Served as team lead for high-profile FDA inspections, including outsourcing pharmacies and unapproved drug manufacturers, resulting in enforcement actions such as Warning Letters, recalls, and permanent injunctions.
  - Authored detailed Establishment Inspection Reports (EIRs) and other regulatory documentation, ensuring accuracy, clarity, and legal sufficiency to support compliance and enforcement decisions.
  - Provided formal classroom and on-the-job training to FDA investigators and state regulatory counterparts, improving consistency and technical proficiency across inspection teams.

- Conducted numerous inspections under Team Biologics of manufacturers of therapeutic biologics, allergenic extracts, and fractionated products, leading to significant compliance improvements.
- Played a key role in regulatory actions including Consent Decrees and Notices of Intent to Revoke, directly contributing to the removal or remediation of products that posed public health risks.

Professional Training and Certification

- Industrial Sterilization for Drugs and Medical Devices / Medical Products Data Integrity Course
- Process Validation / Computer Systems Validation
- Human Drug Compounding Inspections Course / Advanced Drug School
- Active Pharmaceutical Ingredients
- Level II Medical Device / Level II Drug / Level III Drug / Drug Investigator

Education:

- 1987: Bachelor of Science: Biology - University of Arizona - Tucson, AZ
- Series Graduate: Biomanufacturing Training & Education Centre (BTEC) -
  North Carolina State University - Raleigh, NC
  Completed modules in Aseptic Processing, Engineering, Quality Control/Analysis, and Bioprocessing