GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Steve Kehoe

BSc (Hons), or Similar
Senior Consultant

Recognised Areas of Expertise:

A highly experienced pharmaceutical and cGMP consultant with over 16 years' experience supporting global pharmaceutical manufacturers and with extensive expertise in Quality Systems, regulatory compliance, inspection readiness, and Quality Control laboratory operations. Brings more than nine years' experience as a US Food and Drug Administration (FDA) Investigator, including significant involvement in domestic and international pharmaceutical inspections, having conducted more than 235 FDA inspections, including approximately 85 international pharmaceutical inspections as a member of the FDA Dedicated Foreign Drug Cadre, and has worked across a wide range of dosage forms, API manufacturing, sterile and non-sterile products, biologics, biosimilars, and OTC drug manufacturing environments.

Holds a Master of Science in Chemistry from the University of Wisconsin-Madison and has completed extensive FDA professional training in drug law, evidence development, investigation procedures, process validation, industrial sterilisation, pre-approval inspections, API manufacturing, and pharmaceutical investigator training, and FDA Level 1 Investigator Certification. Consultancy experience includes GMP remediation, Quality System design, laboratory and analytical data review, batch record certification, investigation assessment, CAPA, change control, SOP development, equipment qualification, method validation, and preparation for FDA inspections and pre-approval inspections. Has supported global pharmaceutical, API, sterile, biosimilar, OTC, and generic manufacturers with compliance improvement, regulatory response, Quality Unit assessment, and sustainable GMP operations, including FDA commitments following Warning Letters and inspection observations, Quality Risk Management aligned with ICH Q9, and Pharmaceutical Quality Systems aligned with ICH Q10.

- Quality Systems design, implementation, assessment, remediation, and continuous improvement for pharmaceutical manufacturers.

- Selected to serve in the FDA Dedicated Foreign Drug Cadre, performing high-risk inspections of pharmaceutical manufacturers across Europe, Asia, Africa, the Middle East, and North America.
- FDA inspection readiness, pre-approval inspection preparation, FDA 483 response support, warning letter remediation, and regulatory compliance strategy.
- Assessment, review, and approval of quality investigations, including OOS, OOT, deviation, complaint, CAPA, and change control processes.
- Batch record review, analytical data review, batch certification, and evaluation of GMP documentation for sterile, non-sterile, API, OTC, biosimilar, and finished pharmaceutical products.
- Application of FDA's six-system inspection model: Quality Systems, Production, Facilities & Equipment, Laboratory Controls, Materials Management, and Packaging & Labelling.
- Analytical method validation, method verification, cleaning validation, raw material qualification, product specifications, and review of chromatographic and analytical techniques including HPLC, GC, FT-IR, NIR, UV, AA, PSD, TOC, and Karl Fischer water content analysis.
- Audit leadership and execution using FDA inspection principles, including quality management system audits, laboratory assessments, and constructive compliance feedback to site teams.
- Development and revision of SOPs, policies, protocols, quality documentation, training materials, and GMP procedures.
- Project management of complex compliance remediation programs for international pharmaceutical manufacturers across Europe, Asia, Africa, the Middle East, as well as North America.
- Multi-site Quality Culture assessments, across the US, Europe, and India.
- Representative consulting support for multinational and specialist pharmaceutical organisations including Genentech/Roche, Teva Pharmaceuticals, Natco, Shilpa Medicare, Akorn Pharmaceuticals, Curia, Dyno Manufacturing, and Avantor, subject to client confidentiality and public-use approval.
- Strong technical communication, inspection report writing, stakeholder engagement, and collaboration with senior management, Quality Units, regulatory personnel, and multidisciplinary project teams.
- Preparation of Establishment Inspection Reports (EIRs), regulatory evidence packages, and regulatory action recommendations involving significant cGMP and data integrity concerns.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Principal Consultant working on behalf of Steve Kehoe Consulting, LLC

Career History:

- **January 2019 - Present: Steven Kehoe Consulting, LLC – Principal Consultant**

  Provide independent pharmaceutical quality and regulatory consulting services supporting manufacturers in FDA Compliance, Quality System development, inspection readiness, remediation, and technical quality operations. Frequently engaged through leading pharmaceutical consulting organizations to assist clients facing complex regulatory challenges.

  FDA Inspection Readiness & Remediation

  - Guided manufacturers through FDA inspection preparation, regulatory remediation and long-term Quality System improvements.
  - Performed comprehensive assessments of Quality Systems, laboratory operations, investigations, CAPA programs, and manufacturing documentation to identify compliance gaps and reduce regulatory risk.
  - Supported multiple clients responding to FDA commitments following Warning Letters and inspection observations.

  Quality Systems Development

  - Designed and implemented complete pharmaceutical Quality Management Systems, including SOPs, policies, quality documentation, and supporting procedures for OTC manufacturing operations.
  - Assisted organizations with developing validation strategies, equipment qualification documentation, analytical procedures, and product specifications.

  Quality Investigations

  - Performed technical assessments of OOS, OOT, deviation, complaint and CAPA investigations.
  - Reviewed complex batch documentation and quality records to improve investigation quality, regulatory defensibility, and inspection readiness.

  Laboratory & Manufacturing Support

  - Supported laboratory instrument qualification, analytical data review, QC operations, method validation, and equipment qualification activities.

- Assisted clients with process validation, change management, and continuous Quality System improvements.

- **January 2009 – March 2018: US Food and Drug Administration, Maplewood, MO – Consumer Safety Officer & Drug Investigator / Drugg Investigator, Dedicated Foreign Drug Cadre**

  Served as an FDA Drug Investigator responsible for evaluating pharmaceutical manufacturers for compliance with current Good Manufacturing Practice (cGMP) regulations. Conducted complex domestic and international inspections of manufacturers producing APIs, sterile products, biologics, OTC products, and finished dosage forms while assessing product quality, data integrity, manufacturing controls, and Quality Systems.

  Selected to serve in the FDA's Dedicated Foreign Drug Cadre, performing high-risk inspections of pharmaceutical manufacturers throughout Europe, Asia, Africa, the Middle East, and North America.

  - Conducted more than 235 FDA inspections of pharmaceutical manufacturers, medical device firms, and food manufacturers, including approximately 85 international pharmaceutical inspections as a member of the Dedicated Foreign Drug Cadre.
  - Evaluated manufacturing operations producing sterile injectables, oral solid dosage forms, topical drug products, APIs, biologics, transdermal systems, powders, semisolids, and OTC drug products.
  - Led and participated in multidisciplinary inspection teams responsible for evaluating Quality Systems, laboratory controls, production operations, materials management, validation programs, and data integrity practices.
  - Developed multiple regulatory action recommendations involving significant cGMP deficiencies and data integrity concerns requiring FDA compliance action.
  - Prepared comprehensive Establishment Inspection Reports (EIRs), regulatory evidence packages, and compliance documentation supporting FDA decision-making.
  - Worked directly with executive leadership at pharmaceutical manufacturers to communicate inspection observations, regulatory expectations, and corrective action requirements.
  - Applied FDA's six-system inspection model to evaluate Quality Systems, Production, Facilities & Equipment, Laboratory Controls, Materials Management, and Packaging & Labelling operations.

Education:

- 2007: Master of Science, Chemistry, University of Wisconsin, Madison
- 2006: Bachelor of Science, Chemistry, University of Wisconsin, Madison

Continuing Education & Job Related Training:

US FOOD & DRUG ADMINISTRATION

- General Laboratory Training, FDA, Denver, CO
- In-house training on Food and Drug Law, FDA, Lenexa, KS
- In-house training on Collection Reports/ Evidence Development, FDA, Lenexa, KS
- In-house training on Investigation Procedures, FDA, Lenexa, KS
- In-house training on Evidence Development, FDA, Lenexa, KS
- "Basic Food & Drug Law," FDA, San Diego, CA
- "Evidence Development," FDA, San Diego, CA
- "ORA Personal Safety," FDA, San Diego, CA
- "Basic Drug School," FDA, San Juan, PR
- "Process Validation of Drug Manufacturing Operations," FDA, Rockville, MD
- "Industrial Sterilization for Drugs and Devices," FDA, San Juan, PR
- "Pre-Approval Inspections," FDA, Newark, CA
- "Active Pharmaceutical Ingredient Manufacturing," FDA, San Juan PR
- "Pharmaceutical Inspectorate Level III Drug Investigator Training," Rockville, MD