GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Donna Gallien

MPH
Senior Consultant

Recognised Areas of Expertise:

Donna D. Gallien is a highly experienced GCP Consultant and retired FDA Bioresearch Investigator with more than 30 years' experience in quality assurance, auditing, regulatory compliance, and inspection readiness across FDA-regulated industries. She has conducted over 500 complex independent and joint FDA-regulated inspections and investigations, including clinical investigator sites, Institutional Review Boards, sponsor/monitor organisations, bioequivalence studies, biologics facilities, and human tissue operations. Her expertise includes domestic and international GCP audits, mock Bioresearch Monitoring Compliance Program inspections, site inspection readiness assessments, CAPA review, SOP and policy evaluation, and regulatory action support. Donna has also delivered GCP training to clinical research sites and sponsors and has supported FDA foreign inspection activities in Brazil, Canada, Germany, Italy, Japan, and Spain.

During her FDA career, Donna contributed to inspections leading to regulatory and administrative actions, including Untitled Letters, Warning Letters, regulatory meetings, rejection of data, and initiation of disqualification proceedings. She has reviewed and analysed policies, procedures, quality systems, manufacturing and clinical operations, complaint investigations, corrective and preventive actions, and technical documentation to assess compliance with applicable Food, Drug & Cosmetic Act requirements and 21 CFR regulations. Her background also includes biologics and blood bank inspections, donor eligibility and suitability evaluations, GMP and good tissue practice assessments, product complaint investigations, emergency response leadership, and training of new and experienced investigators.

Key Skills and Experience

- GCP auditing, clinical trial compliance, site inspection readiness, and mock BIMO inspection support.
- Extensive FDA inspection and investigation experience across Bioresearch, biologics, blood donor centres, plasmapheresis centres, tissue banks, and transfusion facilities.

- Regulatory compliance assessment against FDA requirements, the Food, Drug & Cosmetic Act, and 21 CFR regulations.
- Quality assurance activities including internal audits, supplier/vendor audits, product complaint handling, CAPA review, and SOP/policy evaluation.
- Clinical investigator, IRB, sponsor, monitor, sponsor-investigator, and bioequivalence study inspection expertise.
- International inspection experience as part of the FDA Foreign Inspection Cadre across multiple countries.
- Training and mentoring of investigators, clinical research sites, sponsors, and regulatory teams on GCP and inspection readiness.
- Leadership experience in supervisory details, emergency response coordination, incident management, and public affairs outreach.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Independent Consultant working on behalf of FDA-regulated industries

Career History:

- **2022 – present: Consulting to FDA regulated industries**
  Experience/projects include:
  - GCP Training to Clinical Research Sites and Sponsors
  - Mock Bioresearch Monitoring Compliance Program (BIMO) inspections
  - Conducting GCP Audits for biotechnology, pharmaceutical, and medical device sponsors.
  - Site Inspection Readiness Audits
  - Audit experience includes:
    - Clinical On-Site Facilities (Private and Public Hospitals, Research Facilities, Private/Group Physicians, Specialty Groups)
    - Institutional Review Boards
    - Sponsor Audits

  Quality Assurance responsibilities, including product complaint handling, internal GCP audits, and supplier/vendor audits. Review of Policies and Standard Operating Procedures

1990 - 2022: U.S. Food and Drug Administration – FDA Investigator

Experience in conducting over five hundred (five hundred) complex independent and/or joint FDA-regulated inspections/investigations and "for cause" audits of:

Bioresearch facilities – Clinical Investigators, Institutional Review Boards, Bioequivalence Studies, Sponsor/Monitor and Sponsor Investigator Sites.

Biologic facilities - blood donor centres, plasmapheresis centres, hospital transfusion facilities (state, private, and federal/military), tissue banks, and component processing centres.

Accomplishments/ Mission Contribution:

- Conducted numerous inspections that resulted in official regulatory and/or administrative actions inclusive of Untitled Letters, Warning Letters, regulatory meetings, rejection of data, and Initiation of Disqualification Proceedings.
- Employ investigative techniques to conduct inspections and review and analyse the firm's policies, procedures, and manufacturing operations/processes, to ensure compliance with the requirements of the Food Drug & Cosmetic Act and 21 Code of Federal Regulation laws.
- Member of the national Foreign Inspection Cadre, conducting inspections in the countries of Brazil, Canada, Germany, Italy, Japan, and Spain. Inspections were conducted at clinical investigator sites, inclusive of U.S. military bases. If necessitated, regulatory meetings were conducted with management when it was determined that sites failed to comply with the requirements set forth by the Code of Federal Regulations, Title 21, and applicable parts.
- Trainer: Health Canada – FDA Inspection Readiness
- Member of the New Orleans District training team, responsible for training new/veteran investigators in Bioresearch and Biologics programs, Inspection and Investigative GCP audits, donor fatality audits, CAPAs, consumer complaints, collection reports and audit recalls. Evaluation of Quality Assurance programs, donor eligibility/suitability, product testing, production and processing systems, good manufacturing practices (GMPs), good tissue practices, facility design and layouts to ensure suitability for the operations performed; and adequacy of procedures used at regulated firms in the biologic and human tissue industries.
- Member of state and federal agency team investigations, working in partnership with:
    - Federal Bureau of Investigations (FBI)
    - Drug Enforcement Administration (DEA)
    - Louisiana Board of Pharmacy
    - Louisiana State Food and Drug Administration

    - Tennessee State Food and Drug Administration
    - The U.S. Marshall Service.
- Level II Biologics Certification - Blood Banks and Plasmapheresis.
- Conducted Consumer Complaint investigations and other special assignments by collecting factual statements and vital information (via statement of facts) to determine counterfeiting or tampering of products.
- Analyse procedures, policies, and other technical documents, corrective/preventive actions.
- Review of the firm's CAPA as a response to an FDA audit to prevent reoccurrence and promote effectiveness.
- Summation and findings of audits reviewed with CEOs, Physicians, Lawyers, and other FDA employees via conference calls, in writing, and face-to-face meetings.
- Perform Consumer Complaint investigations and other special assignments by collecting factual statements and vital information (via affidavit) to determine if counterfeiting/tampering has occurred.

Key projects

- Performed 90-day details as Acting Supervisory Investigator, responsible for work planning, maintaining adequate job coverage, evaluating personnel work to achieve maximum performance, and resolving personnel issues.
- Performed a 90-day detail as New Orleans District Office Emergency Response Coordinator. Responsible for developing emergency plans for the states of Alabama, Louisiana, Mississippi, and Tennessee. Developed strategy for regional and local response to natural disasters and other emergency crises.
- Member of New Orleans District (Nashville, TN) Incident Management Team. (FEMA Certified) Member of FDA Hurricane Katrina and Hurricane Rita Response Group - 90-day deployment as Deputy Operations Chief, as a member of the Hurricane Harvey Incident Command Team.
- Public Affairs Coordinator – numerous 30-day details. Responsible for community outreach, liaison with public and private healthcare establishments, career recruitment for high schools, colleges, and universities; and health and wellness presentations

Education:

- 1990 Master of Public Health
  Tulane University School of Public Health and Tropical Medicine, New Orleans, Louisiana
- 1988: Bachelor of Science, Public Health Management
  Dillard University, New Orleans, Louisianna

Professional Memberships

- American Public Health Association
- Society of Quality Federally Employed Women (F.E.W.)
- Delta Sigma Theta Sorority, Incorporated – New Orleans Alumnae Chapter
- Tulane School of Public Health and Tropical Medicine Alumnae

Continuing Education / Job Related Training

- Annual Meeting: Society of Clinical Research Associates - SOCRA (Presenter)
- Food and Drug Law
- GCP Inspections
- Bioequivalence Inspections
- Clinical Bioresearch Monitoring Orientation to International Inspections
- Advanced Clinical Bioresearch Monitoring
- Non-Clinical Bioresearch Monitoring
- Advanced Non-Clinical Bioresearch Monitoring Institutional Review Boards
- Trace-Back Epidemiology (Donor Fatality and Foodborne Illnesses)
- Computer Aided Inspections
- Evidence Development
- Verbal Judo/Situational Planning, Investigative Interviewing Techniques Interviewing and
- Interrogation Techniques
- ICS-300 Intermediate ICS Command and General Staff – Complex Incidents
- ICS-400 Advanced ICS Command and General Staff – Complex Incidents
- ER958 Incident Command System – Deputy Operations Chief