GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Colleen F. Hoyt

Senior Consultant

Recognised Areas of Expertise:

- Respected strategic leader with more than 35 years of experience spanning biological and pharmaceutical operations, regulatory compliance, and quality assurance. Demonstrated success in overseeing complex programs, guiding high-performing teams, and elevating operational performance within highly regulated environments.
- Multiple-time recipient of the FDA Commissioner's Special Citation for leadership in public health emergency responses, including Zika virus, H1N1 Influenza Pandemic, and Necrotizing Enterocolitis investigations.
- Led high-impact regulatory initiatives that enhanced pharmaceutical manufacturing compliance and operational efficiency.
- Core Competencies;
    - Pharmaceutical Manufacturing & Compliance
    - Global Regulatory Affairs & Quality Assurance
    - Good Manufacturing Practices (cGMP) & Risk Management
    - Inspection & Investigation Leadership
    - Strategic Planning & Policy Development
    - Cross-Functional Team Leadership
    - Advanced Manufacturing & Emerging Technologies
    - Staff Professional Development

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited

Career History:

- **May 2020 – April 2025: US Food & Drug Administration, Rockville - Branch Director, Office of Inspections and Investigations, Division of Human and Animal Drug Global Operations**

  Leadership and Program Management

  - Led a team of National Expert drug and pharmacy compounding investigators and Drug Program Experts responsible for assessing domestic and international pharmaceutical regulatory compliance and manufacturing practices.
  - Developed and implemented strategic operational priorities to align with industry advancements and regulatory expectations.
  - Responsible for domestic and international inspection and investigation programs. Assessed inspection findings for compliance with US FDA regulations and international standards. Recommended Agency regulatory action, as appropriate.
  - Collaborated with global regulatory bodies such as Pharmaceutical Inspectorate Cooperation Scheme (PIC/S) and International Council for Harmonisation (ICH) to drive development of guidance to address innovation in manufacturing technologies and regulatory practices, such as ICH Q12 Pharmaceutical Product Lifecycle Management and Q13 Continuous Manufacturing.
  - Provided executive oversight on policy development, risk assessments, and strategic planning initiatives.
  - Represented the US FDA by conducting audits of international regulatory authorities as part of the Mutual Reliance Agreement (MRA) joint assessment program to assess competency and capabilities against key indicators.

  Inspectorate Training and Development

  - Responsible for overall new hire drug inspectorate training and development, to include non-sterile, API, and sterile manufacturing curriculum development and Subject Matter Expert (SME) speaker assignments. Directed staff SMEs to ensure existing curriculum was up to date with current policies and procedures and develop new courses to address advances in pharmaceutical manufacturing.
  - Instrumental in the creation and implementation of the first OHADI Investigator Inspection Qualification Program, specifically, the development of investigator eligibility, audit criteria, roles and responsibilities of auditors, and defining audit results.
  - Directed the revision of the pharmacy compounding and outsourcing facility inspection training to include the addition of hands-on training activities to enhance student learning

- Directed and served as Editor in Chief for the creation of an OHADI internal pharmacy compounding quarterly newsletter to showcase new compounding policies, aseptic processing case studies, and investigator spotlights.
- Developed quarterly new hire investigator cohort onsite training, specifically to welcome new investigators, create and develop relationships with office management, train staff on investigative operations and administrative functions of the job in a small, informal setting. This course was met with high ratings and remarks from student evaluations.
- Maintained strong collaborative relationship with OII Office of Training and Development to ensure schedule of fiscal year training courses and funding were aligned with staff needs and scheduled appropriately.
- Identified and forecasted investigator training needs by monitoring industry manufacturing advancements. Collaborated with CDER and industry Subject Matter Experts (SMEs) to develop comprehensive training programs to enhance investigator's technical expertise in manufacturing operations to include continuous manufacturing of drug substance and drug product, use of isolators in aseptic processing.
- Member of CDER's Emerging Technology Team. Collaborated with CDER SMEs to identify opportunities for National Expert drug investigator participation in application review and onsite inspection. These experiences would then be shared with larger inspectorate as training sessions.
- Served as lead for the Office of Pharmaceutical Quality Operations "Pharma Training Series", a quarterly seminar series for drug and biologics investigators and compliance officers to provide training on a wide range of topics from administrative to technical. Identified subjects and speakers and cleared presentations. Moderated sessions and led Q&A.
- Sought after industry and academia facilities to collaborate and build hands on inspectorate training on drug formulation and filling through aseptic processing, laboratory operations, batch release.
- Supported and encouraged National Expert staff to volunteer and create availability for speaker requests from academia and organizations for conference speaking engagements on pharmaceutical and pharmacy compounding inspection subject matter.

- **April 2011 – May 2020: US Food & Drug Administration, Rockville - MD Staff Director, Team Biologics, Office of Inspections and Investigations, Office of Biological Products Operations**

  Leadership and Program Management

  - Managed a team of expert investigators conducting complex domestic and international inspections of vaccine, biological drug and device manufacturers producing products for the US market.

- Managed FDA approved domestic and international vaccine manufacturer inventory.
- Represented the US FDA in global regulatory collaborations, including Mutual Reliance Agreements (MRA) foreign regulatory authority assessments.
- Evaluated and endorsed inspection reports, ensuring adherence to FDA regulations and cGMP compliance.
- Provided strategic guidance on manufacturing assessments, risk management, and regulatory decision-making.
- Developed and implemented quality process improvements to enhance staff efficiency and productivity.

Inspectorate Training and Development

- Served as a member of the Course Advisory Group for the development and oversight of Biopharmaceutical (biotech) Manufacturing course for drug and biologics investigators.
- Collaborated with Centre (CBER) product experts to develop and deliver inspectorate training on new product and manufacturing advances such as CAR-T cell, cell and gene therapy and hemopoietic cord blood.
- Spearheaded Advanced Manufacturing Technologies initiatives to include collaboration with FDA's Office of Counterterrorism and Emerging Threats to forecast inspectorate training needs on modular clean rooms.
- Participated in on-site evaluation of Dept of Defence (DOD) contracted biological therapeutic and vaccine manufacturer, along with representatives from BARDA to assess facility capabilities to respond to biothreats.

- **October 2003 – April 2011: US Food & Drug Administration, Silver Spring, MD Compliance Officer, Centre for Drug Evaluation and Research, Manufacturing Assessment and Preapproval Compliance Branch**
  - Conducted facility risk assessments of international pharmaceutical manufacturers to determine cGMP compliance.
  - Advised on regulatory actions for preapproval inspections of new and innovative pharmaceutical products.
  - Developed strategic inspection assignments and led compliance initiatives for high-risk manufacturing facilities•
  - Reviewed and assessed investigations related to drug manufacturing defects, ensuring product safety and regulatory adherence.
  - Conducted domestic and international preapproval and surveillance inspections of pharmaceutical manufacturers to assess compliance with the Food, Drug & Cosmetic Act (FD&C), 21 CFR Code of Federal Regulations 210 and 211

- **October 1989 – October 2003: US Food & Drug Administration, Rockville, MD Various Positions (Clerk to Compliance Officer) Centre for Biologics Evaluation and Research**
    - Progressed through multiple roles, gaining extensive experience in regulatory compliance, quality assurance, and pharmaceutical manufacturing oversight.

Professional Training & Certifications:

- Regulatory Compliance & Quality Assurance: current Good Manufacturing Practices (cGMP) for Biological Drug and Pharmaceutical Manufacturing, Pre-Approval Inspections, Active Pharmaceutical Ingredient Manufacturing, Food and Drug Law
- Leadership & Management: Resilient Leadership, Performance & Conduct Accountability, Supervisory Training.
- Specialized Training: CAR-T Cell Therapy Manufacturing, Biologics & Biotech Manufacturing, Emergency Use Authorization Facility Reviews. Education Montgomery College, Rockville, MD Biology, Biotechnology, Law Enforcement Concentration

Education:

- Montgomery College, Rockville, MD - Biology, Biotechnology, Law Enforcement Concentration