



CURRICULUM VITAE

Colleen F. Hoyt

Senior Consultant



Recognised Areas of Expertise:

- Dynamic, respected 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;
 - Programme oversight
 - Driving cross-functional collaboration across domestic and global teams
 - Implementing innovative process improvements
 - Maintaining rigorous adherence to international regulatory standards
 - 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**
 - Led a team of National Expert drug and pharmacy compounding investigators and Drug Program Experts overseeing domestic and international pharmaceutical regulatory compliance and manufacturing practices.
 - Developed and implemented strategic operational priorities to align with industry advancements and regulatory expectations.
 - Oversaw domestic and international inspection and investigation programs, assessing 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 and Q13.
 - Identified and forecasted training needs and develop comprehensive programs to enhance technical expertise in pharmaceutical quality operations.
 - 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.
- **April 2011 – May 2020: US Food & Drug Administration, Rockville - MD Staff Director, Team Biologics, Office of Inspections and Investigations, Office of Biological Products Operations**
 - 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.
 - Developed and implemented quality process improvements to enhance staff efficiency and productivity.
 - Represented the US FDA in global regulatory collaborations, including Mutual Reliance Agreements (MRA) foreign regulatory authority assessments.

- Spearheaded Advanced Manufacturing Technologies initiatives.
 - 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.
 - Participated in on-site evaluation of Dept of Defense (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, Center 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.
- **October 1989 – October 2003: US Food & Drug Administration, Rockville, MD Various Positions (Clerk to Compliance Officer) Center 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