GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Tyanna Hadley

M.S.
Senior Consultant

Recognised Areas of Expertise:

A strategic regulatory compliance professional with extensive experience across FDA inspection, pharmacovigilance, bioresearch monitoring, REMS, and pharmaceutical quality oversight. With a strong scientific and regulatory background, bringing valuable insight from work as a US FDA Investigator, conducting more than 50 inspections across pharmaceutical, biologic, medical device, veterinary medicine, CRO, IRB, sponsor, pre-clinical, clinical, and pharmacovigilance environments.

Experience spans regulatory agency, pharmaceutical industry, nonprofit leadership, and consulting roles, supporting organisations with inspection readiness, compliance remediation, risk management, and sustainable quality systems. Combining regulatory expertise, scientific knowledge, and strong leadership capability to help teams navigate complex compliance challenges while maintaining a clear focus on patient safety, healthcare quality, and operational excellence.

Key Skills and Areas of Expertise

- FDA and global regulatory compliance, including GxP, ICH, and bioresearch monitoring requirements.
- FDA inspection conduct, inspection readiness, audit preparation, and regulatory response support.
- Pharmacovigilance, drug safety oversight, REMS compliance, and global regulatory reporting.
- Corrective and Preventative Action development, root cause analysis, risk mitigation, and compliance remediation.
- Cross-functional leadership, stakeholder engagement, scientific writing, and regulatory communication.

- Quality system development, programme management, nonprofit governance, coaching, and professional development.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Chairman and Founder of MAE We Help Inc
- Principal Consultant and Owner of TNH Consulting LLC
- Independent Coach and Founder of Faith And Authority LLC

Career History:

- **June 2025 – Present: MAE We Help Inc - Chairman and Founder**
  - Founded MAE WE Help®, a 501(c)(3) nonprofit, providing medical advocacy and education resources to both patients and providers.
  - Lead board governance implementing legal procedures and regulatory compliance for nonprofit operations.
  - Manage regulatory and financial filings ensuring organizational compliance.
  - Developed public resources supporting patient health tracking and medical condition management.

- **May 2025 – Present: TNH Consulting LLC - Principal Consultant and Owner**
  - Provide strategic regulatory advisement on GCP and GVP inspection readiness, implementation, quality process improvements, ongoing compliance, and responses to the US FDA.
  - Perform root cause assessments and CAPA development addressing deviations and regulatory violations.
  - Assess clinical and postmarketing adverse event reporting compliance, processes, and oversight.
  - Conduct mock inspections and FDA inspection preparedness based on former FDA investigator experience.

- **August 2021 – April 2025: United States Food and Drug Administration (US FDA) – Investigator, Office of Bioresearch Monitoring Inspectorate Program**
  - Conducted more than 50 thorough inspections of pre-clinical research according to good laboratory procedures (GLPs), clinical bioequivalence (BEQ) studies, Clinical Investigators (CIs), application sponsors, Contract Research Organizations (CROs), Institutional Review Boards (IRBs), Post-Marketing Adverse Drug

Experience (PADE) pharmacovigilance activities, Risk Evaluation and Mitigation Strategies (REMS) activities, and Radioactive Drug Research Committees (RDRCs).
    - Discovered violative conditions as cited on issued Form FDA 483s at more than 65% of the inspected firms indicating violative actions and an official action with issuance of a warning letter.
    - Interviewed and assessed regulatory compliance of interdisciplinary teams for activities such as IRB reviews and approvals, clinical site monitoring, clinical study oversight, data management, statistical analysis, protocol deviation management, safety management and oversight, vendor selection and oversight, individual case safety report (ICSR) processing and submission, aggregate report submissions, electronic data capture, and data exchange.
    - Inspected and assessed compliance of activities related to pharmaceutical drugs, biologics, medical devices, combination products, and veterinary drugs.
    - Presented US FDA pharmacovigilance regulations to global health authorities.
    - Conducted international inspections and a domestic, joint-inspection with European Medicines Agency (EMA) investigators.

- **January 2020 - Present: Faith And Authority LLC – Independent Coach and Founder**
    - Provide professional coaching services focused on goal achievement and strategic planning.
    - Facilitate root cause identification and resolution planning for goal-hindering obstacles.
    - Develop SMART action plans for client accountability and measurable outcomes.

- **August 2015 – May 2018: Philadelphia College of Osteopathic Medicine - Student Doctor**
    - Assisted with wound debridement, suturing, grafting, additional surgical procedures, phlebotomy, primary care, surgical procedures, and post-operative evaluation of patients at various Level 1 and 2 trauma centres.
    - Clinically trained under various services: Internal Medicine, Cardiology, General Surgery, Surgical subspecialties: trauma, burn, oncology, vascular, and thoracic, Family Medicine, Psychiatry, Paediatrics, Obstetrics & Gynaecology, Osteopathic Manipulative Medicine, Emergency Medicine/Ultrasound.
    - Utilised electronic health record systems (Cerner and Epic) for comprehensive patient documentation.

- **September 2012 – June 2015: Novartis Consumer Health, Inc. - Drug Safety & Pharmacovigilance Compliance Associate**
    - Analysed global aggregate safety report (PSUR, PBRER) submission compliance metrics for 177 countries in accordance with GVP Module VII, ICH (E2C) R2, and local health authority mandates.
    - Collected, reconciled, and categorized country-specific post-marketing regulatory reporting requirements.
    - Investigated, documented, and managed affiliate deviations through thorough root cause analysis, appropriate CAPA implementation, and monitoring corrective action effectiveness.
    - Provided effective affiliate training increasing global aggregate report submission compliance to 100%.
    - Authored quarterly and annual aggregate report submission compliance reports for executive leadership.
    - Supported audits by fulfilling and coordinating data requests.
    - Reviewed and reconciled corporate quality standard procedure training documentation, Pharmacovigilance System Master File (PSMF) addendum documentation, and procedure listings.
    - Served as Drug Safety Compliance representative for project management advisement on materiovigilance.

- **March 2012 – August 2012: Novartis Consumer Health, Inc. - Team Lead, Consumer Service Representative**
    - Led Medical Affairs team distribution of work, colleague support, work-flow tracking, and functioned as an interdepartmental liaison with Quality Assurance, Legal, and Drug Safety.
    - Performed adverse event and technical complaint data entry from multiple sources.

Education:

- 2011: Stevenson University, M.S. Forensic Science
- 2009: University of Delaware, B.S. Biochemistry

Professional Memberships:

- American College of Surgeons (ACS)
  - Women in Surgery Committee Medical Student Member (2017 – 2019)
- Student National Medical Association (SNMA)
  - National Minority Association of Premedical Students (MAPS) Osteopathic Co-liaison (2017-2018)
  - Region VIII MAPS Liaison (2016 – 2017)
  - Philadelphia College of Osteopathic Medicine Chapter, Treasurer (2016 – 2017)
  - Health Professions Recruitment and Exposure Program (HPREP) Mentor (2015 – 2017)

Continuing Education / Job Related Training:

- 2023: US Food and Drug Administration Clinical Bioresearch Monitoring Investigator Certificate
- 2020: HarvardX Prescription Drug Regulation, Cost, and Access: Current Controversies in Context
- 2020: Living the Empowered Life Academy Life Coach Certification
- 2019: LinkedIn Coaching Skills for Leaders and Managers Certificate of Completion
- 2019: LinkedIn Critical Thinking Certificate of Completion