GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Paul Dexter

MSc (Microbiology)
Senior Consultant

Recognised Areas of Expertise:

Drug product quality and microbiology expert for the Food & Drug Administration with 21 years of well-rounded regulatory experience. Combines deep industry knowledge of human and animal drug products for product quality microbiology, chemistry manufacturing and controls, drug manufacturing process, facility, and regulatory compliance. Strong leader of teams to effectively manage FDA regulatory timelines with high quality science-based review work and decision making. Retired CAPT of the United States Public Health Service (USPHS).

Skills and experience;

- Sterile and non-sterile drug product manufacturing expert (small and large molecules), with hands-on and oversight experience across the product lifecycle—from process development and tech transfer through commercial manufacturing and lifecycle management.
- Regulatory compliance and cGMP: strong working knowledge of FDA and international expectations; experienced in inspection readiness, risk-based compliance, and resolution of observations through effective CAPA and quality system improvements.
- Pharmaceutical drug compounding expertise, including formulation principles, aseptic technique considerations, environmental and microbiological controls, and robust documentation to support patient safety, product quality, and regulatory expectations.
- Chemistry, Manufacturing and Controls (CMC): experienced in assessing and developing CMC content (e.g., control strategy, specifications, stability, comparability, and manufacturing changes) to support submissions, supplements, and lifecycle updates.
- Drug manufacturing process and facility expertise, including process characterization and validation, contamination control strategy inputs, and facility fit assessments (e.g., utilities, cleanrooms, equipment, EM program) to ensure compliant, reliable operations.
- Team leadership: proven ability to lead and mentor multidisciplinary teams, align stakeholders on quality and regulatory strategy, and deliver high-quality, science-based outcomes under aggressive timelines.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- CEO and Independent Consultant for Dexter Biotech Solutions, LLC

Career History:

- **2025 – Present: Dexter Biotech Solutions, LLC, Denver, CO – CEO & Independent Consultant**
  - Compliance consultant for sterile and non-sterile drug product and drug device combination manufacturing.
  - Product quality microbiology expertise in small and large molecule drug process manufacturing.
  - Assist in the response to FDA Form 483, Untitled Letters, and Warning Letters.
  - Performs mock audits to gap assess for compliance to FDA and EU regulations.

- **2023 – 2025: Leachman Consultants Inc, Westbury, NY – Senior Director, Compliance**
  - Compliance consultant for sterile and non-sterile drug product and drug device combination manufacturing.
  - Product quality microbiology expertise in small and large molecule drug process manufacturing.
  - Assist in the response to FDA Form 483, Untitled Letters, and Warning Letters.
  - Performs mock audits to gap assess for compliance to FDA and EU regulations.
  - Employee Shout Out of the Quarter – Q1 2024

- **2020 – 2023: U.S. Food & Drug Administration, Silver Spring, MD - CDER (Centre for Drug Evaluation and Research) - Senior Pharmaceutical Quality**
- **2017 – 2020: U.S. Food & Drug Administration, Silver Spring, MD - CDER - Senior Regulatory Reviewer**
  - Lead for a six-person team tasked with performing drug product quality review of Investigational New Drugs (IND), New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA), Drug Master Files (DMF) for microbiology, drug manufacturing process, extractables & leachable, and cGMP facility assessment.
  - Experienced assessment of drug product facility preparedness by review of Establishment Inspection Reports, 483 response evaluation, and CDER compliance actions (untitled letters, warning letters, consent decrees).

- Experienced assessment of Code of Federal Regulations (CFR) related to 21 CFR 210/211 for good manufacturing practices for pharmaceuticals, 21 CFR 212 for Positron Emission Tomography drugs, and 21 CFR 312 for Investigational New Drugs.
- Subject matter expert for drug substance and product quality microbiology issues consulted for non-compliance regulatory escalation actions, drug product shortage, post-approval supplement grant/deny decisions, and combination drug products that cross CDRH (devices), CBER (biologics), and CDER (drugs).
- Subject matter expert for the microbiological expectations related to the manufacture of aqueous non-sterile drug products (e.g., USP <51>, <60>, <61>, <62>, and <1111>).
- Biologic sterile drug product assessment of CDER-regulated Biologic License Applications (BLA) and A/NDA (e.g., Parathyroid Hormone, Heparin, and fermentation derived antibiotics).

- **2015 – 2017: U.S. Food & Drug Administration, Silver Spring, MD - CVM (Centre for Veterinary Medicine) - Animal Drug Compounding Coordinator**
  - Centre coordinator and leader of a six-person team for all issues related to establishing regulatory policy and compliance for animal drug compounding.
  - Represented CVM for response to U.S. Congress, CDER human drug compounding, and industry stake holders to communicate the issues relevant to animal drug compounding.
  - Experience with FD&C Act regulations related to drug compounding by section 503A (compounding pharmacies) and 503B (registered outsourcers) and USP <795> and USP <797>.

- **2006 - 2015: U.S. Food & Drug Administration, Silver Spring and Rockville, MD -**
  CDER - Division of Microbiology / Branch Chief - 2015
  CDER - Division of Microbiology / Deputy Director - 2013 – 2015
  CDER - Division of Microbiology / Team Leader - 2008 - 2013
  CDER - Division of Microbiology / Senior Regulatory Reviewer - 2006 – 2008
  - Assisted director leading a division of 50+ microbiologists tasked with performing drug product quality review of Investigational New Drugs (IND), New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA), Drug Master Files (DMF) for product quality microbiology.
  - Performed annual Branch employee performance appraisals for 12 microbiologists and assisted in recruiting, hiring, and training of new microbiology staff.
  - Product quality microbiology subject matter expert consulted for post-approval supplement grant/deny, drug product shortage, CDER compliance actions, and combination drug products.

- Prior Approval Inspectional (PAI) experience at an FDA regulated facility for aseptic filling of ophthalmic drug products.

- **2003 – 2006: U.S. Food & Drug Administration, Lakewood, CO - ORA - SWID (Office of Regulatory Affairs - Southwest Import District) / Denver District Laboratories**
  - Product quality bench microbiologist for food, drug, and cosmetic analysis.
  - Performed sterile drug product analysis in an aseptic clean room setting.
  - Performed as district select agent monitor for care and safe handling of high-risk microbial agents and toxins (e.g., Clostridium botulinum, Bacillus anthracis.)
  - Gained membership to FERN (Food Emergency Response Network) in collaboration with the Centres for Disease Control (CDC) by Pulse Field Gel Electrophoresis certification of Salmonella and E. coli species.
  - Surveillance inspectional experience at FDA regulated facilities for food distribution and production.

Education:

- 1999: Master of Science / Microbiology – Washington State University, Pullman, WA
- 1994: Bachelor of Science / Medical Technology – University of Montana, Missoula, MT

Certifications

- 2008: Certificate of Public Health – Georgetown University, Washington, DC
- 2004: Consumer Products and Quality Assurance: Food and Dairy - National Registry Of Microbiologists | American Society of Microbiology

Professional Affiliations

- 2023 – 2025: Parenteral Drug Association (PDA) Member ID # 121983
- 2023: International Society For Pharmaceutical Engineering (ISPE) Member ID # 1118845
- 2024: Society For Sterility Assurance Professionals (SfSAP) Working Group – Radiation
- 2023 – Present: FDA Alumni Association
- 2024 – 2025: Big Brothers Big Sisters (Washington County, MD) Board of Directors & Big Brother Mentor
- 2025 – Present: Gelli's Community Fridge (Denver, CO) Chief Financial Officer & Volunteer
- 2025 – Present: Soldier's Angels (Denver, CO) U.S. Veteran Volunteer