GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Prabhu P. Raju

BSc, Biomedical Engineering
Senior Consultant

Recognised Areas of Expertise:

Highly accomplished regulatory and compliance expert with over 34 years of experience at the U.S. Food and Drug Administration (FDA) and as an independent consultant. With a career spanning advanced manufacturing, biological product safety, international regulatory inspections, and public health leadership.

Held pivotal roles in the approval and oversight of critical medical products, including COVID-19 vaccines and novel gene/cell therapies, and has been recognized with numerous FDA awards for leadership and contributions to public health. Known for expertise in inspectional and investigational techniques, regulatory policy development, and cross-functional collaboration with industry, academia, and global regulatory authorities. Work has directly impacted the approval and safety of high-profile biological drugs, medical devices, and advanced therapies worldwide.

Key Areas of Expertise

- FDA Regulatory Inspection & Compliance: Over 300 inspections of licensed biological products and medical devices, including domestic and international sites.
- Advanced Manufacturing & Emerging Technologies: Program Expert for FDA's Emerging Technologies Advanced Manufacturing (ETAM) Team; subject matter expert in advanced manufacturing processes, 3D printing, AI in pharma, and novel control/testing strategies.
- Biological Product Safety: Authority on manufacturing and inspection of vaccines (COVID-19, influenza, bacterial, viral), plasma derivatives, cell/gene therapies (CAR-T, HPC, cord blood), and in-vitro diagnostics.
- International Public Health & Foreign Inspections: Led high-profile foreign inspections in Europe and Asia; instrumental in the approval of the Novavax COVID-19 vaccine and other global products.

- Leadership & Program Management: Acting Staff Director for Team Biologics; led teams, set priorities, and managed complex inspectional assignments during critical public health events.
- Training & Mentorship: Developed and delivered FDA training modules; mentored new investigators; coordinated industry and academic training collaborations.
- Regulatory Policy & Guidance Development: Contributor to FDA guidelines, compliance programs, and international regulatory harmonization efforts (e.g., Annex 1, ICH9, ICH13, EU Annex 16).
- Awards & Recognition: Multiple FDA Honor Awards, including the Commissioner's Citation for COVID-19 vaccine work, and numerous performance and leadership awards.
- Technical & Scientific Expertise: Certified at the highest levels in drug and medical device inspection; advanced training in biomanufacturing, data integrity, and quality systems.
- Professional Affiliations: Active member and contributor to ISPE Northwest, PDA Northwest and Life Science & Tech Consultants Association.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited

Career History:

- **May 2023 – May 2025: FDA / ACOII / MPI / ETAM – Program Expert, Advanced Manufacturing**

  As the Program Expert for Advanced Manufacturing on the Emerging Technologies Advanced Manufacturing (ETAM) Team. Duties included the following:

  - Provided expert Advice and Counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other Agency Leaders on inspectional and compliance operations.
  - Served as a subject matter expert in inspectional and investigational techniques and provided authoritative advice to ORA Senior Leadership in advanced manufacturing for medical products.
  - Collaborated with industry groups, professional organizations, and academia to evaluate and leverage training expertise from outside FDA.
  - Engaged with various stakeholders (industry, academia, foreign regulatory authorities) to keep abreast of emerging product technologies, advanced

manufacturing process, innovative control and testing strategies and novel platform technologies.
    - Engaged early with Centres on advanced manufacturing initiatives to identify novel technologies in the pipeline and to understand technical and regulatory issues with advanced manufacturing to help dictate and inform operational policies.

- **January 2022 – May 2023: FDA / OBPO / Team Biologics – International Consumer Safety Officer, Foreign Expert**
    - Promoted to the position of International CSO, Foreign Expert, and served as a foreign expert and senior functional foreign investigative specialist, and authoritative expert for licensed biological drugs and devices.
    - Conducting high profile foreign inspections in Germany, India, Austria, Japan, Korea, and Singapore.
    - ORA Lead for the inspection of Serum Institute of India (4/22), that was critical for the approval of the Novavax Vaccine, the third COVID-19 Vaccine approved for distribution in the US.

- **August 1999 – January 2022: FDA / OBPO / Team Biologics – Senior Investigator / Consumer Safety Officer**
    - Senior Investigator/Consumer Safety Officer/Engineer for the Office of Biological Product Operations (OBPO)/Biological Products Inspection Staff (BPIS) (Team Biologics)
    - International CSO/Foreign Expert, duties included but are not limited to being a nationally recognized authority on inspectional and investigational techniques in advanced biological product manufacturing.
    - Lead Investigator involved in the first surveillance inspection, post Emergency Use Approval (EUA), of a COVID-19 Vaccine Manufacturer (5/2021), Pfizer.
    - Lead Investigator for conducting inspections related to the most complex, controversial, and precedent setting products in the area licensed biological drug products and licensed medical devices.
    - Serving as an authority in inspectional and investigational techniques in the major functional areas of CBER licensed biological drug and device products: vaccines, hematopoietic progenitor cells cord blood (HPC-C), CAR-T gene therapy, plasma fractionation products, allergenic products, in vitro diagnostics, and CDER biotech products.
    - Specialized expertise in the last several years in participating in Pre License/PreApproval inspections of COVID-19 vaccines, and novel gene/cell therapy manufacturers, some of the most important critical products that FDA regulates.

- Participated in the preapproval and surveillance inspections of CAR-T manufacturers, which have been only recently approved in the last three-four years.
- During the COVID-19 Vaccine Pandemic, I was lead investigator for the PreLicense inspection for the Pfizer COVID-19 Vaccine.
- In 2020 I completed a 45-Day Detail as Acting Staff Director for Team Biologics, Division II (TBIOL2)
- Received national award recognition for leading the approval of a novel gene therapy and for contributions to the Vaccine Training Series Development Team.

- **April 1991 – August 1999: Seattle District Medical Team – Senior Leader**
  - Senior leader and specialist on this team and conducted several domestic and foreign high profile inspections of medical device manufacturers.

Education:

- 2010: North Carolina State University – Biomanufacturing Principles and Training, Technical or Occupational Certification
- 1995: United States National Guard – Combat engineering, Technical or Occupational Certification
- 1990: University of Massachusetts – Electrical Engineering
- 1988: Johns Hopkins University – Biomedical Engineering

Affiliations:

- ISPE Northwest - Member
- PDA Northwest - Member
- Biopharm International - Member
- Pacific Region Society of Quality Assurance – Member

Professional Publications:

- Due to the nature of my position, I cannot author publications but have participated in the development of FDA Guidelines and Compliance Programs. Most recently I contributed to the Annex 1, Manufacture of Sterile Medicinal Products (2/2018), and Compliance Policy Guides regarding licensed IVDs (2019, 2020), & ICH9, ICH13, and EU Annex 16 (2021, 2022). Was part of Distributed Manufacturing Guidance, 21CFR207, CDER/ FRAME group.