CURRICULUM VITAE

Deyaa Shaheen

BSc
Independent Consultant

Recognised Areas of Expertise:

Transformational Quality and Compliance Leader with 25+ years of experience across pharmaceutical, biopharmaceutical, sterile, and biologics operations. Former FDA Drug Investigator with 50+ pre-approval and surveillance inspections conducted across APIs, finished dosage forms (OTC and generics), and sterile manufacturing—three resulting in nationally impactful Warning Letters. Led 250+ mock audits of clients, CMOs, and contract laboratories across multiple modalities. Recognized Data Integrity SME with deep expertise in CGMP, inspection readiness, and remediation strategy.

Proven track record developing and executing CAPA, remediation, and risk-management programs to close major compliance gaps and address FDA 483s and Warning Letters. Experienced in managing global quality teams and driving enterprise-wide quality culture improvements. Skilled in regulatory engagement, acting as senior liaison with FDA and global authorities. Strong technical oversight of OOS/OOT investigations and analytical testing (KF, HPLC, UPLC, FTIR, GC, ICP-MS). Multilingual communicator and respected industry speaker on CGMP, data integrity, and quality systems.

60th Annual FDA Honor Awards – Group Recognition (2020**):** Recognized for cross-centre collaboration in managing pharmaceutical complexity via the implementation of the "FDA Concept of Operations."

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Founder of XFDA Pharma Advisors Consulting Services

Career History:

- **May 2025 - Present: XFDA Pharma Advisors Consulting Services – Founder**
  - Drove strategic growth and business development—expanding market presence through new opportunities, partnerships, and client engagements—while serving as the firm's key external representative and trusted regulatory advisor.
  - Ensured seamless alignment between business development and operations to deliver high-quality services and sustained client satisfaction.

- **June 2024 – May 2025: Lachman Consultant Services, NY – *Senior Director/FDA Expert***
  - Led global inspection readiness and remediation programs—including mock PAI/PLI inspections (ANDA, NDA, BLA), SME coaching, storyboards, and real-time inspection management—ensuring sustained regulatory compliance.
  - Developed formal FDA 483 and Warning Letter responses and drove cross-functional remediation across multiple product modalities while managing timelines and delivering key compliance milestones.
  - Provided expert guidance on FDA, EMA, ICH, USP, and CGMP requirements, demonstrating strong leadership, communication, and problem-solving in resolving complex regulatory and quality challenges.

- **July 2023 – May 2024: Baxter HealthCare Inc., Deerfield, IL - *Senior Director, Corporate Audit & Inspection Readiness***
  - Led global corporate audit and regulatory inspection readiness functions—including planning, execution, budgeting, and resource allocation—while overseeing domestic and foreign health authority readiness programs.
  - Established a robust, risk-based compliance and audit program; identified systemic gaps; aligned global and site-level objectives; and drove culture change and continuous improvement.
  - Collaborated with senior leadership and regional teams to resolve audit findings, implement corrective actions, and strengthen internal controls across the enterprise.
  - Directed global governance programs to analyze inspection outcomes, manage agency communications, and ensure consistent regulatory compliance.
  - Coached and developed global audit teams, enhancing technical skills, data integrity practices, and cross-functional coordination in support of FDA, EMA, ICH, USP, and CGMP requirements.

- **July 2021 – July 2023: KBI BioPharma, RTP, NC - *Director, Global Compliance, CMO and CDMO***
  - Led global inspection readiness for surveillance, PAI, for-cause, due diligence, and clinical-phase inspections, managing mock audits, steering committees, and real-

time inspection rooms in alignment with FDA, EMA, MHRA, Health Canada, ICH, and other global requirements.
    - Directed evaluation of inspection outcomes, authored responses to regulatory observations, and oversaw global SOP governance, change control, and risk-based internal audit programs to close compliance gaps and drive continuous improvement.
    - Managed global compliance performance, including CAPAs, deviations, investigations, client audits, DMFs, complaints, and KPI metrics—while coaching QA teams, developing training programs, and strengthening internal audit capabilities.
    - Led quality councils and improvement committees, maintained compendial and regulatory surveillance programs, and supported the design of QMS, RACI, and Quality Improvement Plans across the enterprise.

- **April 2020 – July 2021: Merck & CO - *Associate Director, Quality Systems & Compliance GMP Auditing Group***

    - Conducted audits of Merck sites, CMOs, suppliers, and contractors—on-site and virtually—ensuring compliance with FDA, EudraLex Volume 4, ISO 9001:2015, IPEC-PQG GMP standards, and Merck's internal requirements.
    - Evaluated third-party audit reports, tracked and assessed CAPAs, contributed to distributor qualification programs, and led the implementation of EXCiPACT certification and data integrity guidelines for excipient and raw material suppliers.

- **December 2014 – April 2020: United States Food and Drug Administration, Silver Spring, MD - *Regulatory Compliance Officer***

    - *Global Compliance Branch FDA/CDER/OC/OMQ* (2018 - April 2020)
    - Conducted global CGMP compliance analyses of drug product manufacturing facilities, identifying risks, trending quality issues, and initiating regulatory actions—including FARs, import alerts, recalls, inspections, warning/untitled letters, and regulatory meetings—to ensure drug safety and efficacy.
    - Provided expert guidance on CGMP, QMS, and technical scientific matters, reviewed firm responses, identified deficiencies and data integrity gaps, and collaborated with domestic and foreign regulatory authorities to achieve global compliance.
    - Drafted regulatory communications, including CRLs, memos, and reports, researched legal precedents, and supported agency task forces in developing policies and programs with national and international impact.

- **December 2014 – April 2020: *Drug Investigator FDA//ORA* - Office of Regulatory Affairs Rockville, MD**

    - Conducted domestic and international pre-approval and surveillance inspections across APIs, finished drugs, sterile, transdermal, biologics, OTC, and generics, identifying systemic compliance gaps and drafting FDA Form 483 citations.

- Served as SME in quality, CGMP, data integrity, CMC, laboratory testing, manufacturing processes, and analytical methods, evaluating process validation, batch records, and scientific data for identity, purity, strength, and potency.
- Prepared investigation reports, assessed inspection findings, and supported regulatory compliance and enforcement actions, ensuring drug safety, efficacy, and adherence to FDA, ICH, and global standards.
- Reviewed ANDA and NDA submissions, electronic and hardcopy scientific data, and cross-functional processes to maintain data integrity, regulatory compliance, and product quality.

- **May 2012 – October 2014: Hospira Inc (Generic Biosimilars APIs), Boulder, CO – *Lead Technical Data Reviewer/QA Compliance Auditor/QA Specialist***

  - Executed internal audits and inspections for commercial and non-commercial products, identifying CGMP deficiencies, systemic trends, and quality gaps, and preparing reports while supporting FDA inspection readiness and global remediation plans.
  - Evaluated and approved CAPAs, stability studies, process and analytical validation protocols, DMFs, and IQ/OQ/PQ equipment reports, ensuring data integrity, regulatory compliance, and adherence to FDA and ICH guidelines.
  - Investigated OOSs and deviations, assessed impact, tracked remediation effectiveness, and collaborated cross-functionally with QC, QA, Operations, and VRCS to implement corrective actions and best practices.

- **March 2011 – September 2011: 21st Century Healthcare, Arizona - *Quality Control Manager/Consultant - Nutraceuticals & OTC Products***

  - Led and managed Quality Control operations, ensuring consistent product release, adherence to CGMP, data integrity, and regulatory compliance across raw materials, in-process, and finished products.
  - Developed, reviewed, and approved SOPs, validation protocols, and stability programs while identifying process bottlenecks, investigating deviations/OOS/OOT, and implementing CAPAs to drive continuous improvement.
  - Supervised and trained QC staff, coordinated cross-functional activities, oversaw vendor qualification and equipment maintenance, and monitored KPIs to ensure product reliability, process efficiency, and inspection readiness.

- **November 2008 – March 2011: National Vitamin Company, Arizona – *QC Lead Analytical Chemist* (Nutraceuticals & OTC Products)**

  - Performed comprehensive analytical testing of APIs, raw materials, in-process, finished, and stability samples using FTIR, HPLC, UPLC, ICP-MS/OES, and GC, including potency, dissolution, elemental, and organoleptic analyses.
  - Developed, validated, transferred, and verified analytical methods per USP and ICH guidelines, reviewed and reported results, and ensured CGMP compliance, data integrity, and proper documentation.

- Investigated OOS/OOT and customer complaints, conducted root cause analysis, implemented CAPAs, monitored systemic trends, trained and supervised staff, and supported internal audits and FDA inspection readiness.

- **October 2005 – October 2008: IVC Industrial Coatings, Arizona - *Quality Assurance / Research & Development Chemist***
  - Established raw material specifications and process parameters to ensure product consistency, reduce costs, eliminate waste, and optimize efficiency and productivity.
  - Investigated product non-conformities and customer complaints, conducted root cause analysis, and implemented corrective actions.

- **February 2001 – September 2005: Alison Pharma, QC, Canada – *QA Supervisor***
  - Enforced CGMP compliance with Health Canada regulations, approving specifications and final test results for raw materials, in-process, and finished products using HPLC, FTIR, and wet chemistry.
  - Led internal and customer audits, identified deficiencies, followed up with CAPAs, and escalated findings based on severity.
  - Investigated OOS/OOT, conducted root cause analysis, approved certificates of analysis, and trained staff on annual CGMP refresher programs while monitoring performance.

Education:

- B.Sc. in Chemistry, Alexandria University, Egypt
- EMBA (in progress), Swiss School of Business and Management, Geneva
- Certified Quality Auditor (CQA, ASQ)
- Lean Six Sigma Green Belt (LSSGB) Year: Additional courses

- **Job Related Training**
  - Lean Six Sigma Green Belt (Lean principles, 5S, Kaizen, Value Stream Mapping, DOE, SPC, Error Proofing), CMQ/OE (ASQ, 2022); FDA Drug School I & II; FDA/CDER Aseptic Processing; FDA Medical Products Data Integrity (MP 324); Data Integrity in Drug Chemistry Labs; Process Auditing & Integrated Quality Management (ASQ); Risk-Based CGMP Regulations; Tablets & Capsules Hands-On Course (Univ. of Maryland); PDA/FDA Joint Regulatory Conferences (2018–2021); SERVICE Focused Leadership.