**SUMMARY**

An accomplished Therapeutic Goods Regulator with 9.5 years of experience dedicated to ensuring the quality, safety, and efficacy of pharmaceuticals, and therapeutic products in adherence to national and international regulatory standards. Proficient GMP/ GCP Auditor, specializing in GMP compliance. Expertise in evaluating Bio/ Pharmaceutical submissions in the CTD format and conducting testing and analysis of medical products, possesses interpersonal skills and an unwavering commitment to excellence.

**SKILLS**

* Expert in Testing and Analysis of Bio/ pharmaceutical Drug Products.
* Proficient in GMP/ GCP auditing with a focus on Risk-based Inspections.
* Skilled Assessor of Bio/Pharmaceutical dossiers presented in CTD format.

**EXPERIENCE**

**Deputy Director/ Federal Government Analyst, National Control Laboratory for Biologicals, Drug Regulatory Authority of Pakistan, Islamabad.**

**February 2023-Present**

* Federal Government Analyst (sole position in Pakistan in terms of biological products) based on technical expertise.
* Team Member (associate) of WHO Network of National Control Laboratories for Biologicals (WHO-NNB).
* Officially nominated as GMP/ GCP auditor by DRAP to conduct Risk Based Inspections (RBIs) of Bio/ Pharmaceuticals units (for APIs and Finished products), Government notified testing laboratories, and Clinical/ investigational sites and central laboratories.
* Lot Release reviewer of biological products as per WHO guidelines (Summary Protocol Review and/ or testing).
* Performs testing/ analysis, including physical, chemical (Hi-Tech equipment e.g., HPLC, GC-MS, Gel Documentation, Flow Cytometry, ELISA, and PCR) & microbiological assessments (Cell Line technique, sterility, and BET) of Biological Drug Products.
* Execute validation/ verification of methods including bioassays of biological products.
* Conducts internal audit and Laboratory Management System (LMS) based on ISO/IES 17025:2017.
* Hands-on expertise in LIMS installed at NCLB.
* Team member of Lot Release (LR) and Laboratory Testing (LT) tools of WHO-GBT for attaining maturity level III.
* Draft Guidelines and SOPs for Lot Release and Testing Protocols for Biological Products.
* Execute Qualifications and Calibration activities to ensure the highest quality standards.

**Deputy Director, Drug Regulatory Authority of Pakistan (Division of Biological Evaluation & Research).**

**December 2024 – Present**

* Conducts evaluations of biopharmaceutical dossiers in Common Technical Document (CTD) format.
* Officially nominated as GMP/ GCP auditor by DRAP to conduct Risk Based Inspections (RBIs) of Bio/ Pharmaceuticals units.

**Assistant Director/ Manager, Laboratory Operations, National Control Laboratory for Biologicals, Drug Regulatory Authority of Pakistan, Islamabad.**

**September 2021 – February 2023**

* Team Member (Associate) of WHO Network of National Control Laboratories for Biologicals (WHO-NNB).
* Conducted testing/ analysis, including physical, chemical (Hi-Tech equipment e.g., HPLC, GC-MS, Gel Documentation, Flow Cytometry, ELISA, and PCR) & microbiological assessments (Cell Line technique, sterility, and BET) of Biological Drug Products.
* Officially nominated as GMP/ GCP auditor by DRAP to conduct Risk Based Inspections (RBIs) of Bio/ Pharmaceuticals units (for APIs and Finished products), Government notified testing laboratories, and Clinical/ investigational sites and central laboratories.
* Executed validation/ verification of methods including bioassays of biological products.
* During Covid-19 Pandemic, provided laboratory services in terms of biological including vaccines.
* Conducted internal audit and Laboratory Management System (LMS) based on ISO/IES 17025:2017.
* Hands-on expertise in LIMS installed at NCLB.
* Team member of Lot Release (LR) and Laboratory Testing (LT) tools of WHO-GBT for attaining maturity level III.
* Team member of Market Control and Survey (MC) tool of WHO-GBT for attaining maturity level III.
* Drafted Guidelines and SOPs for Lot Release and Testing Protocols for Biological Products.
* Executed Validation, Qualifications and Calibration activities to ensure the highest quality standards

**Assistant Director, Drug Regulatory Authority of Pakistan (Division of Pharmaceutical Evaluation & Registration).**

**August 2022 – February 2023**

* Conducted evaluations of pharmaceutical dossiers in Common Technical Document (CTD) format, encompassing Modules 2&3.
* Officially nominated as GMP/ GCP auditor by DRAP to conduct Risk Based Inspections (RBIs) of Bio/ Pharmaceuticals units (for APIs and Finished products), Government notified testing laboratories, and Clinical/ investigational sites and central laboratories.

**Assistant Director, Drug Regulatory Authority of Pakistan (Health & OTC Division).**

**October 2018 - September 2021**

* Meticulously assessed dossiers related to Nutraceuticals / Health Products.
* Conducted comprehensive evaluation of dossiers associated with Herbal/ Unani medicines.
* Evaluated dossiers of Homeopathic/ bio-chemic medicines.
* Demonstrated leadership by drafting regulatory guidelines aimed at enhancing the quality of life through the effective regulation of Health Products and Alternative Medicines.
* Participated as a panel member in the inspection of Health Products/ Alternative Medicines manufacturing units ensuring adherence to GMP standards.

**Assistant Director, Drug Regulatory Authority of Pakistan (Division of Quality Assurance and Laboratory Testing Division).**

**August 2016 - September 2018**

* Assumed the role of Focal person of high-impact campaign aimed at eradicating spurious/ un-registered therapeutic goods in Pakistan.
* Undertook the rigorous evaluation of reports concerning Substandard and Falsified (SF) drugs, declared by Drug testing laboratories, ensuring the safety and quality of bio/pharmaceutical products.
* Demonstrated ability to manage and evaluate drug-related complaints, aligning with the commitment to safeguarding public health and product excellence.
* Acted as panel member in the inspection of manufacturing units ensuring adherence to GMP standards.

**Drug Analyst/ Assistant Pharmaceutical Chemist, Drug Testing Laboratory, Multan-Pakistan.**

**February 2016 - August 2016**

* Performed tests/ analyses including physical, chemical, and microbiological assessment of pharmaceutical drugs.
* Conducted internal audit and Laboratory Management System (LMS) based on ISO/IES 17025:2017.
* Part of team responsible for obtaining WHO-PQ status for DTL-Multan.
* Performed critical laboratory Operations ensuring the initiation and evaluation of OOS results, while effectively implementing CAPAs in alignment with Change Control, Deviation Control, Complaints reports and Quality related issues.
* Executed Validation, Qualifications and Calibration activities to ensure the highest quality standards.

**INTERNATIONAL ENGAGEMENT**

**Team Member of WHO Network of National Control Laboratories for Biologicals (WHO-NNB).**

**December 2021-Present**

* Actively participate in the WHO-NNB, contributing to global efforts to enhance vaccine access.
* Play a key role in sharing critical quality information, facilitating the recognition of responsible National Regulatory Authorities’ (NRA’s) Lot Release by recipient countries, supporting the efficient and safe distribution of vaccine worldwide.

**Expert Member of Group # 15 (Vaccine & Sera), European Pharmacopeia Commission (Volunteer Activity).**

**March 2024-Present**

* Contribute scientific knowledge and expertise for method development, validation/ verification of vaccines and sera related monographs.
* Actively participating in implementation of 4Rs policy for replacing the in-vivo testing with in-vitro testing of vaccines.
* Playing the role as an expert in advancing the quality and standards of Vaccines and Sera within the European Pharmacopeia.

**Expert Member of Vitamin Working Party (VWP), European Pharmacopeia Commission (Volunteer Activity).**

**March 2022-Present**

* Contribute scientific knowledge and expertise for method development, validation/ verification of vitamins related monographs.
* Playing the role as an expert in advancing the quality and standards of Vaccines and Sera within the European Pharmacopeia.

**International Society for Pharmaceutical Engineering (ISPE) (Volunteer Activity).**

**October 2023-Present**

* **Reviewer of ISPE Technical Guidelines.**
* **Expert member of QC/ Analytical CoP Steering Committee**: Dedicate efforts to enhance the acceptance, awareness, and practical application of Good Laboratory Practices (GLP), focusing on latest analytical methods development/ validation/ verification and its impact in the bio/pharmaceutical firms (including QC laboratories)
* **Expert member of GAMP South Asia CoP Steering Committee:** Dedicate efforts to enhance the acceptance, awareness, and practical application of the latest Good Automated Manufacturing Practices (GAMP) Guide, focusing on Data Integrity in GxP Computerized systems and its impact on the bio/pharmaceutical engineering field.
* **ISPE Mentor Program 2024:** Sharing of Bio/ pharmaceutical technical and regulatory knowledge to assigned mentees.

**Co-lead/ Expert Member of Parenteral Drug Association (PDA)(Volunteer Activity).**

**October 2023-Present**

* **Peer Reviewer of PDA Technical Series.**
* **USP:** part of commenting effort team on General draft Chapter 660 (Glass Containers) & 1660 (Evaluation of Inner Surface Durability of Glass Containers).
* **PDA Transport Validation Survey Team.**
* **FDA:** part of the commenting effort team on NDRP Modernization draft Guidance Document.
* **FDA:** provided technical comments on FDA draft guidance document for BIMO Inspections.
* **WHO-GMP: Prevention and Control of nitrosamine impurities in pharmaceuticals:** Provided substantial commenting effort on above-mentioned WHO draft guidance document.
* **Chinese Pharmacopeia guidance document- Pharmaceutical Water:** Providing substantial commenting effort on above-mentioned ChP draft guidance document.
* **Microbiology & Environmental Monitoring Interest Group:** Technically reviewed USP general chapters 1119 (Bioburden Monitoring & 1119.1 (Bioburden Testing).
* **Advanced Manufacturing and Applied Process Digitalization Interest Group:** Technically reviewed PDA-TR 74 *(Reprocessing of Biopharmaceuticals)*.
* **Sterile Processing Interest Group:** Technically reviewed *PDA-TR 69 (Bioburden and Bio-film Management in Pharmaceutical Manufacturing Operations)*.
* **GxP Auditing and Inspections Interest Group:** Provided substantial input and comments for the US-FDA Guidance Document “*Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities*”.
* **GxP Auditing and Inspections Interest Group:** Driving collaborative Commenting Effort for the US-FDA Guidance Document “*Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications*”.

**Secretary of Scientific Archiving Specialty Section (SASS) of Society of Quality Assurance (SQA) (Volunteer Activity).**

**(June 2025-Present)**

**Observer of Expert Committees of United States Pharmacopeia (USP) (Volunteer Activity).**

**October 2024-Present**

* Biologics 4-Antibiotics Expert committee
* Biologics Monograph 2-Proteins Expert Committee
* General chapter Expert Committee
* Complex Excipient Expert Committee.

**EDUCATION**

* **M.Sc. (Drug Regulatory Affairs)/ University of Nicosia, Cyprus 2025-Present**
* **M.Phil. Pharmacology / Bahauddin Zakariya University, Multan- Pakistan 2016**
* **Pharm-D/ The Islamia University of Bahawalpur-Pakistan. 2014**

**COURSES & CERTIFICATES**

* French Language Certificate- National University of Modern Languages, Islamabad-Pakistan.
* 5th Virtual cGMP Training Marathon for Vaccine Manufacturing- WHO-LPA.
* Laboratory Management System (LMS) and Internal audit based on ISO/IEC 17025:2017-Pakistan National Accreditation Council (PNAC) approved by Asia Pacific Accreditation Forum (APAC).
* Mentor under Society of Quality Assurance (SQA), USA Mentoring Program Q3/4, 2024.
* FDA Clinical Investigator Training Course (CITC) 2023- US-FDA.
* Advanced Good Manufacturing Practice (GMP) Inspections Course 2023- WHO-GLO.
* WHO Good Reliance Practices (GRelP)- WHO.
* Antimicrobial Stewardship Programs in Health Care Facilities in Low- and Middle-Income Countries (LMICs)- WHO.
* Regulatory Aspects of Pharmacovigilance- Uppsala Monitoring Centre (UMC) e-Learning.
* GMP Fundamentals: Records and Reports- International Society for Pharmaceutical Engineering (ISPE).
* GMP Fundamentals: Holding and Distribution- International Society for Pharmaceutical Engineering (ISPE).
* 2024 ISPE Online Seminar Series Module 01: QMS & Documentation.
* Pharmaceutical Systems Strengthening 101- Global Health e-Learning Center.

**ACCOMPLISHMENTS**

* Lead auditor in observed audit of a pharmaceutical firm, subsequent report writing on PIC/S pattern, and acknowledged by Ex-Chairman, TGA-Australia & PIC/S.
* Served as an observer in WHO Pre-Qualification (PQ) audits of Drug Testing Laboratory, Rawalpindi-Pakistan and Central Drug Laboratory, Karachi-Pakistan.
* Played as active role as an auditor in WHO observed audit during the Risk-based inspection of a Bio-pharmaceutical institute aiming for WHO Global Benchmarking Tools (GBT) Maturity level III.
* Conducted laboratory audit by WHO-GBT in terms of LR & LT tools.
* Appointed as a member of committees responsible for revising and reviewing the Global Benchmarking tool-Lot Release (LT) and Laboratory Testing (Vaccine) Indicators.
* Designated as the Focal Person of National Task Force (NTF) for the campaign to eradicate un-registered and spurious medicines (March 2018- September, 2018).

**MEMBERSHIPS AND HONORS**

* Membership of PDA (Parenteral Drug Association) along with member of following Interest Groups (IGs):
* Microbiology/ Environmental Monitoring
* Pharmacopeial
* Biopharmaceutical Manufacturing
* Bio-similar
* Sterile Processing/ Parenteral Drug Manufacturing
* Vaccines
* Advanced Virus Detection Technologies
* Facility & Engineering
* Process Validation
* Quality Risk Management
* Data Integrity
* Visual Inspection of Parenterals
* Technology Transfer
* Regulatory Affairs
* Pharmaceutical Water System
* Filtration
* Advanced Manufacturing and Applied Process Digitalization
* Membership of American Society of Microbiology (ASM).
* Reviewer of AAPS Journal.
* Reviewer, PDA.
* Reviewer for Journal of Ethno-pharmacology.
* Reviewer for Biomedical and Pharmacology Journal.
* Member, Punjab Pharmacy Council.

**LANGUAGE**

* English
* French (B1 level)

**PUBLICATION**

* **Potential Biomedical applications of *Araucaria araucana* as an Antispasmodic, Bronchodilator, Vasodilator and Antiemetic: Involvement of Calcium Channels.**

[Journal of Ethnopharmacology.](Journal%20of%20Ethnopharmacology.) <https://doi.org/10.1016/j.jep.2022.115651>.

**COMPUTER RELATED SKILLS**

* Proficient in utilizing various software tools and applications to enhance productivity and streamline processes, including:
* Microsoft Office Suite: Proficient in Word, Excel, PowerPoint, and Outlook for creating and managing documents, spreadsheets, presentations, and email communication.
* Statistical Software: Using statistical analysis tools to interpret data and derive meaningful insights for informed decision-making in LIMS, Empower.

In addition to the above, I possess a strong aptitude for quickly adapting to new software platforms and technologies to effectively address complex challenges and achieve objectives.