GAMAL ALDAGHADY

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Career Objective

Experienced in various quality control, compliance, and validation roles in the pharmaceutical and biotechnology industry; expertise includes reviewing and approving validation qualification documents for cleaning validation, sterilization, analytical lab equipment, change control, QC teams, audits, inspections, and CAPAs documentation in the GxP environment. Well-versed in FDA, IRB, ICH, and ISO standards and guidelines.

Summary Of Qualifications

- Over 20 years of multiple cross-function experiences in quality control, compliance, and validation expertise in the pharmaceutical and biotechnology industry. Skilled in GXP, FDA, ICH, and ISO standards, QC team management, laboratory operations, audits, inspections, and CAPAs.
- A detail-oriented, analytical, and problem-solving leader passionate about quality excellence and improvement.
- Awarded a certificate in recognition and appreciation of loyalty and diligence in Alzheimer's disease research BACE1 Inhibitor FIM, Merck Co. & Inc.
- Experience with FDA and IRB procedures and compliance in handling research and ethical issues.
- Documentation through 21 CFR part 11, GCP, and ICH guidelines.
- Experience in reviewing and modifications of existing CRFs, e-CRFs, Protocols, and SOPs
- Validating Computer Systems applications software and hardware with GXP (cGMP, GCP/GLP/GDP)
- Comprehensive working experience with analytical laboratory equipment, manufacturing, and documentation.
- Quality-related system compliance activities of Regulatory Risk Assessments (RRA), Regulatory Information Management (RIM), Data Migration Plan & Strategy (DMP & DMS), Requirements Specification (RS (URS/FRS)), Pre/Post Executed Test Scripts, Traceability Matrix, and the overall maintenance of system state of control.
- Experience with electronic document management systems (e.g., QMS, DocIT, and SharePoint); application development and lifecycle management (e.g., HP-ALM and JIRA); and IT service management systems (e.g., ServiceNow, SuccessFactors, and SAP Solution Manager).
- Experience with electronic (QMS) Quality Management Systems, including TMS, eTMFs, Argus, Documentum, SharePoint, TrackWise, and Veeva Vault systems.
- Reviewing and executing batch records for completeness and compliance with regulatory filings and executing the batch disposition process.
- Reviewing and approving validation qualification documents for sterilization and analytical lab equipment.
- Experience with MS Office software applications, excellent written and oral communication skills, and strong interpersonal.

- Self-motivated, focused achiever and team player; can work under pressure, leadership qualities; good interfacing with both clients and co-workers.
- Experience in manufacturing/packaging pharmaceutical products and collaboration with CMOs and 3rd party suppliers, including scale-up, technology transfer, and process optimization to ensure project objectives are met.
- Efficient operation of LC/MS/MS, HPLC, UPLC, GC – Headspace, TGA, TLC, UV-visible, FTIR, automated/manual dissolution apparatus, and dry/wet chemical techniques.
- Modified test methods to meet development needs under company SOP and ICH guidelines.
- Data acquisition systems include Turbochrom, EZ-Chrom, Totalchrom, Chemstation & Agilent Cerity NDS, Millennium (Empower I/II/III), and Masslynx V 4.1/4.2
- Ensured full compliance with cGMP, GCP, GLP, SOPs, USP/NF, ICH, OSHA, and FDA regulations.
- Support NDA filing processes, working independently in analytical, method development, Validation, and technical support services departments in various manufacturing and analytical environments.
- Reviewed promptly according to company SOP, test results, technical document data in LIMS/ lab notebook, and GMARS.
- Prepared Lab. investigation reports for (OOS) Out-of-specification samples and (IND) investigations of New Drug applications according to SOP and protocol guidelines.

Education/Certification

- Walden University, Minnesota, Master of Science in Clinical Research Administration, 2012.
- Cairo University, Egypt, Bachelor of Science in Chemistry, 1985.
- Certified CRA by Qtech-Sol Professional Development Center, Somerset, NJ, 2017.
- (Private Vocational School - Approved by Department of Education - State of New Jersey).
- Waters HPLC Acquity and Alliance 2695 PM/ Repair Service Training Certification.
- Waters HPLC Millenium + Empower data Acquisition Service Training Certification.
- Agilent HPLC 1100/1200 SERVICE Training Certification.
- Agilent GC 6890/7890 Headspace SERVICE Training Certification.
- Waters Quattro Micro LC/MS, Acquity LC/MS & ZQ2000 PM/ Repair Service Training Certification

Moderna Inc.

Sep 23 - May 2024
1 Moderna Way
Norwood, MA 02062

Sr. Validation Engineer (Consultant)

- Provide development and execution of QMS procedures, ICH Q1 (Stability Protocols / Reports), CFR 21 Part 211, 820, ICH Q8, ICH Q9, and ICH Q10
- Partner with the Digital team to expand and optimize digital systems such as LIMS (Lab Vantage) system, Smart QC Robot equipment, etc.
- Provide qualification and validation activities for projects involving GxP relevant to equipment qualification documents such as HPLC, UHPLC, CAD, GC, GC-Headspace,
- Experience with electronic asset management systems such as BMRAM and Maximo to submit and approve equipment requests (AIREQs, WREQs, CREQs, DREQs, etc.)
- Perform OOS/OOT investigation and deviation, follow the change control processes, and close all tasks before the due date.
- Experience with eQMS systems such as TrackWise1000 and Veeva Vault to provide trend analysis, impact/risk/root cause analysis, risk assessments, and CAPA effectiveness implementation.
- Provide technical training to new hires and cross-functional departments.
- Develop and execute validation deliverables to support project activities, including requirements specifications (URS/FRS), Pre/Post-Executed Test Scripts, a Traceability Matrix, and the overall maintenance of system state of control.

- Facilitate the Computer System Validation risk assessment to identify validation deliverables and requirements during project development.
- Ensured a comprehensive System Development Lifecycle Methodology aligned with GAMP 5 requirements, FDA regulation, and ICH guidelines.
- Comply with data integrity principles (ALCOA++) to ensure system validation meets the requirements of FDA regulations and ICH guidelines.
- Perform deviation investigations to identify root causes for non-conformance results via five-whys analysis, initiate deviation in the QMS, provide investigations as needed, and define corrective and preventative actions (CAPA).
- Responsible for conducting internal audits and inspections from regulatory agencies.
- Design, review, and execute validation document activities such as Factory acceptance test (FAT), Installation qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) for equipment /utilities/facilities and generate reports that summarize results specification and its acceptance criteria.
- Experience in electronic document management systems (e.g., QMS, DocIT, DocuSign, and SharePoint); application development and lifecycle management (e.g., Client ALM and JIRA); and IT service management systems (e.g., Service Now, Success Factors, and SAP Solution Manager).

Garden State Scientific, LLC
Jun 2021- Sep 2023
55 Madison Ave, Morristown, NJ 07960
Sr. Validation Engineer Manager

- Provides technical support and guidance on equipment installation, qualification, and site readiness activities.
- Ensure assigned processes comply with cGMP and FDA/EMEA guidelines.
- Review work plans, work records, and interfaces with lab personnel to ensure all expectations are met for QC equipment.
- Executes laboratory equipment implementation projects, including scheduling, procurement, site prep, IQ/OQ/PQ, and turnover to the business area.
- Performed solubility testing to assess the dissolution capacity of substances in designated solvents under controlled conditions, ensuring accurate analysis of compound behavior.
- Provide troubleshooting, repair, PM, qualification, and validation activities for GXP equipment.
- Establishes and maintains a safe laboratory working environment, trains employees on new SOPs, and maintains training records.
- Evaluate the root cause of failures and out-of-specification results and provide corrective and preventive actions (CAPA).
- Performed TOC (Total Organic Carbon) analysis to determine the total organic carbon accurately levels in various samples, ensuring a reliable assessment of organic material content.
- Prepare, create, and review validation protocols and execute validations/qualifications per Standard Operating Procedures (SOPs) and regulatory guidelines, analysis of ANDA.
- Analyzes statistical data and specifications to determine conformance with standards and established quality requirements and prepares final reports.
- For projects GxP, provide qualification and validation activities for equipment such as HPLC, UHPLC, CAD, GC, LC/MS/MS, and GC-MS.
- Performs re-qualification of equipment, facility, and utilities after each repair as required.
- Works closely with the maintenance and facility teams to complete new equipment installation, Commissioning/decommissioning and Validation are as per project requirements.

- My leadership style is collaborative and supportive. I focus on empowering team members to reach their full potential.
- Setting clear goals and expectations, providing regular feedback and coaching, and fostering a positive and inclusive work environment where everyone feels valued
- Ensured a comprehensive System Development Lifecycle Methodology aligned with GAMP 5 requirements, FDA regulations, and ICH guidelines.
- Comply with data integrity principles (ALCOA++) to ensure system validation meets the requirements of FDA regulations and ICH guidelines.
- Perform deviation investigations to identify root causes for non-conformance results via five-whys analysis, initiate deviation in the QMS, provide investigations as needed, and define corrective and preventative actions (CAPA).
- Experience in electronic document management systems and IT service management systems (e.g., Service Now, Success Factors, and SAP Solution Manager).

BMS Pharmaceutical Inc.
August 2020 – April 2021
New Brunswick, NJ 08901
GxP IT Quality Assurance & E-Compliance SME Lead (Consultant)

- Developed and implemented policies and procedures related to Quality related system compliance activities on Regulatory Information Management (RIM), Regulatory Risk Assessments (RRA), Data Migration Plan & Strategy (DMP & DMS), Requirements Specification (RS (URS/FRS)), Pre/Post Executed Test Scripts, Traceability Matrix, and the overall maintenance of the system state of control.
- Participated in study strategy development, eTMF, CTMS, and Summary Report Preparation.
- Created and implemented corrective action plans when performance expectations were unmet.
- Attends cross-functional meetings as needed to represent Clinical Operations and study-specific issues.
- Ensured a comprehensive System Development Lifecycle Methodology aligned with GAMP 5 requirements, FDA regulations, and ICH guidelines.
- Guided on quality issues that affect the integrity of the data or the system.
- Provided support services and governance to all supporting IT areas to ensure global alignment to the computer compliance, global Validation, and change control standards.
- Provided support to assigned Quality programs, such as Data Integrity Governance, Investigations, and Global Quality Headquarters Training as assigned.
- Electronic document management systems (e.g., QMS, DocIT, and SharePoint); application development and lifecycle management (e.g., Client ALM and JIRA); and IT service management systems (e.g., ServiceNow, SuccessFactors, and SAP Solution Manager).
- Experience with electronic (QMS) Quality Management Systems, including CTMS, eTMFs, Argus, Documentum, SharePoint, TrackWise, and Veeva Vault systems.
- Reviewing and executing batch records for completeness and compliance with regulatory filings and executing the batch disposition process.
- Ensured enterprise-level metrics and tracking for Corporate Computer-related CAPAs are maintained, periodically reviewed, reported appropriately, and recommended corrective actions.
- Approved validated computer system-related change requests.
- Ensured all departments comply with the Company's policies and procedures, including safety rules and regulations.
- Partnered with the IT Validation team (ITQM) to ensure and oversee risk assessments, ALM test scripts, and incident management aligned with corporate and data protection standards.

Fordoz Pharma Inc.
July 2014 – June2020
East Windsor NJ 08512
Validation Engineer Manager

- Wrote SOP and executed protocols to validate and maintain CAPA's annual periodic review with FDA regulations.
- Validated Empower software development lifecycle applications (SDLC) based on GXP (cGMP, GCP/GLP) guidelines.
- Managed Change Controls, System Requirements Analyses, and Process Improvement Activities.
- Reviewing and approving vendor validation qualification documents for sterilization and analytical lab equipment.
- Did project Management and automated mass calibration via IntelliStarTechnology, manual quadrupoles' calibration, MRM sensitivity (ES+/ESI-), maximize/optimize the resolution of quadrupoles mass analyzers (MS1/MS2), sample tuning and full scan, MRM & SIR method development.
- Calibrated, PM, and repair multi-vendor instruments such as LC/MS/MS (Waters Quattro Micro/ ZQ2000/TQD/UPLC/HPLC/GC- Headspace), Agilent 1100/1200/1290 HPLC, Waters HPLC 2695/2790/717, 600 Delta Prep sys, 2525, 2545, 2676 Fraction Liquid Handler, 2024, 2487, 2489, 2475 FLR, 2998, 2996/996 PDA detectors with minimum supervision.
- Performed IQ, OQ, and PQ for Agilent and Waters systems and completed all documentation with accuracy and compliance with regulatory standards.
- Data acquisition systems configuration such as Mass Lynx, Empower II, III, Totalchrom, and Chemstation.
- Interpreted, optimized & processed technical data based on SOP guidelines.
- Provided training to the scientists with course material on LC/MS/MS (Waters TQD/UPLC/HPLC/GC-Headspace).
- Comply with safety guidelines to ensure compliance with a GXP according to ICH and OSHA guidelines.
- Provided remote troubleshooting resolution both on-site and via telephone.
- Demonstrated ownership and manage expenses within the company budget and control inventories.

Merck Co. & Inc. via Perkin Elmer
Jul 2007 – Apr 2014
Rahway, NJ 07065
Sr. Validation Engineer

- Executes laboratory equipment implementation projects, including scheduling, procurement, site prep, IQ/OQ/PQ, and turnover to the production area.
- Executes CTU's (Controlled Temperature Units) qualification and Incubators.
- Provide troubleshooting, repair, PM, qualification, and validation activities for GXP equipment.
- Calibrated, PM, and repaired multi-vendor instruments such as Agilent 1100/1200/1290 HPLC and GC HP 5890/6890, Waters HPLC 2695/2790/717, 600 Delta Prep sys, 2525, 2545, 2676 Fraction Liquid Handler & 486, 2014, 2487, 2489, 2475 FLR, 2998, 2996/996 PDA detectors with minimum supervision.
- Performed PM and repair of Waters Quattro Micro & ZQ2000 LC/MS hardware, Waters UPLC (classic), (H&I- class) & Nano Acquity, Agilent 6400 ICP-MS, Teledyne Isco Combiflash RF200 & companion, and Perkin Elmer GC220 – Headspace

- Validating facility and utilities include HVAC systems for clean rooms, sterile products, Mille-Q purified water, USP water-for-injection, clean compressed air, and nitrogen and packaging equipment.
- Oversee applicable computerized systems and ensure compliance with FDA, USP, and EU guidelines.
- Technical operation lead and testing sample analysis are conducted in compliance with all applicable SOPs, Compendial Monographs, and approved protocols.
- Perform oligonucleotide analysis such as antisense oligonucleotides (ASOs) and small interfering RNAs (si-RNAs), to establish Single Stranded RNA purity, impurities and quality.
- Perform method development and validation testing on various studies, including Clinical, Microbiology, and Analytical Chemistry sample characterization.
- Evaluating and re-qualifying in-house developed methods, SOPs, or compendia procedures.
- Complied with SOPs and Safety Guidelines to ensure compliance with a cGMP, GCP/GLP according to FDA regulations, EMDA and ICH guidelines.
- Interpreted, optimized & processed technical data based on protocol guidelines.
- Software instruments configuration experience includes MassLynx, Millennium, Empower I/II, Chemstation, Mass Hunter, and Totalchrom.
- Provided diagnostic analysis and problem resolution both on-site and via telephone.
- Maintained expenses within departmental guidelines and controls inventory and all company property.

Merck Co. & Inc.
Jul 2003 – Apr 2007
Rahway, NJ 07065
Stability Research Scientist

- Maintains expertise on global product stability, including attributes that impact performance.
- Designs and executes required premarket stability program in support of post-approval changes.
- Complied with OSHA safety rules, GxP, and FDA regulations and followed procedures according to EUO, SOPs, ICH, and USP/NF guidelines.
- Perform standard API, in-process, stability sample, and finished product samples testing using LC/MS, HPLC, GC/MS, UV visible, FTIR, AAS, ICP/MS, TGA automated/manual dissolution apparatus, and wet/chemistry techniques.
- Interpret, optimize & process technical data, and document results in both technical lab notebook & LIMS according to SOP and protocol guidelines.
- Perform an impact assessment on change control activities and document the stability assessment in the change control documentation.
- Review and endorse change controls as an expanded reviewer. Initiate change controls related to stability operations.
- Review and approve study-specific protocols and batch enrollment forms; provide technical requirements in a Master Stability Protocol.
- Coordinate the annual commercial stability program for assigned products, including
- Issues, open Change Controls Request, and implement CAPA if necessary.
- Updated SOP; wrote test methods, method validation protocols, and reports.

Merck Co. & Inc.
Jul 2003 – Apr 2007
Rahway, NJ 07065
Stability Research Scientist

- Maintains expertise on global product stability, including attributes that impact performance.

- Designs and executes required premarket stability program in support of post-approval changes.
- Complied with OSHA safety rules, GxP, and FDA regulations and followed procedures according to EUO, SOPs, ICH, and USP/NF guidelines.
- Perform standard API, in-process, stability sample, and finished product samples testing using LC/MS, HPLC, GC/MS, UV visible, FTIR, AAS, ICP/MS, TGA automated/manual dissolution apparatus, and wet/chemistry techniques.
- Interpret, optimize & process technical data, and document results in both technical lab notebook & LIMS according to SOP and protocol guidelines.
- Perform an impact assessment on change control activities and document the stability assessment in the change control documentation.
- Review and endorse change controls as an expanded reviewer. Initiate change controls related to stability operations.
- Review and approve study-specific protocols and batch enrollment forms; provide technical requirements in a Master Stability Protocol.
- Coordinate the annual commercial stability program for assigned products, including
- Issues, open Change Controls Request, and implement CAPA if necessary.
- Updated SOP; wrote test methods, method validation protocols, and reports.

Sandoz (Novartis) Pharmaceutical Inc.
Apr 2001 – Apr 2003
Dayton NJ 08810
Stability and Cleaning Validation Scientist

- Perform standard API, in-process, stability sample, and finished product sample testing by using LC/MS, HPLC, GC/MS, UV visible, FTIR, AAS, ICP/MS, TGA automated/manual dissolution apparatus, and wet/chemistry techniques to determine assay & impurities.
- Complied with OSHA Safety Guidelines, cGMP, GCP, GLP, and GDP according to the FDA, ICH, and USP/NF guidelines.
- Interpret, optimize & process technical data based on protocol guidelines and document results in a technical lab notebook.
- Experience with instrument software acquisition systems such as Millennium, Empower I/II Chemstation, and TotalChrom.
- Performed Validation, calibration, P.M., and repair of laboratory instruments.
- Provided validation engineering such as IQ, OQ, PQ for GC, HPLC, UV, and FTIR
- Provided diagnostic analysis and problem resolution on-site.
- Maintained expenses within departmental guidelines and controls inventory and all company property.
- Experience with Cleaning Validation, Sterilization, & Aseptic Processing Validation of cleaning reusable product contact equipment.
- Perform Clean-in-Place (CIP) or Clean-out-of-Place (COP) technology to demonstrate that the cleaning methods employed are/are not effective in removing product and process residues, cleaning agents, and microbial contaminants to predetermined acceptable levels.
- Executed swab surface testing to collect samples from surfaces for detecting microbial contamination
- Solubility testing determines a substance's ability to dissolve in a particular solvent under specific conditions.
- Utilizing MACO testing (maximum allowable carryover) of a product from one batch to the next to ensure that product contamination is within acceptable limits.