MOHAMMED H. KHAN

M.Sc, PGDCP, MS, LSSGB, PMI®-PMP, PMI®-ACP

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PROFESSIONAL SUMMARY

Pharmaceutical, biotech, medical device and cosmetics leader with **25+ years** of combined experience across drug development, CMC, quality, regulatory operations and project management, from Fortune 500 companies and mid-size generics to biopharma start-ups and multinational device manufacturers. Certified PMP and PMI-ACP with 9+ years of project management experience (Agile and Waterfall), 11+ years in quality management, and 12+ years in R&D and QC laboratory management. Has managed multimillion-dollar projects and teams of 11 to 32, led pre- and post-approval FDA inspection readiness, and supported EU MDR remediation and EMA IDMP implementation.

CORE COMPETENCIES

Project & Program Management

- PMP and ACP certified; Agile, Waterfall, SDLC, PDLC, PLM
- RAID logs, RACI, stakeholder and risk management
- Site separations for two major M&As
- MS Project, JIRA, Confluence, SharePoint

Quality & Compliance

- cGMP / cGLP / cGXP, ISO 13485, 21 CFR 210/211, 820, Part 11
- CAPA, OOS, change control, Six Sigma RCA
- Supplier, CRO and CMO audits (21+ sites)
- FDA 483 responses, inspection readiness

Regulatory & CMC

- EU MDR remediation, MDD to MDR rollover
- EMA IDMP / SPOR, VEEVA Vault RIM
- CMC Modules 3, 4, 5; IND, CTX, NDA, ANDA, BLA
- USP, EP, BP and ICH guidelines

Analytical & Laboratory

- HPLC/UPLC, GC, LC-MS, FT-IR, dissolution, TOC
- USP <787>, <788>, <467>, <698>
- 60+ stability-indicating methods developed
- IQ/OQ/PQ and instrument calibration

Biologics & Dosage Forms

- Proteins; upstream and downstream processes
- Solid oral, parenteral, lyophilized, topical
- Sterile drug and device combinations
- Stability programs per ICH

Systems & Software

- Empower, LIMS / GLIMS, EZChrom, TrackWise
- Veeva Vault, Salesforce, MasterControl
- JMP, DryLab, ACD HPLC software
- Office 365, Visio, Box

PROFESSIONAL EXPERIENCE

United States Pharmacopeia (USP)

Rockville, MD | 02/2025 – Present

Senior Donations Engagement Manager, Regions & Program Operations (Small Molecules)

- Engage the global biopharma market on USP's donations program to develop monograph standards for drug substances and drug products.
- Manage **72+ pharma and biopharma accounts**, tracking document submissions for monograph development in Salesforce.
- Secure bulk material from donors for USP reference standards and follow Pharmacopeial Forum proposals through FDA comments.
- Use the Orange Book and Cortellis to evaluate NDA and ANDA submissions; deliver market research and customer insights.

Bausch & Lomb Pharmaceuticals

Tampa, FL | 10/2023 – 11/2024

Project Manager, GLIMS Instrument Implementation

- Led implementation and connectivity of laboratory instruments to the Global LIMS (GLIMS), keeping milestones aligned to the master project plan.
- Project manager for the instrument site separation from B&L Corporate to the Tampa site; authored site policies and procedures.
- Produced full validation lifecycle documentation (URS, SRS, risk and GxP assessments, traceability matrix, IOQ protocols and reports).
- Managed QCRs and ITCRs for instrument software, updated SOPs, and presented weekly status to the GLIMS team and senior management.

Takeda Pharmaceuticals Boston, MA | 09/2022 – 08/2023

Business Project Manager, IDMP Implementation

- Managed implementation of IDMP (ISO 11238, 11239, 11240, 11615, 11616) for EMA: data enrichment and migration, RIM configuration, validation and training.
- Validated the new Veeva Vault RIM system and migrated data from legacy systems (PRISM, MOSAIC, ShEDS, GRACe).
- Built the project charter and plan (MS Project), maintained the RAID log, and ran change control and risk tracking in JIRA and Confluence.
- Worked on SPOR, the PMS FHIR interface and DADI to replace electronic application forms with web-based forms.

Indiana Botanic Gardens / Topical Pharmaceuticals Hobart, IN | 12/2018 – 09/2022

Director, Quality Assurance / Quality Control

- Led the complete Quality Management System and regulatory compliance for the site, with **28 direct reports** across manufacturing, QC, shipping and receiving, and engineering.
- Interacted directly with the FDA on submission responses; ran gap analyses and risk assessments and implemented SOPs and quality systems.
- Launched change control, OOS/deviation and CAPA systems; built vendor management and contract-lab programs; led site and supplier audits.

Baxter Healthcare Corporation Round Lake, IL | 05/2018 – 11/2018

Project Manager, Medication Delivery: MDD to EU MDR Remediation

- Led full-lifecycle EU MDR remediation for **487 product lines** (Class I, IIa, IIb, III), covering IFU and CE-marking priorities.
- Ran cross-business-unit workstreams: Design & Construction, Labelling, CER, hazardous materials, economic operators, QMS and third parties.
- Supported PMS, PMCF and clinical data evaluation for CERs, DHF remediation, and team training on MDR with TUV and BSI.

Johnson & Johnson, Global Source Quality / WuXi Therapies Skillman, NJ | 09/2016 – 05/2018

Manufacturing / Quality / Project Manager, Contract Manufacturing Sites

- Managed projects across J&J contract manufacturing sites for manufacturing, quality and supply chain, including equipment commissioning.
- Co-audited sites, drove remediation plans, and brought sites to cGMP and cosmetic-regulation standards using Six Sigma processes.
- Led artwork and label projects for a consumer product line; authored SOPs, deviations and CAPAs; presented quality trending to senior management.

Therapeutic Proteins Intl (TPI) / Adello Biologics Chicago, IL | 07/2014 – 07/2016

R&D and Quality Manager: R&D, CMC, Validation and Quality Control

- **Saved about $500K** by bringing TOC, conductivity, sterility, endotoxin and residual DNA testing in-house and setting up a micro lab.
- Acted as liaison through the separation of TPI from Amneal and its merger with Kashiv Biosciences during the large-molecule launch.
- Managed qualification and calibration of 100+ instruments, stability testing, and transfer of HPLC, bioassay, ELISA, SDS-PAGE and iCE3 methods to QC.
- Audited testing labs and worked with CROs on DNA, kanamycin, glycine, cyanide and clearance studies for downstream readiness.

Priority Care, Inc. Elgin, IL | 06/2012 – 04/2014

Quality Manager: QC / QA / Validation

- Led QC and R&D for the full product line (14 direct and 2 indirect reports); built the ICH stability program and method validation function.
- Owned equipment and instrument IQ/OQ/PQ, vendor qualification, change control, and quality and service agreements; reviewed validation protocols and batch records.

Coldstream Laboratories, Inc. Lexington, KY | 06/2011 – 06/2012

Project Manager, Analytical R&D

- Managed small to large multi-department projects in MS Project; served as liaison between business development and clients and presented stage-gate milestones.
- Developed GC methods for residual solvents and particulate methods for parenterals (USP <787>).

Consultant at Pfizer and Baxter Chicago Heights, IL | 08/2009 – 06/2011

Customer Analytical Support: Method Development and QC Scientist

- Remediated HPLC methods to answer FDA concerns, transferred numerous HPLC methods to UPLC, and trained colleagues.
- Developed and validated stability-indicating HPLC/UPLC methods for 12 vitamins in a lyophilized multi-vitamin formulation.

Eli Lilly & Company, Lilly Research Laboratories Indianapolis, IN | 07/1994 – 06/2009

Assistant Senior Analytical Scientist: CMC, New Products to Launch (15 years)

- Provided project management for cross-functional and third-party teams from initiation through launch; co-led Global Product Development Teams.
- Developed and validated 18 early-phase and 9 late-phase methods; led global method transfers to Lilly sites in the US, Brazil, Germany, France, Belgium and Mexico.
- Authored CMC sections for IND, CTX and NDA filings and supported pre-approval inspections with the FDA and EU regulators.
- Negotiated CMO and CRO contracts, ran ICH stability studies for Zones I to III, and supervised 2 associate scientists and 4 technicians.

EDUCATION

M.S., Analytical Chemistry	Northeastern Illinois University, Chicago, IL	1994
M.Sc., Analytical Chemistry	Aligarh University, India (minor: Organic Chemistry)	1986
B.Sc., Chemistry	Osmania University, India (minor: Biology)	1984
PG Diploma, Computer Programming	Setwin Institute of Management and Computer Sciences, India (3.4/4.0)	1987

CERTIFICATIONS

Project Management Professional (PMP)	Project Management Institute	2024
Agile Certified Practitioner (PMI-ACP)	Project Management Institute	2023
Six Sigma Green Belt	Management & Information Technology Solutions	2019
PM Knowledge Base, Agile and MS Project	Management & Information Technology Solutions	2018

AWARDS, AFFILIATIONS & RESEARCH

- **Awards:** Eli Lilly Time Management Award; Aligarh University Merit Scholarship (1984); Northeastern Illinois University Certificates of Excellence (1992–94) and Outstanding Research Certificate (1994).
- **Affiliations:** Project Management Institute (PMI), American Chemical Society, Pharmaceutical Chemists Association.
- **Research:** Developed a micellar HPLC method for cotinine and nicotine in plasma, urine and saliva, compared with GC; introduced new chemistry experiments for Illinois Board of Governors universities. Presented and published at the 2nd and 5th student research symposia.