

MD. HUMAYAN KABIR

Pharmaceutical Quality Assurance Professional | Regulatory Compliance | Research

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Professional Summary

Pharmacy professional with an MSc in Pharmaceutical Technology (CGPA 3.81/4.00), a B.Pharm (Honours), and more than six years of experience across pharmaceutical quality assurance and quality control. Experienced in deviation investigation, CAPA, root-cause analysis, change control, quality risk management, audit readiness, and pharmacopeial testing within facilities operating to US FDA, UK MHRA, EU GMP, TGA, and ANVISA expectations. Research interests include pharmaceutical quality systems, medication safety, pharmacovigilance, regulatory science, and healthcare quality optimization.

Professional Experience

Renata Ltd.

Bangladesh

Assistant Manager – Quality Assurance

Present

- Lead and review more than 100 deviation investigations, ensuring evidence-based root-cause analysis, defensible conclusions, and timely closure.
- Coordinate corrective and preventive action (CAPA) implementation across multidisciplinary teams and monitor effectiveness to reduce recurrence.
- Conduct quality risk assessments aligned with ICH Q9 principles and support risk-based decisions within the pharmaceutical quality system.
- Support inspection and audit readiness for international regulatory authorities, including documentation review, gap identification, and follow-up actions.
- Contribute to continuous improvement of deviation, CAPA, and compliance processes in a globally regulated manufacturing environment.

The ACME Laboratories Ltd.

Bangladesh

Executive – Quality Assurance

2020 – 2022

- Coordinated the change-control lifecycle, including initiation review, impact assessment, implementation tracking, documentation, and closure support.
- Assisted with self-inspection programs and follow-up activities to strengthen GMP compliance and operational discipline.
- Contributed to Quality Management Review documentation by consolidating quality-system information and supporting management oversight.

Aristopharma Ltd.

Bangladesh

Officer – Quality Control

2018 – 2019

- Performed raw-material sampling and finished-product analysis in accordance with approved procedures and applicable pharmacopeial requirements.
- Documented analytical activities accurately and supported laboratory compliance, data integrity, and timely release decisions.

Education

University of Asia Pacific

Dhaka, Bangladesh

Master of Science in Pharmaceutical Technology; CGPA: 3.81/4.00

2019

University of Asia Pacific

Dhaka, Bangladesh

Bachelor of Pharmacy (Honours); CGPA: 3.68/4.00; 162 credits

2018

Core Competencies

Quality Systems: Deviations, CAPA, root-cause analysis, change control, self-inspection, Quality Management Review, effectiveness checks, and continuous improvement.

Compliance and Risk: GMP, ICH Q9 quality risk management, audit readiness, data integrity, document review, and cross-functional compliance coordination.

Laboratory and Technical: Raw-material sampling, finished-product analysis, pharmacopeial testing, dissolution profiling, pharmaceutical equivalence, and analytical documentation.

Regulatory Environments: Experience supporting operations in facilities approved or inspected against US FDA, UK MHRA, EU GMP, TGA, and ANVISA requirements.

Research and Academic Work

- Master's Project: Review of Transdermal Drug Delivery Systems** University of Asia Pacific
– Evaluated transdermal delivery mechanisms, permeation enhancers, formulation considerations, and pharmacokinetic implications.
– Critically examined clinical-translation barriers and the factors affecting successful delivery-system performance.
- Bachelor's Project: Comparative In-Vitro Analysis of Ranitidine Tablet Brands** University of Asia Pacific
– Conducted comparative dissolution profiling and quality assessment of marketed tablet brands.
– Evaluated pharmaceutical-equivalence parameters and interpreted in-vitro performance differences.
- Joint Publication** Co-author
– Contributed as a co-author to one joint publication in pharmaceutical sciences.

Selected Academic Coursework

Postgraduate: Advanced Pharmaceutical Technology, Modern Drug Delivery Systems, Biopharmaceutics and Pharmacokinetics, Pharmaceutical Manufacturing Management, and Advanced Pharmaceutical Engineering.

Undergraduate: Pharmaceutical Regulatory Affairs, Advanced Pharmaceutical Analysis, Hospital and Community Pharmacy, Pharmaceutical Biotechnology, Pharmaceutical Packaging Technology, Pharmaceutical Engineering, Medicinal Chemistry, and Pharmacology.

Academic Honours

- Vice Chancellor's List of Meritorious Students** Spring 2017
– Achieved a semester GPA of 3.98/4.00 and was recognized by the University of Asia Pacific for exceptional academic performance.
- Dean's List of Meritorious Students** Fall 2016 and Fall 2017
– Recognized for outstanding academic performance after earning semester GPAs of 3.86/4.00 and 3.79/4.00.

Industrial Training

- Beximco Pharmaceuticals Ltd.** Bangladesh
In-Plant Training May 27 – Jun. 6, 2018
– Observed manufacturing activities, processing equipment, oral solid and liquid dosage-form operations, large-volume parenteral production, and quality-control laboratory instrumentation.
– Developed practical understanding of pharmaceutical production systems and quality-management controls.

Professional Training and Development

- **GMP Level-1 Certification** – foundational GMP principles and regulated pharmaceutical operations.
- **Lean Manufacturing and Production Optimization** – process efficiency and waste-reduction concepts.
- **Data Integrity and 5S Methodology** – reliable data practices, workplace organization, and operational discipline.
- **Australian Pharmacist Registration Preparation** – preparing for the Australian Pharmacy Council OPRA pathway.

Research Interests

Pharmaceutical Quality Risk Management | Medication Safety and Pharmacovigilance | Clinical Pharmacy Outcomes Research | Healthcare Service Optimization | Regulatory Science and Policy | Data-Driven Healthcare Quality Systems

Language Proficiency

- **Bangla:** Native proficiency.
- **English:** PTE Academic overall score 63 – Listening 68, Reading 56, Speaking 65, Writing 65; tested September 28, 2025 and valid through September 28, 2027.

Additional Information

- Career objective: integrate doctoral research with clinical pharmacy practice and pharmaceutical quality improvement in Australia.
- Professional references are available upon request.