Mohammed Ashfaq Hussain

Quality Assurance Associate

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PROFESSIONAL SUMMARY

Accomplished pharmaceutical professional with over **10 years of diverse experience** in in-process quality assurance, quality management systems, equipment validation, drug product quality assurance, and project plants. Proven ability to lead cross-functional teams, drive process improvements, and ensure compliance with regulatory standards. **Seeking a mid-senior level position to leverage my expertise and contribute to innovative advancements in the sterile pharmaceutical industry.**

Core competencies:
Quality Management & Compliance – Managed QMS documents (change controls, deviations, CAPAs), conducted GAP & Root Cause Analysis, ensured compliance with corporate and regulatory policies, and supported audits.
Validation & Equipment Qualification – Developed and executed validation protocols (IQ/OQ/PQ) for GMP computerized systems and equipment like sterilizers, washing machines, tunnels, and lyophilizers.
Process Improvement & Troubleshooting – Led new process development, troubleshooting, and radiation audits per EMA guidelines; provided solutions through investigations.
Regulatory Support & Documentation – Assisted in regulatory inspections (USFDA, EMA), presented data in audits, and developed quality systems and procedures for facility start-up.
Training & Team Collaboration – Conducted training on quality and validation procedures, supervised validation teams, and worked effectively with cross-functional teams using tools like Microsoft Office, Yokogawa, and Kaye Validator.

Application's Handling:
MES (Werum PAS-X) – Hands-on experience in designing and managing electronic Batch Manufacturing Records (eBMR), ensuring compliance with GMP and real-time production monitoring.
Dochub – Creation, review, and approval of Standard Operating Procedures (SOPs) with effective document control and compliance assurance.
Eval – Expertise in evaluating qualification and validation documents to ensure adherence to industry regulations and operational standards.
SAP – Skilled in resource planning, inventory management, and procurement to optimize production efficiency.
DCMS – Proficient in handling deviations, implementing change controls, and managing CAPA processes to maintain regulatory compliance and process integrity.

EXPERIENCE

Quality Assurance Associate — Jan '22 — Present
Dr. Reddy’s Laboratories Ltd — Hyderabad
Quality management system, Manufacturing assurance and shop floor compliance (Project plant)

Quality Assurance Sr. Executive — Dec '18 — Dec '21
Aurobindo pharma Ltd Unit XVI — Hyderabad
In-Process Quality Assurance

Quality Assurance Executive — Aug '16 — Nov '18
Biocon Ltd — Bangalore
Equipment Validation and Compliance (Project plant)

Quality Assurance Executive — Nov '14 — Aug '16
Aurobindo pharma Ltd Unit XII — Hyderabad
QA Reviewer & In-Process Quality Assurance (Project plant)

EDUCATION

M- Pharmacy in Pharmaceutics, Pulla Reddy institute of Pharmacy (GPA: 64.88) — 2014 — 2016, Hyderabad

B-Pharmacy in Pharmacy, Arya College of Pharmacy (GPA: 67.5) — 2010 — 2014, Hyderabad

Bi.P.C in Intermediate, Nagarjuna Junior College (GPA: 69.9) — 2008 — 2010, Sangareddy

SSC in , Sai Grace High School (GPA: 67.5) — 2008, Sangareddy

CERTIFICATIONS

Certificate of Appreciation for ARC 101 Product PAC, Dr. Reddys Laboratories Ltd — Jan '25

AWARDS

Team award for the MES Application and Participation in Volunteering activities Nov '23
Dr. Reddy's Laboratories Ltd

SKILLS

Technical Skills Quality Management, Equipment Qualification, Data Analysis, Process Quality Improvement
Leadership & Project Management Skills Team Management, Project Coordination, Problem Solving
Soft Skills Communions, Critical Thinking, Collaboration

WORK EXPERIENCE AND RESPONSIBILITIES

Handled and investigated Quality Management System (QMS) documents, including change controls, deviations, and Corrective and Preventive Actions (CAPAs).
Developed computer system validation content, controlled documents, and protocols for GMP computerized systems, including steam sterilizers, washing machines, tunnels, filling and sealing machines, and lyophilizers.
Conducted GAP analysis, Root Cause Analysis (RCA), and Corrective and Preventive Actions (CAPA); managed incident reporting within the quality management system.
Ensured compliance with corporate and legislative validation policies; supported regulatory inspections and provided responses to auditors.
Prepared, executed, and reviewed validation protocols (IQ/OQ/PQ) for various equipment, including autoclaves, SIP cycles, deep freezers, refrigerators, cold rooms, and more.
Established validation parameters for radiation audits and conducted quarterly radiation audits according to EMA (EN 285) guidelines.
Coordinated new process development and troubleshooting; managed validation activities per SOPs and regulatory guidelines.
Worked effectively in team settings, providing support and guidance; proficient in Microsoft Office Suite, Yokogawa, and Kaye Validator.
Managed multiple projects, prepared status reports, and supported associate engineers and technicians with their projects.
Presented data in regulatory, customer, corporate, and internal audits; developed quality systems and procedures for facility start-up.
Conducted training on quality and validation procedures for cross-functional teams; supervised validation specialists and technicians.
Interacted with various regulatory bodies (USFDA, EMA, etc.); supported audit-facing teams and acted as SME and scribe for validation activities.
Aided in investigations and troubleshooting as part of a multi-functional team to provide solutions and recommendations for improvements.

ACHIEVEMENTS & LEARNING

Reduced deviations by 30% through enhanced in-process QA protocols.
Appreciation for involving in Qualification activities of Devices and Facility project B2 Fill Finish.
Computer System Validation (CSV & Quality) in pharma – Udemy.
Learned Overview of the Course and Career opportunities, Product Life Cycle, Risk Assessment, GMP and Pharma Regulations and Quality Management System (QMS) Framework.
A Managers Guide: Work Responsibilities and Psychology – Udemy.
Used this course to learn various responsibilities, including; delegation, motivation, mentorship, Communicating and collaborating, Leading a team effectively.
Post graduation diploma in guidance and counselling: Psychology -Galgotias University.
I bring a deep understanding of human behavior and effective communication skills, enhancing my ability to lead teams and manage quality assurance in a dynamic pharmaceutical environment

DECLARATION

I hereby declare that the above-mentioned information is true and correct and I bear the responsibility for the correctness of the above-mentioned particulars.

Place:
Date: **(MOHAMMED ASHFAQ HUSSAIN)**