Shabbir H Malik

House No.321, 8th Main, 1st Block,
HRBR Layout, Kalyan Nagar
Bangalore - 560033.
E-mail:shabbirmh@hotmail.com

M: **+919611197673**
M: +91**8283801338**

Experienced Pharmaceutical Quality Operations Professional

Leader with an ability to define vision for organization, focus on the same, set high expectations & produce results, seeking senior level assignments with an organization of repute.

PROFILE-

- High-performing professional and Competent Technical person with twenty five years of experience in state- of- art plants in Sterile & Non-Sterile dosage formulations and Sterile API's & Biological manufacturing in leading Indian & Multinational Pharmaceutical Organizations catering to high regulated markets.
- Hands on experience in new plant set-up, Qualification, Technology transfer, Validation, Designing Quality system, Data Integrity, Quality Risk Management, GDP, Contract manufacturing, and Auditing.
- Proven track record of heading Corporate QA, Site Quality Operations of Indian & Overseas sites.
- Well versed in people management and compliance with market requirements and regulations.
- Manager with expertise in handling business dynamics, quality, regulatory & cost sense.
- Strong understanding of 25 years in Aseptic processing, Media fills, Sterilizations, Fermentation, Microbiological principles, Lyophilization and Solid dosage formulations.
- Understanding of technicalities of Facilities, Machineries and Utilities.
- Exceptional mentoring skills in transforming low performers to a high performing team through design & implementation of training programs for fostering high energy levels and team spirit.
- Excellent interpersonal and communication skills.
- Well groomed to manage higher responsibilities through various training & wide exposures.
- Experienced in Plant Quality, Corporate Quality & Regulatory.
- Developing Quality culture in manufacturing organization.
- Designing Quality Metrics & reducing waste on the Cost of Quality.

Hold the credit of -

- Handled successfully various QA functions like Plant Quality Operations, & Corporate Quality Assurance.
- New facility set-up, quality system designing & implementation in Parenterals, Vaccines, Biotech products Oncology, High potent products, and Solid Oral dosage.
- Core member of strategic team to provide an overall leadership and guidance for facility approval & regulatory inspections.
- Faced more than 50 regulatory inspections, majority of them with USFDA & UK MHRA in Sterile Operations (USFDA, UKMHRA, EU, TGA, AFSSAPS, ANVISA, PIC, MCC, WHO Geneva and others).
- Conducted over 60 quality audits in several countries for Sterile & Non-sterile API's, Biologicals, Primary packaging and contract manufacturing sites.

Technical Competencies:

- ❖ **Quality Management Assurance, cGMP and Regulatory Inspections.**
- ❖ **Aseptic Processing and Sterilizations.**
- ❖ **Quality Risk Management – Designing & implementation of QRM policies for Aseptic, Biological & OSD facilities/Operations.**
- ❖ **Excipient Risk Assessment.**
- ❖ **Auditing & Regulatory compliance and Technical training.**
- ❖ **Failure Investigations & Resolving regulatory complications.**
- ❖ **Qualification, validations and technical transfers of Sterile & Non Sterile dosages.**
- ❖ **Containment of Cytotoxic, Steroids & Biological Hazards.**
- ❖ **Due diligence, Quality system integration.**

- ❖ **Sound understanding of HVAC, Water system, Cleaning validation, Equipment & process qualification, lyophilization, etc.**
- ❖ **Design & Developing Quality Metrics.**

EXPERIENCE & PROFESSIONAL DEVELOPMENT

Vice President - Corporate Quality Assurance & Quality Operations, Medreich-meiji, Bangalore
August 2014 – Till Date

Medreich is a leading CRAMS organization involved in manufacturing of formulations for multinationals like GSK, Pfizer, Sanofi Aventis, Wyeth, Adcock Ingram, Mylan, Actavis and many other customers. The manufacturing sites are with accreditations from UK MHRA, PMDA, Japan, TGA, MCC, PIC/S and other regulatory bodies.
Medreich is 100% owned subsidiary of **Meiji group**, Japan.

- Responsible for Corporate Quality Assurance function & Site Quality operations of 8 manufacturing sites.
- Improving Quality governance at manufacturing sites.
- Represent QA at senior management, project, board and review meetings.
- Part of the quality leadership team and work with senior management for devising strategies.
- Provide oversight for Quality Assurance across Medreich and Contract manufacturing sites.
- Formulate and execute strategy on quality management to ensure that the manufacturing facility is continuously in compliance with cGMP.
- Formulate & execute strategy for continuous enhancement of Pharmaceutical Quality System (PQS) in-line with the new trends in the industry and proactively upgrade PQS to be in compliance with the new guidelines.
- Manage the overall quality assurance by reviewing all plant-related documents & processes of the manufacturing organisation on an ongoing basis.
- Travel to the manufacturing facility periodically and continue to monitor, update, and ensure that the plant is in compliance with all the expectations of regulatory bodies.
- Enhance, upgrade and improve quality management system at the facility.
- Ensure that cGMP requirements and Quality standards are recognized, understood and maintained across the company.
- Key player in the integration of Quality systems between Medreich Global & Meiji.
- To review and study various industry trends such as warning letters and 483s given to other companies; attend industry events and conferences; and remain abreast with new guidelines from FDA, UK MHRA, EU and work on preventive actions so as to proactively avoid such observations in our own manufacturing organisation.
- Plan and execute continuous evaluation & enhancement programmes related to compliance in-line with Good Manufacturing Practices (GMP) along with the team in India.
- To review, analyse, and evaluate Quality Management Documents and make corrective & preventive action plans, and work in sync with the team in India for the closure of the same.
- Execute quality assurance initiatives in auditing, gap assessments, quality management system implementation, training, QMS maintenance, vendor management and technical writing.
- Driving Excipient Risk Management in accordance to EMA guidelines.
- Identify trends in rejections, deviations, Out of Specification reports, annual product reviews, complaints, CAPA, Change control; and analyse, investigate and make required action plans to work with the Indian team to conclude root-cause analysis with risk mitigation plan.
- Design & Successful implementation of Quality Metrics.
- Driving Qualty Risk Management across manufacturing sites.

- To review the Quality Governance Systems and continuously enhance them to increase management bandwidth of the quality organisation to align with the opportunities for growth.
- To review the organisational design & effectiveness of the quality team and formulate & implement Quality Improvement Plan (QIP), various training & organisational development programmes along with management.
- To impart training to the quality & manufacturing teams of all the manufacturing organisations to enhance knowledge and skills of the members.

Head of CQA, Panacea Biotec Limited, September 2012 – August 2014

- Designed & implemented Corporate Quality guidelines and policies encompassing cGMP expectations from various regulatory agencies.
- Overarching Quality problems.
- Educated Site Quality Heads on critical quality management skills, including decision-making, handling of quality exceptions, staff development, personnel and budget requirements planning, etc.
- Provided leadership and direction to ensure achievement of accountabilities of plant QA for Biologicals, Oncology & Pharma.
- Performed analysis of audit findings, prepared and presented results to process owners and to site management. Escalated the critical findings to higher management.
- Communicated regulatory audit findings of one manufacturing site to all other sites to ensure overall compliance with cGMP & QS regulations.
- Resolved critical product quality and safety issues escalated from sites.
- Initiated Quality Review Management program for all manufacturing sites.
- Implemented harmonization of Quality systems and procedures across Biological & Pharma manufacturing sites.
- Helped building competencies across sites.
- Lead prospective & retrospective Quality Risk Assessment program for Biological & Pharma facilities & processes.
- Effectively implemented Corporate Quality guidelines and policies across vaccine sites.

Achieved successful **WHO**, Geneva Re-Qualification for Vaccine Bulk & Fill Finish facilities in March 2013 and successful **USFDA** inspection of Pharma & Oncology facility in Oct 2013 & 2014.

Deputy General Manager Corporate Quality Assurance, Wockhardt Ltd, June 2010 –September 2012

- Setting regional Quality goals, objectives, and strategic direction in alignment with Global Quality goals.
- Overseeing Wockhardt's US, UK and Indian manufacturing sites for aseptic operations & Biopharmaceuticals.
- Educated Site Quality Heads within the region on critical quality management skills, including decision-making, handling of quality exceptions, staff development, personnel and budget requirements planning.
- Provided leadership and direction to ensure achievement of all regional accountabilities for QA and QC at sites within the region.
- Executed global internal audit program, including follow-up and facilitation of corrective actions.
- Conducted Quality sub-system audits at all Wockhardt's internal manufacturing sites globally to assure adequacy and compliance with established Quality Systems and facilitate corrective actions.
- Reviewed, monitored and supported Internal audit management and provided necessary support to Wockhardt units during external GMP inspections.

- Analysed audit findings and presented results to process owners and/or site management. Escalated the critical findings to higher management.
- Formulated Quality policies, Systems and Procedures across the Formulation plants and ensured their cGMP compliance.
- Resolved critical product quality and safety issues escalated from sites.
- Conducted for-cause audits at site in case of issues such as serious market complaints.
- Executed Quality Management Reviews comprising of all sites within the region.
- Executed global vendor audits for all the Wockhardt site for API's, critical excipients, primary & printed packaging components.
- Facilitated harmonization and consistent implementation of Quality Systems and procedures at sites within the region, in alignment with Corporate Quality policies/ procedures.
- Assured all-time readiness at sites for regulatory agency inspections and appropriate implementation and documentation of corrective actions taken to address agency observations.
- Directed initiatives that continuously improve effectiveness, efficiency, and Compliance of regional quality operations.
- Provided technical training to build competencies across the sites.
- Facilitated regulatory/customer inspections and made it successful in co-ordination with plant functions.
- Assured that all the Wockhardt sites are working in accordance with the cGMP and regulatory standards of market being serviced and meet the desired Pharmacopoeia and Wockhardt standards.
- Achieved significant progress in QMS document closure through audit compliance & CAPA management.
- Achieved harmonised compliance for regulatory agency reports across region.

➢ Led more than 14 successful regulatory inspections directly & secured facility approval **by USFDA, UK-MHRA** across the Wockhardt sites & **ANVISA** for Biotech products.

Director Quality Assurance & Validations, Tabuk Pharmaceuticals & Mfg. Co., Tabuk City, KSA
(A joint venture with Sanofi, France) August 2008 – June 2010

- Established audit and compliance function at site.
- People development & Team building - significant improvement in team performance & engaged in building quality culture in a global environment.
- All time readiness for regulatory inspections.
- Implemented reduced sampling & testing for RM's resulting in significant cost saving.
- Changed philosophy of investigation in the organization; developed and implemented appropriate tools for root cause investigation.
- Implemented OOT evaluation for all key quality attributes of finished products before batch release.
- Implemented Quality Risk Management program across company and made it integral part of quality system. Implemented moving risk prioritization index.
- Developed & implemented QRM for Cephalosporin cross-contamination.

➢ Faced 4 regulatory inspections & secured facility approval by **UK-MHRA, AFFSAPS, GCC & USFDA** for Injectables, Solid orals and semi-solids.

Assistant General Manager – Quality Assurance, Alkem Labs Ltd, Daman April 2006 – August 2008

- Ensured plant compliance with EU, UKMHRA and FDA cGMP regulations.
- Drafted, reviewed and approved all customer complaint responses, audit non-conformances, OOS investigations and CAPAs.
- Successfully streamlined Quality operations at site.
- People development & Team building.
- Led Quality Risk Management program for Penicillin & Cephalosporin cross-contamination.
- All time readiness for regulatory inspection.
- Introduced QRM in Equipment qualification studies for critical equipment(s), appreciated by UKMHRA inspectors.

➢ Led site for more than 6 successful regulatory Inspection like **USFDA, UKMHRA, ANVISA, WHO-Geneva** & various customer audits for their B-Lactam, Cephalosporin & General product block producing Injectables and Oral solids.

Manager – Quality Assurance & Validations, Serum Institute of India Ltd., Pune
April 2004 to April 2006

- Played key role in commissioning of New Project of Viral vaccine meeting WHO regulations & Oncology facility with Isolator Technology for US FDA.
  - ❖ Completed commissioning and qualification in 9 months time for MMR vaccine manufacturing block.
  - ❖ Played active role in designing QMS per FDA regulatory expectations.
  - ❖ Designing and Implementation of cleaning validation program for vaccines & oncology faciltiies.
  - ❖ Performed Qualifications of Facility, Systems (e.g. HVAC, Water) Equipments (e.g. Sterilizers, Lyophilizers, Filling Lines, Vial/Ampoule washers, Laminar flow units, Isolators) and Utilities (e.g. Water system, Gases, Pure Steam).
  - ❖ Performed Process simulation for Vaccines and Sterile Pharmaceuticals.

- Responsible for cGMP compliance.
- Developed and conducted training for plant personnel cGMP and quality SOPs.

➢ Successful **WHO** approval of Viral & Quadruple Vaccine facilities.

Site Head - Quality Assurance, Dr. Reddy's Lab. Ltd., Hyderabad July 2000 - April 2004

- Ensured plant compliance with EU cGMP and UKMHRA regulations.
- Coordinated regulatory audits and investigated and responded to market complaints.
- Performed GMP quality functions including manufacturing batch record reviews, investigations into process deviations, review and approval of management of change initiatives, pest control program, execution and/or review of validation (IQ/OQ/PQ) protocols and reports.
- Key role player in Facility, Equipment, Process & Cleaning Validation of Solid oral & injectable formulations.
- Designed & developed Validation Policy and Validation Master Plan for Branded Formulations Unit I & II.
- Developed and conducted training for plant personnel cGMP and quality SOPs.

- Drafted, reviewed and approved all customer complaint responses, audit non-conformances, OOS investigations and CAPAs within Trackwise database.
- Active member of 'Technology Transfer' & 'Product Standardization Task Force'
- Internal faculty for 'Technical Training' & Facilitator for suggestion scheme.

➢ Led various successful regulatory inspections, **ANIVSA** in Branded Formulation facilities for Oncology injectable facility & **PIC/S** audit for Injectables, Aerosols, OSD & **UKMHRA** for Oral solid dosage forms.

Executive – Production, Lupin Laboratories, Mandideep **April 1994 - June 1998**

- Supervised and coordinated the start-up, validation and running of sterile bulk facility and Sterile powder filling lines.
- Headed the 'Task Force' for documents like SOPs, BMRs, BPR's, etc.
- Key role player for INTERNAL QUALITY AUDITS.
- Shop floor In-process Checks & controls.
- Conducted, media fills, process & cleaning validations.
- Maintained daily manufacturing quotas, assuring adherence to department procedures and supervision of production operations.

Senior Officer – Production, Roche, Mumbai **October 1991 - April 1994**

- Supervised the production operations for sterile formulations in accordance to cGMP.
- Upgraded Operating procedures in adherence to the regulatory requirements and expectations.
- Qualification of Equipments and processes.

EDUCATIONAL CREDENTIALS

BACHELORS OF PHARMACY
From,
Rajasthan University, 1991

MASTERS OF BUSINESS ADMINISTRATION (Full Time)
From,
University of Delhi, 1998 - 2000

TRAININGS ATTENDED

Various training programs on leadership & Technical skills

PROFESSIONAL AFFILIATIONS

Parenteral Drug Association (PDA)
American Society of Quality (ASQ)
Society of Quality Assurance (SQA)
International Society for Pharmaceutical Engineering (ISPE)