Dr. MADHU RAJU SAGHEE
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A passionate and resilient quality professional with profound experience in sterile and aseptic operations, combination products, quality systems and regulatory compliance. Skilled in all aspects of quality operations with in-depth expertise in sterility assurance, validations, digitisation, failure investigations, data governance and microbiology. Adept in ensuring compliance proactively in accordance with ever changing regulatory requirements and implementing effective remediation strategies, passionate about preventing the typical errors that organizations make when in this situation.

PROFESSIONAL SUMMARY

- **16 Years of experience in quality and compliance, at present working with Encube Ethicals as Vice President- Head of Quality reporting to Managing Director.**
- **Previously worked in Corporate Quality at Aurobindo Pharma Limited** responsible for **Injectable facilities focussing** on quality improvement and remediation plan, audits, and compliance.
- **Microbiologist by education and edited industry recognised books, "Achieving Quality and Compliance Excellence in Pharmaceuticals"** and **"Microbiology and Sterility Assurance in Pharmaceuticals and Medical Devices".**
- Strategic and tactical implementation of quality, compliance, and process excellence programs without compromising project key performance indicators (KPIs).
- **Recipient of the coveted "Young Pharmaceutical Analyst Award" from Indian Drug Manufacturers Association (IDMA).**
- **Inspectional Exposure: 21 USFDA (5 inspections resulting in zero 483s), MHRA, ANVISA, INFARMED, PMDA and ANSM.**
- **Spearheaded Corporate Remediation Plans, Designed Quality strategies leading to site transformations from unacceptable (OAI) to acceptable (VAI) status.**
- Handled all critical QA systems like complaints, deviations, change control, risk management and failure investigations using structured root cause analysis.
- Quality representative to foster and maintain relationships with regulatory authorities to facilitate interactions.
- Led Remediation Action for handling Data Integrity targeted regulatory inspection that was cleared successfully.
- Responsible for investigation of quality impacting issues pertaining to EM excursions, sterility failures, media fill failures and process non-conformances across all the formulation units.
- Involved in Green field projects, layout reviews, qualifications and technology transfer projects and ensured smooth executions.
- **Project Lead for rolling out Human Performance Initiative to reduce human error and creating a Culture of Quality.**
- **Implemented enterprise level Industry 4.0 platforms such as Process Pad for Continued Process Verification, MES (PASX) for Electronic Batch Record Management, Automated Audit Trail review (E&Y EWS), CLEEN (Cleaning Validation), QMS and LIMS.**
- **Attended Level 4 training by Peter Baker, GMQA for Forensic Review and Data Governance.**
- **Editorial Board Member for "Clean Air and Containment Review" and "GMP Review" Journals published by Euromed Press, UK.**
- Creator of the world's largest LinkedIn group "Sterility Assurance Discussion Forum" bringing subject matter experts and microbiologists (around 15000 members) together to address the common issues faced by injectable firms.
- Active Member of industry association i.e., PDA (member since 2012) and ISPE (member since 2013).

TECHNICAL CAPABILITY

- Implementing pharmaceutical quality systems.
- Holistic sterility assurance program for aseptic operations.
- Leveraging quality risk management tools for ensuring proactive quality outcomes.
- Designing effective environmental monitoring and contamination control.
- Deploying scientifically sound visual inspection and particulate matter control program.
- Integrating risk management into quality systems.
- Risk based process and cleaning validation and cross contamination controls.

- Handling inspections and remediation of enforcement actions.
- Handling Change Management, Investigations and CAPA.
- Utilising advanced Root Cause Analysis tools.
- Designing and implementing data governance.
- Human performance and Error Proofing.
- Incorporating Deming's quality principles and creating a culture of quality.
- Statistical Process Control and Multivariate Analysis.
- Deploying continuous improvement initiatives and interventions.

EMPLOYMENT EXPERIENCE

Vice President, Head of Quality with oversight of all the Sites and R&D (Reporting to Management Director) at Encube Ethicals from Dec 2019 – Present. Team Size: 180

- Responsible for providing strategic and tactical direction on all matters related to quality and cGMP compliance across sites and R&D.
- Setting the expectations and improving the QA team performance through periodic team discussions and reviews to ensure consistency in achieving product quality and compliance.
- Responsible for driving Continuous Improvement Program and Quality Enhancements based on changing regulatory requirements.
- Ensure that routine situations, trends, and key performance measures are escalated to management, and prioritized according to the processes and risks involved.
- Review and approval of Change Controls, Corrective and Preventive action plans, Process non-conformances, Failure investigations, Quality Metrics and Risk management.
- Interviewing, hiring, and training employees; planning, assigning, and directing work; appraising performance; rewarding and disciplining employees; addressing complaints and resolving problems.

Head- Corporate Quality Systems and Compliance (Reporting to Chief Quality Officer)
Aurobindo Pharma Limited, Assistant General Manager, Feb 2016 – Dec 2019

- Responsibility involves providing Quality Oversight and Compliance across all Sterile Formulation Sites and leading the corporate Quality Management Systems.
- Responsible for Inspection Management of all sterile formulation sites, spearheading and aligning the team under pressure and intense regulatory scrutiny.
- Responsible for Continuous Improvement Program and Quality Enhancements based on changing regulatory requirements.
- Review and approval of Change Controls, Corrective and Preventive action plans, Process non-conformances, Failure investigations, Quality Metrics and Risk management documents across all the units.
- Lead for hosting regulatory inspections, remediation of the audit findings and response preparation to findings.
- Interface with FDA and other regulatory agencies during inspections and ensuring alignment of regulatory strategy to business strategy across all functional areas.
- Subject matter expert for Qualification and Validation, Microbiology, QMS and investigations.
- Responsible for investigation of quality impacting issues pertaining to EM excursions, sterility failures, media fill failures and process non-conformances across all the formulation units.

Assistant General Manager, Corporate QA (Reporting to Director-Technical)
Micro Labs Limited, Dec 2013 – Feb 2016
Led Sterile Ophthalmic facility and established sterility assurance system.

- Lead for implementing Remediation Action Plan for the Import Alert Sterile Unit which was cleared USFDA Inspection successfully.
- Lead for Corporate Data Integrity Risk Assessment Plan that involves gap assessment of all the sites and strategic planning for implementing preventive measures.
- Measuring key and quality performance indicators of all the sites to minimize the compliance risk.
- Conducting site Quality meetings escalating reviews and Quality metrics to the management.
- Handling of deviation, CAPA, change control and continuous improvement systems.
- Expertise in designing a holistic facility contamination control plan using risk-based approach.

- Implementing and maintaining the validation and qualification system in line with cGMPs.
- Expertise in designing and performing aseptic media fill simulations using a risk-based approach.
- Expertise in validation of sterilization process, area qualification (HVAC), qualification of visual inspection operators, designing environmental monitoring system using a risk-based approach.
- Writing and updating VMP, validation/qualification protocols and SOPs and VMP.
- Training Lead for understanding Human Error and Behaviour and creating a Culture of Quality.

Assistant Manager, Quality Assurance & Compliance (Reporting to Head, QA India & SEA)
Novartis India Limited, February 2013 – December 2013

Assistant Manager, Corporate Quality Assurance (Reporting to Chief Technical Officer)
Gland Pharma Limited, December 2008 – February 2013,
M/s. Gland Pharma Ltd is the first USFDA approved parenteral facility in India. Gland Pharma is well known for the manufacture of high-quality sterile formulations.

JOB RESPONSIBILITIES
- Preparation of Quality plan and Quality Management System documents as per Regulatory Requirements.
- Conducting investigations stemming from the complaints, non-conformances to identify potential failure modes and risks.
- Support the overall Quality and Compliance activities during the product development life cycle processes and ensure related practices adhere to market(s) Health Authority regulatory requirements as well as the Quality standards.
- Maintain open lines of communication with cross-functional team. Engage cross-functional team (CFT) in investigations, change controls, and batch disposition.
- Assist in resolution of roadblocks that prevent optimal effectiveness of the Investigation and CAPA processes.
- Reviewer and author of sterility assurance validation packages [SAVPs] for regulatory submissions.

EDUCATIONAL BACKGROUND
PhD in Microbiology from Rayalaseema University (Bioremediation and Metagenomics)
Master of Science in Microbiology from Andhra University (Distinction)
Master of Science in Chemistry from Acharya Nagarjuna University
MBA in Operations Management from Pondicherry University

CERTIFICATIONS
- Advanced Program in Pharmaceutical Quality Management (APPQM) Certification from NSF, UK
- Certified Six Sigma Master Black Belt from Karl Pearson Institute, UK
- Investigation and Effective CAPA System Certification from BEC Global, USA
- Minitab Certification-Statistical Tools for Pharmaceuticals, Q-sutra, India
- Certified Master Trainer in Human Error Reduction Program, HES, USA
- Senior Expert Certification from Human Error Solutions, USA
- IRCA Certified GMP PQS Lead Auditor, NSF, UK

SELECTIVE ACHIEVEMENTS
- Instrumental in succeeding USFDA follow-up inspections with zero 483s, MHRA Data Integrity Inspection and Warning Letter Remediation.
- Developed and Improved the Quality Culture Index and Patient Centric Quality Behaviours using leading quality indicators that led to reduction of 70% Human Error, 40% reduction in procedural errors as part of SOP simplification.
- Keynote Speaker and Resource Person at various conferences and workshops on Quality Management, Investigation & Root Cause Analysis, and Sterile Operations.

AWARDS
- **"Young Pharmaceutical Analyst Award"** by Indian Drug Manufacturers Association (IDMA) in 2013

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PUBLICATIONS

BOOKS EDITED

- **Microbiology and Sterility Assurance in Pharmaceuticals and Medical Devices**, Business Horizons, India, 2011.
- **Achieving Quality and Compliance Excellence in Pharmaceuticals: A Master Class GMP Guide,** Business Horizons, India, 2012.
- **Cleanroom Management in Pharmaceuticals and Healthcare**, Euromed Press, U.K, 2nd Edition, 2017.
- **Pharmaceutical Regulatory Inspections**, Euromed Press, U.K, 2nd Edition, 2020.

PAPERS IN PEER REVIEWED JOURNALS

- Sandle, T. and **Saghee, M. R.** (2011): Some considerations for the implementation of disposable technology and single-use systems in biopharmaceuticals, *Journal of Commercial Biotechnology,* Vol. 17, No. 4: 319–329
- Sandle, T. and **Saghee, M.R.** (2012). Application of Sterilization by Gamma Radiation for Single-Use Disposable Technologies in the Biopharmaceutical Sector, *Journal of GXP Compliance*, Spring 2012
- Co-author of IDMA Technical Monograph No:5, Environmental Monitoring in Cleanrooms, 2010

ARTICLES

- Saghee, M.R: **Responding to 483's**, *Express Pharma*, May 2010.
- **Scientific Aspects of Aseptic Processing with James Agalloco and James Akers,** in Pharma Times - Vol. 42 - No. 10 - October 2010.
- **Saghee, M.R.** and Sandle, T. (2010), **'Embracing quality risk management: The new paradigm'**, *Express Pharma, Pharma Technology Review*, 16th - 30th September 2010
- Sandle, T. and **Saghee, M.R.** (2010): Advances in cleanroom technologies, *Express Pharma*, 16th-30th September
- **Saghee, M.** and Sandle, T. (2018) **Proposed EU Guidelines to GMP Annex 1:** main changes that trigger enhancements to your sterility assurance programme*, GMP Review*, 17 (1): 4-8
- **Saghee, M.R**., Das P and Sandle, T. (2019): **Regulatory inspection of sterile facilities – focal points, Part 1: Visual inspection of Particulate Matter,** *GMP Review*, 18 (1): 13-18
- **Saghee, M.R**., Das P and Sandle, T. (2019): **Regulatory inspection of sterile facilities – focal points, Part 2: Airflow Visualisation,** *GMP Review*, 18 (3): 15-20

PRESENTATIONS AND KEY NOTES DELIVERED

- 13th IDMA pharmaceutical analysts' convention, Mumbai, October 2010
  Topic: How to Deal with 483s?
- Microbial Contamination Control Conference, organized by Microrite, November 2011
  Topic: Recent Enforcement Trends Pertaining to Sterility Assurance in India
- Cleanroom Principles and Practices organized by Insight GMP, October 2012
- IDMA-DOP, Govt of India, GMP Workshop for SMEs- Ahmedabad, September 2015
  Topic: "Building a Robust Quality Management System for Sustainable Compliance"
- UBM-2nd Annual Sterile Pharma Workshop, - Mumbai, November 2015
  Topic: "Developing a robust Environmental Monitoring Program for sterile manufacturing facility" and "Understanding ways to design and validate aseptic processing"

PERSONAL INFORMATION

Date of birth	: 18th July 1985
Marital status	: Married
Current address	: Flat 8/301, Milroc Kadamba, Old Goa–403402

For recommendations, please access my LinkedIn profile https://www.linkedin.com/in/madhurajusaghee/