SUDHA SHUKLA

CONTACT

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EDUCATION

May 2015
M.Sc.: Bioanalytical Sciences
Mumbai University, India
GPA: 6.12

April 2013
B.Sc.: Microbiology
Mumbai University, India
GPA: 56%

February 2010
H.S.C
Maharashtra Board
GPA: 61%

March 2008
S.S.C
Maharashtra Board, Mumbai, MH
GPA: 66%

CERTIFICATIONS

- 2015-03 MS office basics, MS-CIT (Maharashtra State Certificate in

PROFESSIONAL SUMMARY

Experienced in preparing and submitting regulatory documentation, reviewing materials, and ensuring accuracy of filings. Strong data analysis, report writing, and recordkeeping skills. Successfully executed dual role in Quality Assurance and Regulatory Affairs, demonstrating versatility and expertise in both areas.

SKILLS

- QMS compliance and documentation for ISO 9001:2015, ISO 13485:2016 and ISO 17025:2017 along with IVDR and MDR
- WHO-GMP compliance
- Medical device regulations
- Change management
- Document control and management
- Audits
- Data Integration for GLP, GDP compliance
- Regulatory submissions for IVD products
- Regulatory training
- Regulatory audits and License renewals
- Technical documentation
- Post-marketing surveillance

WORK HISTORY

June 2024 - Current
Assistant Manager – Quality and Regulatory, ***HaystackAnalytics***

- 1. Equipment Qualification
- 2. Documentation and document control for QMS compliance of ISO 13485
- 3. CE IVD compliance as per MDR 2017:746
- 4. NABL experience on ISO 15189 and ISO 17025

Information Technology)

- 2022-02 Internal Lead auditor
- 2022-07 ISO 9001:2015
- 2022-08 ISO 17025
- 2023-04 ISO 15189
- 2023-08 MDR 2017

LANGUAGES

English

Hindi

Marathi

- 5. Lab monitoring
- 6. Site monitoring

April 2022 - January 2024

Sr. QA Molecular Biologist, ***HiMedia Laboratories Pvt. Ltd.***, Mumbai

1. QMS compliance of ISO 9001:2015, ISO13485:2016 for IVD Products and ISO 17025:2017 for sequencing services for NABL compliance. Maintain trackers, filing systems, and submission logs to ensure the mentioned compliances.
2. ISO 15189 trained and lab maintenance.
3. IVDD and IVDR documentation and registration of the same in EU countries along with ISO 15223, ISO 13485, ISO 14971, ISO 9001 compliance.
4. CDSCO licensing and documentation using Sugam portal, preparation and compilation of DMF for Manufacturing Licenses – Fresh, Endorsements, Renewals
5. Registration of IVD products for Vietnam, Saudi Arabia. Coordination and followup responses to address regulatory queries and information requests.
6. Documentation and registration for ANVISA of IVD products
7. Facing External audits of Quality Austria, TUV SUD, SFDA and CDSCO audits. Supporting the site audit preparation.
8. Planning and Conducting Management review meeting Awareness of CLSI and ICH guidelines for Stability studies Working on FSSAI and ISO 18583
9. Monitoring and maintenance of lab as per ISO 14644
10. Worked on SAP transactions and Flink ISO
11. WHO-GMP compliance
12. Documentation for OOS, NIDR, Change control, CAPA and Root cause Investigation
13. Lead Internal Auditor
14. supervision of calibration/ validation of instruments, HVAC
15. Monitoring production activities and sites
16. Assistance in CE marking documentation for Instruments as well.
17. Handling NOC certificates

August 2018 - March 2022

Assistant Molecular Biologist Regulatory , ***HiMedia Laboratories Pvt Ltd.***, Mumbai, India

1. ISO 13485 compliance with respect to QMS compliance, lab monitoring and maintenance
2. CE IVD registration for IVD kits
3. Training personnel with respect to geneal QMS
4. Conducting and performing Internal audit and non-compliance closure

June 2017 - July 2018

Assistant Professor in Bioanalytical Sciences, ***G.N. Khalsa College***, Mumbai

- 1. Delivered lectures on Quality attributes as ICH guidelines,QA-QC, Regulatory compliance, Schedule Y,M,H,T and Instrumentation of Analytical Instruments
- 2. Conducting practical's and demonstration for SD-PAGE, Chromatography techniques, Infrared spectroscopy, Microbiology, Physical and Chemical evaluation for plant morphology
- 3. Knowledge sharing on Patent Claim drafting, understanding research papers and Self-development through presentation skills
- 4. Problem solving & troubleshooting.
- 5. Critical thinking

August 2015 - June 2017

CQA Executive, ***Marico Limited***, Mumbai

- 1. Analytical and stability testing of the cosmeceutical products as per ICH guidelines
- 2. Technical Documentation of regular analysis
- 3. Method transfer
- 4. Market trend analysis
- 5. Customer feedback and survey
- 6. Understandings about Audit

Internship, ***Padmaja aerobiological***

- 3 months Internship Daily calibration, microbiological analysis followed by analysis on IR and AAS