

CURRICULUM VITAE

Chethan J M.Sc. Biotechnology

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Chanjimale, Vemagal 563101

PROFESSIONAL SUMMARY

Dynamic professional with a strong background in FMCG (tobacco sector) at ITC, spanning 1.7 years, complemented by 2 years of experience in the medical device industry, focusing on Class 2 and 3 products. Skilled in navigating complex regulatory landscapes, driving business growth, and ensuring product excellence. Seeking to leverage my expertise to drive success in a challenging role

AREA OF EXPERTISE

- Well-versed in ISO 11135, which specifies requirements for the validation and routine control of ethylene oxide sterilization processes.
- Familiar with ISO 14644 standards for cleanroom classification and monitoring, essential for maintaining controlled environments in medical device manufacturing facilities.
- Adept at interpreting and implementing regulatory guidelines, including those outlined International Organization for Standardization (ISO).
- Demonstrated ability to ensure compliance with regulatory requirements throughout the testing and manufacturing processes.
- Conducted calibration and validation of medical devices to ensure accuracy, performance, and compliance with regulatory standards and internal quality requirements.

PROFESSIONAL EXPERIENCE

- **Quality Control - Analyst**
- **ITC India Private Limited – Bangalore**
- **March 2022 – October 2023**
- **Job Responsibilities - Quality control**

- Raw material Inspection for the products manufactured in the industry
- Finished goods testing for the finished products
- Played a key role in maintaining laboratory equipment, including
 - incubators
 - water bath
 - Ph meter
 - Sonicator
 - Tensile testing machines

- Microwave and hot air oven
 - Gas Pressure leak test
 - Microscopes
 - KF Titrator
 - Viscometer
 - Weighing Balance
 - Conductivity Meter
- Ensuring their proper functioning and calibration, and troubleshooting any issues to minimize downtime and maintain laboratory efficiency.
 - Ensured strict adherence to safety protocols in the laboratory environment, including proper handling and disposal of hazardous materials, implementation of personal protective equipment (PPE) protocols, and adherence to good laboratory practices (GLP) and standard operating procedures (SOPs).
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 - Develop validation protocols and reports, documenting findings and ensuring traceability of validation activities.

QA/QC Executive

Veiva Scientific India Private Limited – Vemagal, Kolar

Job responsibilities

- Conduct Wide range of product testing from the Raw material to finished goods.
- Utilized technical expertise in microbiology to perform validation studies for sterilization processes, including ethylene oxide (ETO) sterilization ensuring the efficacy of sterilization methods and compliance with regulatory requirements
- **Product Knowledge:** Extensive experience with a wide range of medical products Including:
 1. Stents
 2. Balloon Catheters
 3. Guide Wire
 4. Y connectors
 5. Inflation device
 6. Manifold
 7. Introducer needle
 8. Control Syringe
 9. Angio catheter
 10. Amplatz sheet

ACHIEVEMENTS

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- Implemented new quality control procedures that improved product quality and consistency.

- Successfully managed audits conducted by various internal and external bodies, demonstrating adeptness in regulatory compliance and quality management.
- Implemented and maintained ISO 13485 audit management system, ensuring adherence to international quality standards in medical device manufacturing.
- Collaborated effectively with cross-functional teams, resulting in streamlined processes and improved alignment with regulatory requirements.

INSTRUMENTS HANDLING

- Incubators (walk in type and BOD incubators)
- Stability Chamber
- Water bath
- Weighing balance
- Ph meter
- Sealing machines
- Auto Wrapping machines
- Microscope
- Water bath
- Temperature and Humidity Data loggers
- Mechanical Micropipettes

EDUCATIONAL QUALIFICATION Master of Science in Biotechnology

Bangalore University – Gnanabharathi Bangalore
2018 - 2020

CGPA :6

Bachelor of Science in Biotechnology

GFGC - Kolar
2015 - 2018
CGPA: 67%

DECLARATION

I hereby declare that information furnished above to the best of my knowledge.

Date:

Place: