CURRICULUM VITAE

SANJEEV KUMAR B
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CAREER INTENT:

To work a globally competitive environment on challenging tasks in Quality Assurance and Quality Control, which suits my qualification and domain knowledge that simulates personal and organizational growth by being efficient and extending full co-operation.

PROFILE SUMMARY:

A result-oriented **professional with over 5.8 years** of experience in manufacturing industry in the area of Quality Assurance, Quality Management Systems in Medical Device/Equipment's manufacturing industries **ISO13485:2016.**

- Presently working as **QA Engineer** at Clinisupplies Private Limited, Kunigal, Tumkur-572126.
- Comprehensive knowledge on **QMS, ISO 13485 and FMEA/Risk Management ISO 14971.**
- Hands of experience in **Validation (IQ, OQ & PQ), Area Qualification, Customer Complaint Handling, MSA, CAPA, DCR & Change Control.**
- Faced **CDSCO** and **ISO 13485** Technical audits.
- Strong background in every area of Quality Control, Quality Improvement Professions. Seeking assignment in and Quality Assurance with a growth-oriented organization.
- Experience in Modern manufacturing techniques like **MSA, FAIR, 7 QC TOOLS, SPC,8D** etc.
- Experience in **Class I, Class IIA and Class II B** devices.
- Superb organizational, communication, safety, and time-management skills. Independent and self-motivated and also able to work as part of a tightly knit team.
- Strong ability to maintain positive working relationships with co-workers and to workcooperatively with others.

PROFESSIONAL EXPERIENCE:

Company Name	Designation	Duration
Armor Plast Pvt Ltd., Bangalore	QA Engineer	Jan - 2019 to Apr-2022 (3.4 Years)
Virchow Biotech Pvt Ltd., Hyderabad	Sr.QA-Executive	Apr - 2022 to Aug-2023 (1.4 Years)
Clinisupplies Pvt Ltd-Bangalore	QA/QC Engineer	Sep - 2023 to till date.

Responsibilities:

- Responsible for QMS implementation as per **ISO 13485:2016.**
- Responsible for developing QMS procedures, maintaining QMS documents, revising of QMS documents as per **DCR** (Document Change Request).
- Responsible for Process validation, Equipment validation, AHU validation, Sterilization validation (as per ISO 11135).
- Responsible for preparation of process validation protocols, reports, and statistical analysis data.
- Responsible for preparation of Quality manual, General SOP, Functional department sop, Quality plan and formats.
- Responsible for developing risk management plan, risk assessment and risk management report as per **ISO 14971.**
- Responsible for performing process **FMEA (pFMEA).**
- Responsible for leading **Change control** process from initiation to closure.
- Responsible for Corrective Action and Preventive Action (**CAPA)** initiation to closure.

- Responsible for preparation of Device Master File **(DMF)** for each medical device product as **MDR 2017.**
- Responsible for Preparation of annual internal audit plan, conducting and closing of internal audit by monitoring NC's and CAPA.
- Certified **internal auditor** from SGS.
- Responsible for conducting Management Review Meeting (**MRM)**.
- Responsible for customer complaints investigation and closing of complaints.
- Responsible for leading **Non-Conformance (NC)** initiation to closure.
- Responsible for calibration of all measuring & and Manufacturing equipment's.
- Process improvement through applying various problem-solving tools (Brainstorming, why-why analysis, 6M).
- Responsible for supplier audits for vendors qualification, approving vendors and providing supplier performance rating on periodic basis.
- Review customer specifications and requirements and develop internal QC specifications.
- Responsible conducting monthly review meeting and monitor the process and product compliance by tracking Quality objective.
- Quality check of **products label, UDI and barcode labels** & ensure labels are complying to the regulatory guidelines.
- Responsible for reviewing DHR, Final inspection reports, Incoming inspection reports, COA/COC, sterilization, and sterility reports.
- Review customer specifications and requirements and develop internal QC specifications.
- Responsible for train the people on GDP, GMP, ISO 13485:2016, Entry and exit procedure for cleanroom.
- People development- Provide leadership and guidance to quality team. Ensure timely Performance Evaluation. Driving Team building and associate engagement initiatives.

SKILL TEST:

- Software Application**:** MS - Word, Excel, & Power Point.
- AUTOCAD, PRO-E
- Minitab

EDUCATIONAL QUALIFICATION:

- A bachelor's degree (Mechanical Engineering) from VTU University with 64% aggregate.

PERSONAL DETAILS:

Father's Name	: Hanumantappa
Date of Birth	: 24/04/1996
Marital Status	: Unmarried
Sex	: Male
Languages Known	: English, Hindi, Kannada, and Telugu
Address	: 15ThWard, muchigera oni, Gandhi Circle Gangavathi-583227.

AVOWAL:

I declare with gratitude that all the details cited above are factual and correct to the best of myknowledge.

Place: Bangalore **Yours faithfully**

Date: 01/07/2024 (SANJEEV KUMAR B)