

BRIEF PROFILE



Name : Sathya.S.N.V

Contact : srimsrin190@gmail.com
9420260119

Designation : AGM-Quality

Total Experience : 22 years

Work experience : Tablets/Capsules/Injectable/Parenteral/API/Cosmetics/Devices/Oral Solid Dosage forms (Tablets and capsules), API (Oncology and Anti-viral drugs), Ointments, Creams, Syrups, Eye drops, Nettle drops, Cosmetics & Medicinal products, Liquid orals, Injectable, Large volume & Small volume parenteral, Ophthalmic, Orthopedic devices and solutions.

Job Profile Summary:

- Quality Management System, Audits & Compliance (Certified Auditor and Trainer)
- Trainings (GMP, cGMP, GDP, On the Job)
- Validations/Calibrations/Equipment Qualifications like-
Injectable Manufacturing Lines: - Filling Line, Vial Washing machine, Depyrogenation Tunnel, Autoclave (Steam Sterilization), Autoclave cum Bung Processor, Terminal Sterilizer, External Vial Washing Machine, Automatic / Semi-automatic Inspection Line.
- CAPA, Deviations, Incidents, Change controls, Investigations/control plans/Risk Assessment, HVAC, LAF Qualifications.
- Quality policies and Key Performance Indicators, Clinical trials, New product developments, SOP, Protocol, Specifications, Standards, Policies Batch Controls, Vendor qualifications, Third party activities controls, Market complaints.
- Utilities (Area Qualification-) and Water System.

***Audits-Handled** : EU-GMP,WHO-GMP,ROW-AUDITS,USFDA,MHRA,ANVISA,PICS,WHO, ISO 13485:2016, ISO 9001-2015 etc...

***Software Operated** : LIMS,TRIMS,SAP & ERP etc..

***Qualification** : MSc., Specialization in Biotechnology and Zoology, LLB. Specialization with Intellectual Property Rights and Labour Law, PGDCA

ABOUT ME:

I am highly self-motivated, competitive, confident individual, a quick learner with capability to apply knowledge to achieve expectational performance.

EDUCATIONAL QUALIFICATIONS:

- M.Sc., (Specialization-**Biotechnology**) from Nagarjuna University [A.P] aggregated with 61.8%marks.
- B.Sc., with **Chemistry** from Kakatiya University [A.P] aggregated with 62.6% marks
- 10+2 (Biological Science with **Chemistry**) Board of Intermediate Education [A.P] aggregated with 58.6% marks
- S.S.C (School of Secondary Education) School of Secondary Education [A.P] aggregated with 73.5% marks.

TECHNICAL QUALIFICATIONS:

- Post Graduate Diploma in Computer Applications (Well trained in MS Office tools like -Microsoft Word, Excel, Power Point, Access &Internet applications) aggregate with 65% marks
- Type writing in English (Higher) aggregated with 64% mark, Hindi (Lower) aggregated with 57.5% from Technical Board of Andhra Pradesh State Government.
- Specialization in L.L.B(Intellectual Property rights, Labour Laws and Company Laws)

TECHNICAL QUALIFICATIONS IN PHARMACEUTICALS:

- **Lead Auditor and Trainer**
- LIMS software (Laboratory Information Management System) from Calibre Technologies Pvt.Ltd.
- TRIMS software (Training Information Management System-NICHELON5)
- QMS (Quality Management System) software
- SAP (System Applications and Products in data processing)
- ERP system

EMPLOYMENT HISTORY:

- Present working with Harmony Organics privates Limited at Pune, Maharashtra as a Quality AGM from 26/06/2024 reporting to Quality VP.
- Worked in Ascent Meditech Limited, Gujrat as a Quality Head from 19/07/2022 to 20/06/2024 reporting to Managing Director as a Full time Employee and also working with Merit Organics Limited as a Audit and Compliance Consultancy.
- Worked in OPTHALMIC TECHNOLOGY, H1- 662, RIICO Industrial Area, Khushkhera-

301707, Rajasthan, India from 26/07/2021 to 10/07/2022 as an Asst. General Manager- Quality Assurance.

- Experience with UNICHEM LABORATORIES, Goa. From 11/03/2019 to 20/07/2021 as a New project management.
- Experience with INVEN PHARMACEUTICALS Pvt. Ltd., from 05/12/2017 to 2019 as a Quality Assurance-QMS Manager.
- PENTAGON LABORATORIES PRIVATE LIMITED, IV Fluids & Injectable from 02/01/2015 to 03/03/2017, as a Sr. Executive-QA.
- FRESENIUS KABI GROUP OF PHARMACEUTICALS (Oncology and IV Fluids) (TGA, USFDA) from 14/09/2013-23/12/2014 as a Sr. officer QA/QC.
- HETERO LABS LIMITED (USFDA, EU, WHO other regulatory authorities) from 22/07/2007 to 30/08/2013 as a Quality chemist.
- Madhu Medicare, from 31/10/2004 to 15/07/2007 as a Quality Assurance documentation officer in distribution and release section.

PROFESSIONAL ABRIDGEMENT

- Audit & Compliance (**Internal Audits/External audits/Regulatory audits/Customer audits/Vendor**).
- To review and verify the **GMP** documents to identify the data integrity breaches.
- Handling of Batch manufacturing and Packing records and related documents.
- Ensure compliance of the **Corrective and Preventive Actions (CAPA)** necessitated through various activities such as:
Regulatory Audits, Market Complaints, Product Recall and Annual Product Review.
- Review, and evaluate **risk assessment** reports.
- Carry out gap assessment of the existing **systems, instruments, and equipment**.
- Provide **management information report** to senior management.
- To ensure compliance to the **Data Governance and Data Integrity** requirements through out the lifecycle of the data.
- Quality Review meetings and follow up with Action points of **Quality Review Meeting**.
- **Change controls, Deviations investigation, Out of specifications investigations.**
- Returned products handling,
- Control of **non-confirming** products.
- **GMP, cGMP, GLP, GDP** compliance, physical verification in **Manufacturing and Utility areas**.

- **Raw Material/Packing material** (In-coming material) Management as a part of QA and QC.
- **Stability samples and control samples management.**
- **Equipments/Instruments/Area/HVAC/Water System validations, Calibrations, Qualifications.**
- **Training and evaluation of Quality Assurance and other departments.**
- **Handling of SOP's/STP's/Specifications/Protocols/Reports and all the required documents.**

CTC:

Current total CTC: 21,50,000 Lac.per annum

AUDIT EXPOSURE:

Regulatory/Non regulatory-ROW:

U.S.FDA/M.H.R.A/T.G.A/ANVISA/W.H.O./Various countries local FDA/ISO 13485:2016, ISO 9001-2015 / WHO-GMP/CDSCO/Vendor Audits, Customer Audits (Domestic and International).

PERSONAL PROFILE:

Name : Sathya.S.N.V
Gender : Female
Marital status : Married
Nationality : Indian
Hobbies : Reading books
Communication : Hindi, English

PRESENT & PERMANENT ADDRESS:

Sathya.S.N.V
North Goa-403507, INDIA.

DECLARATION:

I am here by declaring that above given information is correct and complete to the best of my knowledge.

Yours Sincerely,
(Sathya.S.N.V)