Profile-T.Rama Rao, B.Pharma (Gold Medal), M.Pharm ,M.Sc (Psychology)

Full Name	Rama Rao Tumma
Date of birth	15th March 1959
Address, Street, Town	Flat no 302,Air Lines Apartments,Jaya Nagar Colony,New Bowenapally,Hyderabad-500011
Company	M/s.Sai Pharma Consultancy
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Profile (Introduction)

Summary of Experience:

- Total 31 years of experience in ***Pharma Formulation manufacturing Industry*.**
- **11 years** of managerial experience and **20 years of experience in leadership** responsibilities in the areas of **projects, technology transfer, pharmaceutical manufacturing, plant operations management, quality assurance, quality management, quality system automation, *audits & compliance*** *(including First party audits, Second party audits and leading the third party audits for certification and regualtory audits)*
- 3 years of consulting experience with Multiple roles as a Project Consultant, Visiting Professor/Faculty, IMS Auditor, Corporate trainer in the fields of GMP, Quality Management Systems, Audits & Regulatory Compliance, Validations, Medical Devices,ISO 13483, Six Sigma, Quality, Environmental, Health & Safety Management System Standards, and Industry best practices.

Qualifications:

1. M. Pharm in Pharmaceutical Technology from Andhra University, Visakhapatnam
2. M.Sc. (Psychology) from Andhra University, Visakhapatnam
3. Qualified Lead Auditor:
4. QMS (ISO 9001 : 2015) Lead Auditor
5. EMS (ISO 14001 : 2015) Lead Auditor
6. OH&SMS (ISO 45001 : 2018) Lead Auditor
7. MD QMS (ISO 13485 : 2016) Lead Auditor
7. ZED-Assessor (Quality Council of India, QCI)
8. Six Sigma Green Belt certified (Kennesaw State University, USA)

Operations: Manufacturing & Packing ,Ware House & Utility, ,PPIC & Procurement, Quality Control & Aussrance Projects & EHS , HR & Recruitment , Regulatory Audits,

Projects: Green Field Projects :

Neuheght Technologies Pvt Ltd,Hyderabad (OSD)
Aizant Drug Research Solutions Pvt Ltd,Hyderabad (OSD)
Procter & Gamble Hygeine & Health Care Ltd,Baddi (OSD)
APJ Laboratories Pvt Ltd,Paonta Sahib ,HP(Cepholosporins)

Brown field Projects:

Intermed, Chennai (OSD,Liquid Orals)
Hoechst Marion Roussel Ltd,Ankleshwar (OSD)
Ranbaxy Laboratories Ltd,Dewas (SVPs)

Technology /Site Transfer:

Forwin & Calmpose Inj (Ranbaxy)
Avil 25,Lasix, Trental,Festal,Novalhin,Baralgin Tablets (Hoest Marion Roussel Ltd)
Vicks Action 500 Tablets & Vicks Vaporub (P &G)
Valstran, Losartan, Attrovostatin Tablets (Aizant)

Industry Carrier over view:

-Production Supervisor--- 3.5 Years (Manufacturing of Injectables& Eye Drops **Ranbaxy Laboraties Ltd & Rallis India Ltd**)

-Production Officer, Executive, Sr.Exectuive - 9 Years (Mfg & Pkg of Tablets ,Capsules,**Hoectst Marion Roussel Ltd)**

-Production Manager- 5 Years(Mfg & Pkg of Tablets,Capsules,Liquid Orals at **Biological E Ltd**

-Plant Head-10 Years-(Projects,Operations Mgmt of Mfg,Pkg,Ware House,QC,QA,PPIC,HR,Contract Mfg at **P & G,Macleods**)

-VP Operations- 2 Years,Operations & Projects Contract Manufacturing Sites **M/s.Ravianm Life Sciences, PVS Laboratories**

-**CDSCO PMU Consultant** -1 year- Strenthening of State & Central Drug Regulatory and Laboratory Mechanism

Auditing Experience:

GMP Audits:

• Led more than 26 numbers of Regulatory audits (USFDA -2 Times , TGA- 1 time, NAFDAC -3 times,TFDA -1 time,Kenya Audit- 2times ,WHO GMP Audits -10 times ,Customer Audits- GSK, Teva, Lupin,Alembic,Cipla,Zuventis, Zydus, Cadila Health Care as a prime lead in different Pharmaceutical Companies during my industrial on roll service.

• Carried out more than 30 GMP audits as a Principal Auditor for different Pharmaceutical Companies on behalf of Sai Pharma Consultancy in India.

• **External Auditor-TUV SUD** South Asia Pvt Ltd, Hyderabad (ISO 9001:2015, ISO 14001:2015 ,ISO 45001 : 2018)

Carried out more **than 450 man days of audits** as an Auditor for different standardst on behalf of Certification Body TUV SUD South Pvt Ltd, Hyderabad

Training Experience:

Tutor for IA & Awareness -TUV SUD Asia Pvt Ltd ,Academy Division ISO9001) , ISO14001, ISO45001 ,ISO 13485 ,ISO 14971 &LA Programes on ISO 9001 & ISO 13485

• Conducted more than **4750+ hours of CGMP Training courses for pharma & medical devices** and facilitated grooming of more than 1000 + Pharma professionals as Lead Faculty across many Indian Metros and Cities

• Audits & Regulatory Compliances, Validations, Quality Management Systems, Technology Transfers

• PIC/S, EU, USFDA, WHO GMP, ICH Guidelines

• Risk Management, QbD & PAT, Health & Safety Management Systems

.Medical Devices Regulations for USA,EU,JAPAN,China & Asian Countires

Medical Devices standards ICIMED & ISO-13485 ,

Quality Risk Management of Medical Devices: ISO 14791

Quality System Requirements of Medical Devices - 21 CFR 820

Labelling Requirements of medical devices- 21 CFR 801

Medical Device Regulations as per requirements of USA,EU,China,Japan, India

Medical Device Regulations of India-Schedue MIII

Faculty Experience as Visiting Professor:

1. **G.Pulla Reddy College of Pharmacy, Hyderabad**

(Quality Assurance, Pilot Plants, T & T, Scale Up techniques & Technology Transfer,Quality Management Systems(QMS) ,Validation & Verification of Pharmceutical Products,Qualification of Equipments,Various GMP regulations for the countries like US GFDA,MHRA,TGA ,EU ,INDIA and other Asian countries , Medical Devices – Quality System Regulations of Medical Devices ,ISO 13485 ,QRM of Medical Devices ISO14791 ,Validation & Verification of Medical Devices ,Adverse Event Reporting of Medical Devices,Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs, Quality System requirements of 21 CFR Part 820,

Labelling Requirements of 21CFR Part 801 ,Unique Device Idintification UDI,USA ,EU,Asean ,China & Japan Regulations for Medical devices

2.**Shri Vishnu College of Pharmacy, Vishnu Group of Institutions, Bhimavaram**

(Audits & Regulatory Compliances, Quality Management Systems, Health & Safety Management,Medical Devices for the topics mentioned above in point 1.

3.**Empaneled Faculty for QMS in National Institute of** Micro Small and Medium Enterprises (ni-msme) Hyderabad

4.College of Pharmaceutical Sciences Kakatiya University, Warangal, Telangana for HVAC ,Water, Validations & Projects

Possible Assignments.

Locations	Any Location
Languages	English,Hindi,Telugu

Educational Context (Qualification).

Duration (Year)	Institute/university	Qualification
1983-85(2 Yrs)	Andhra niversity,Visakhapatnam	M.Pharm
1978-83 (4 Years)	Andhra niversity,Visakhapatnam	B.Pharm
2018-20 (2 Years)	Andhra niversity,Visakhapatnam	M.Sc, Psychology

Special Skills

GMP ,GDP,GLP,GCP Audits , Medical Devices Vendor Audits , Medical Device Regulations of USA,EU,Asean ,Japan, China & India ,technical support to medical device manufacturing units ,GMP Regulatory Compliances, GMP Trainings, Pharma Operational Excellence, Project Magement,

Publications. (articles, books, e-learning materials)

NIL

Leadership Experience

GM-Operations, Plant Head,Vice President Operations in different organisations

Around 20 years of experience in leadership responsibilities in the areas of projects, technology transfer, pharmaceutical manufacturing, plant operations management, quality assurance, leading GMP regulatory audits & compliance, and quality system automation, Vendor Auditsof Medical Devices, Technical support to Medical device Mfg Units,

Credentials & Awards

1)Awarded **Gold Medal** by Andhra University for first in B. Pharm in the year 1983.
2) **G.P. Nair Award** by IDMA Mumbai for Outstanding performance in B. Pharma in the year 1983.
3) **Project Execution Excellency** award by Procter & Gamble Hygiene and Health care Ltd. In 2006.
4) Letters of appreciation from **Procter & Gamble Hygiene and Health Care Ltd**
5) Letter of **appreciation from Neuheit** for preparing the feasibility report for their project of OSDS including its Conceptual Lay out
6) Letter of **appreciation from Om Pharmaceuticals Ltd, Bangalore** for preparing the QMS set up in accordance with USFDA-CFR-111
7) Certificate of **appreciation by State Drug Control Administration of Andhra Pradesh for training** in Concepts of Validation for the State Drug Regulators Drug Inspectors and Additional Drug Controllers
8) Certificate of Participation at Indo African Conference held at Vagdevi College of Pharmacy, Warangal
9) Certificate of Participation for the lectures delivered at Faculty Development Program me conducted at Kakatiya University, Warangal
10) Letter of **Appreciation/ Testimonial from Cellulose India Pvt Ltd** for the work done on GMP Compliance to M/s Abbott GMP Audit
11) Letter of **Testimonial /Appreciation by G. Pulla Reddy College of Pharmacy**, Hyderabad for the outstanding work done on training their Graduate & Post Graduate Students of Pharmacy the technical skills required for the industry.
12) Letter of **Testimonial /Appreciation by Shri Vishnu College of Pharmacy**, Bhimavaram for the outstanding work done on training their Graduate & Post Graduate Students of Pharmacy the technical skills required for the industry.
13) Letter of **Testimonial /Appreciation by College of Pharmaceutical Sciences, Kakatiya University**, Warangal for the outstanding work done on training their Graduate & Post Graduate Students of Pharmacy the technical skills required for the industry
14) Letter **of Appreciation by M/s Hetero Labd Ltd -Unit 3** ,Jeedimetla ,Hyderabad for the cGMP trainings conducted to the shaft floor emplyoress for a period of one year (12days in a month)