

WELCOME
TO
SAI PHARMA CONSULTANCY

T RAMA RAO
HYDERABAD

About Sai Pharma Consultants

- Promoter and Principal Consultant **Mr. T Rama Rao** is having experience of over a period of three decades in Pharma industry
- Ranbaxy, Hoechst Marion Roussel Ltd, Biological E Ltd, Procter & Gamble Hygiene and Health Care Ltd (operated by SRL) etc are the few companies he has worked with
- M Pharm (Pharmaceutical Technology) from Andhra University, Vishakhapatnam in Department of Pharmaceutical Sciences in the year 1985
- Awarded Gold medals by Indian Drug Manufacturers Association (IDMA) ,Mumbai & Nageswara Rao Pantulu Gold Medal by Andhra University for standing first In B.Pharm ,1983

- Has discharged executive as well as leadership roles In the areas of Design & Development, Manufacturing, Qualification & Validation, Manufacturing, Operations management, Quality assurance, Quality management, Audits & Compliance, Regulatory affairs, Technology transfer, Project management, Development of formulations and Operational excellence.
- Led team of experts in preparing the regulatory filings, facing GMP inspections / audits and responding to the inspectional observations of various regulatory agencies, such as WHO, USFDA, UK-MHRA & TGA
- Regular speaker in industry & academia seminars/ conferences
- Also a trainer on qualification and validation, quality management systems. etc.

- Consists of well experienced and talented people who worked in reputed Indian & Multinational Companies in the following domains:
 - a) Formulation Development
 - b) API Development Process
 - c) Civil Engineering
 - d) HVAC Concepts & Designing
 - e) Electrical Engineering
 - f) Dossier Preparation & Review.

- ❑ Pharma Formulations (Both Sterile and Non sterile)
- ❑ Intermediates & APIS
- ❑ Medical Devices
- ❑ Biotech & Biologicals
- ❑ Ayurvedic & Homeopathic
- ❑ Nuetraceuticals /Dietary Supplements /Food Products
- ❑ Excipients
- ❑ Primary Packing Materials
- ❑ Clinical Research Organisations (CRO)
- ❑ Public Testing Laboratories,
- ❑ Educational Institutions

- Audits & Compliance Management
- Project Management
- Documentation Support
- Training
- Regulatory Support
- Operational Excellence
- Formulation Development
- Education

- Good Manufacturing Practices (GMP) Audit support in accordance With :
USFDA- CFR 210-211, CFR -110, CFR-111 PIC/S ,
EU (Eud ralex Vol 4) ,MHRA,TGA & WHO GMP,ANVISA
- Good Laboratory Practices (GLP) including support for NABL
Certification
- Good Clinical Practice (GCP) Audits
- Facility feasibility Audits and Gap Analysis
- Good Distribution Practices
- Good Documentation Practices
- Data Integrity Audits

For New Projects / Modification of existing Plants

- Plot & Contour Planning
- Plant Layout
- Man & Material Movement Details
- Preliminary Architectural Drawings
- HVAC Concepts
- Preliminary Utility Specifications
- Power Requirement Estimation
- Preliminary Project Cost Estimation & Scheduling
- Environmental & Safety Engineering
- Future Expansion Possibilities

Supporting in the Drafting and Documentation of

- Specifications
- Standard Operating Procedures(SOPs)
- Quality Management Systems
- Validation & Qualification
- Master Formula records (MFR)
- Batch Manufacturing Records(BMR)
- Batch Packing Records (BPR)

Have necessary wherewithal to Develop, Stabilise, Technology Transfer and Scale Up of the following range of dosage forms(New Products / Products having Reproducibility Issues):

- ❑ Oral Solid Dosage forms
- ❑ Small & Large Volume Parenterals
- ❑ Vaccines (General & Genetically Modified)
- ❑ Eye drops / Nasal sprays
- ❑ Liquid oral dosage Forms
- ❑ Semi Solid Dosages Forms
- ❑ Bio technology based Products

We conduct Customised Trainings to employees at all levels who are engaged in the manufacture / storage / distribution on the following areas :

- ❑ Good Manufacturing Practices (GMP)
- ❑ Good Laboratory Practices (GLP)
- ❑ Good Documentation Practices (GDP)
- ❑ Good Warehousing & Distribution Practices
- ❑ Qualification & Validation
- ❑ Auditing & Compliance Management
- ❑ Pilot Plants & Technology transfer
- ❑ Regulatory Guidelines
- ❑ ICH Guidelines

- Optimisation of Process Cycle times.
- Waste Reduction.
- Cost optimisation of Products
- Optimisation of Overhead Costs.
- Optimisation of Cleaning Times.
- Optimisation of Man power.
- Productivity Improvements.
- Supply Chain Management (SCM)

We support in :

- Dossier Preparation & Review
- Regulatory Filing & Review
- Response Strategy & Response Drafting
- Response Documentation Review & Issue Resolution Plan
- Guiding & Supporting for Licence In& Out

We are conducting interactive sessions with the Graduate /Post Graduate Pharmacy students of reputed colleges in India on the below subjects

- Quality Control & Quality assurance
- Regulatory Affairs
- Regulatory Guidelines
- Industrial pharmacy
- Pilot Plants ,Technology transfer ,Scale Ups & Validations

- **PharmEng Technology, Singapore:**

Global compliance Consulting firm serving both Bio Tech & Pharma Industry

- **Compliance Online :**

Is an Industry focused training Centre based in California(USA),

- **Andhra Pradesh MedTech Zone Ltd, (AMTZ) Visakhapatnam :**

Enterprise under the Government of Andhra Pradesh, a 270 Acre zone, dedicated for Medical Device Manufacturing

- **Educational Institutions:**

- 1) Vishnu College of Pharmacy, Bhimavaram, Andhra Pradesh, India.
- 2) G.Pulla Reddy College of Pharmacy, Hyderabad, Telengana ,India.

Please refer our website testimonials page about few words from our customers

- Om Pharmaceuticals Ltd, Bangalore
 - Neuheight Technologies Pvt Ltd, Hyderabad
 - Award from Director General of Drug Control Admn. of Andhra Pradesh
 - Award of Certificate from Kakatiya University , Warangal, Telangana State
 - Award of certificate from Central Drug Standards Control Organisation(CDSCO), New Delhi
 - Project Excellency Award by P & G Hygiene and Health Care Ltd
 - Procter & Gamble Hygiene & Health care Ltd
- a) Mr. Prajay Desai b) Mr. Ashish Dubey c) Ms. Subha Subramanian d) Mr. Homi Kotiwala
e) Mr. Sanjay Mishra



Vivimed



HETERO



Piramal



GRANULES



Abbott



Divis Laboratories Ltd.



Tirupati
lifesciences
Sign of Wellness...



KIMS
HOSPITALS™

T. Rama Rao

Flat no 302, Air Lines Apartments
Jayanagar Colony, New Bowenapally
Secunderabad-500011, Telengana State, India

Mob No: +91 9985538854

Ph.No: +91 4027758360

E Mail : info@saipharmaconsultants.com

Web Site: www.saipharmaconsultants.com

THANK YOU