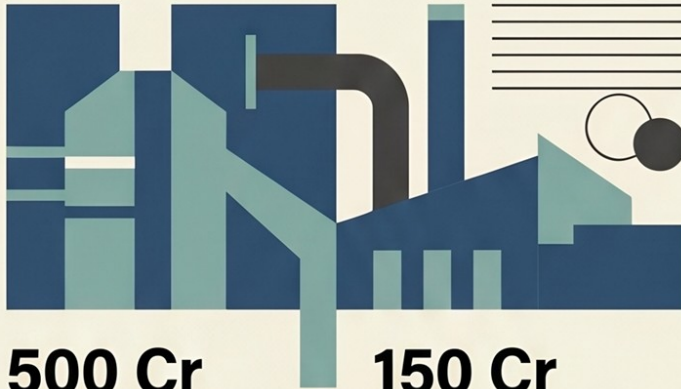


Dr. Tata Santosh: 22 Years of Global Pharmaceutical Excellence & Regulatory Compliance



Global Experience across Bulk Drugs, Intermediates, & Sterile Formulations |
Greenfield & Brownfield Projects up to 500 Cr | Tier-1 Agency Approvals

LARGE-SCALE INFRASTRUCTURE & PROJECT INTERVENTIONS



500 Cr Bulk Drug API Unit

Led comprehensive layout and utilities design for a major greenfield API manufacturing facility.

150 Cr Injectable Unit

Managed the design of layout and utilities for a high-value sterile injectable manufacturing plant.



Turnkey Bulk Drug Unit (200 Cr)

Provided full turnkey solutions, including design, construction, and total quality compliance management.

Brownfield Expansion Mastery:

Executed 50 Cr expansion projects for pellet manufacturing and additional API blocks, focusing on layout and utility integration.

GLOBAL REGULATORY SUCCESS & REMEDIATION



Tier-1 Agency Approvals

Successfully guided companies like Glochem, Ciron Drugs, and NGL Fine Chem to achieve USFDA, TGA, EDQM, PMDA, and EMEA approvals.

FDA 483 Warning Letter Resolution

Cleared critical FDA 483 warnings and EDQM issues by implementing effective CAPA and deviation management systems.

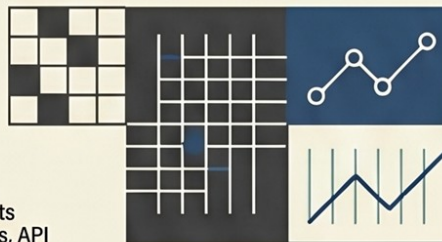
Mastery of 21 CFR Compliance

Expert knowledge of 21 CFR Parts 11, 58, 210, and 211 for the qualification of IT systems, HVAC, and purified water systems.

STRATEGIC AUDITING & INDUSTRY IMPACT

120+ Audits Conducted

Performed extensive audits across testing laboratories, API units, and primary/secondary packaging facilities.



1,500+ Professionals Trained

Educated a diverse range of industry talent, from R&D function heads to production operators, in quality and validation protocols.

Financial & PE Advisory

Conducts techno-commercial viability audits for banks and PE investors to guide financing, re-financing, and facility takeovers.

CORE COMPETENCIES & CERTIFICATIONS



Certified Quality Leadership

Holds elite industry credentials as an APIC Certified Auditor and a Six Sigma Certified Professional.

Transformation via Quality Metrics

Utilizes ICH Q10 and QRM systems to introduce Quality Metrics that transform the overall quality culture of client factories.