



Kotis Consultancy Services (KCS)

*Trusted Partner for USFDA Compliance & cGMP
Excellence*

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About Kotis Consultancy Services



- Established in 2012
- Focused on USFDA & Global cGMP compliance
- Trusted by leading pharma companies across India and globally
- A specialist USFDA compliance and cGMP consulting firm with deep remediation and inspection readiness expertise.

About Kotis Consultancy Services



- **Kotis Consultancy Services established in 2012**, we are engaged into consulting services are designed to help pharmaceutical companies to address compliance challenges and ensure adherence to regulatory standards. With a team of experienced Subject Matter Experts (SMEs) across key areas such as quality assurance, regulatory affairs, manufacturing, validation, analytical R&D, quality control, we deliver customized solutions for FDA compliance remediation. Team experienced in collaborating with top USA GMP consultancy firms, to address cGMP concerns, Failure QMS related Investigations, ANDA reviews, FDA Six Systems gap assessments and Audits, Batch certification, FDA 483/Warning letter responses, and remediation.
- We perform thorough audits to identify gaps in processes and systems, providing detailed corrective action plans to address deficiencies. Our experts collaborate with client teams to implement improvements that align with FDA guidelines, minimizing the risk of inspection failures, product recalls, or penalties. We also assist in preparing for FDA inspections, developing necessary documentation, and crafting effective responses to FDA observations or warning letters, ensuring full compliance and resolution.
- KCS provides expert regulatory and compliance solutions by Offering:
 - cGMP consulting, Auditing and FDA Regulatory compliant Solutions.
 - Mock USFDA cGMP Audits, Assist During Regulatory Audits
 - Drafting FDA 483s, Warning Letters, Remediate Gaps as needed
 - FDA Six Systems Compliance Trainings
 - Dedicated consultants are deployed just in time to ensure compliance with regulatory commitments
 - Data Integrity and GxP Compliance Audits



Our Consulting Philosophy

Practical • Risk-Based • Consistent Compliance

Core Capabilities & End to End Services

- FDA Six Systems Compliance
- cGMP and Data Integrity Trainings/Work Shops
- 21CFR Part11 and CSV Compliance
- GxP Consulting & Third-Party Audits
- Mock USFDA Audits & Inspection Support
- FDA 483 & Warning Letter Responses
- Hands-on cGMP remediation support
- Regulatory Affairs & USFDA Meetings

Core Regulatory & cGMP Consulting Capabilities



- **Quality Management Systems (QMS)**

Design, develop, review, and remediation of robust QMS aligned with USFDA expectations

- **Regulatory Affairs & USFDA Interactions**

Strategic support for USFDA meetings and regulatory communications.

- **FDA Six Systems Compliance**

Detailed gap assessments and remediation across all FDA Six Systems.

- **GxP Consulting & Independent Third-Party Audits**

Risk-based GxP audits to assess regulatory inspection readiness

- **Mock USFDA Audits & Inspection Readiness Support**

Real-time mock inspections to prepare staff, systems, and documentation for USFDA audits.

- **FDA 483 & Warning Letter Responses**

Expert drafting, review, and remediation of FDA 483 observations and Warning Letters.

- **Hands-On cGMP Remediation Support**

On-site and remote execution support to close gaps and meet regulatory commitments.



Proven USFDA Track Record

- Serving 65+ Pharmaceutical companies with Quality and Expertise
- 45+ USFDA site audits completed
- 9000+ professionals trained on cGMP topics.
- Warning Letter Remediation • FDA 483 Responses • GxP Audits • GxP SMEs will be deputed as needed to remediate inspectional observations

Our People Make the Difference

Senior SMEs with deep USFDA inspection experience

- Mr. B.H. Koti Reddy – 25 Years
- Dr.JP Narayan-27 Years
- Mr. Rajesh Varma – 21 Years
- Mr. Sanjeev Mahajan – 32 Years
- Dr. J.P. Srinivasa Reddy – 32 Years
- Mr. L. Srikanth Reddy – 25 Years



Key Client Engagements-USFDA approved Sites

S.NO	Company Name –USFDA Sites	Time period worked	Type of Regulatory services provided
1	Famycare/Jai pharma/Mylan	2014-2018	cGMP Audits, QMS review ,FDA 483 responses review
2	Srikrishna Pharma	2017 -2020	cGMP trainings and Lab Systems GAP Audit
3	Unimark Remedies	2017 -2019	FDA Warning letter remediation
4	Sidmark-Dehradun	2017	cGMP trainings and Lab Systems GAP Audit
5	Salicylates and Chemicals- Hyderabad	2017	cGMP Trainings, Third Party Audits for USFDA readiness & Support for FDA 483 Responses
6	IPCA - Indore	2018	USFDA Warning letter remediation
7	Jubilant – Mysore & Roorkee	2018 - 2023	USFDA Warning letter remediation
8	Wockhardt - Aurangabad	2019	Third Party Audit for USFDA commitment
9	Sun Pharma – Mohali- Chandigarh	2019 to 2023	Third Party Audit for USFDA commitment & Support for FDA 483 Responses
10	Lupin – Tarapur and Mandideep	2020 & 2023	USFDA Warning letter remediation
11	Aarti Drugs-Biosar,Mumbai	2019 - 2024	USFDA Warning letter remediation
12	Mac-Chem India - Mumbai	2018-Ongoing	Third Party Audit for USFDA & Support for FDA 483 Responses
13	Calyx Chemical & Pharma - Mumbai	2018	FDA Warning letter remediation
14	Encube Ethicals-Goa	2020,2024,2025	cGMP trainings and Lab Systems GAP Audit
15	Intas-Ahmedabad	2023-Ongoing	Batch Certification and FDA Warning letter remediation
16	AET Labs-Hyderabad	2018-2022	Third Party Audits for USFDA readiness & Support for FDA 483 Responses
17	Pinnacle Life Sciences-Baddi	2019-Ongoing	cGMP Audits, QMS review ,FDA 483 responses review
18	Graviti Pharma-Hyderabad	2022-Ongoing	cGMP Audits, QMS review Audits for USFDA readiness.
19	Hetero –Unit-9-Nakkapally	2025-Ongoing	USFDA 483 response and cGMP assessments
20	Unexo life-Delhi	2024-Ongoing	USFDA Warning letter remediation
21	Granules India-Hyderabad	2026	USFDA Warning letter remediation

Performed 65 + USFDA Sites Third Party cGMP customer audits

Successfully trained 9,000+ cGMP professionals on FDA Six Systems in more than 45 companies

Why Clients Choose KCS



Experience • Credibility • Execution Excellence

Contact Details

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Thank you