RM ANALYTICAL

Quality & Regulatory Excellence

Building Confidence Through Compliance, Data Integrity, and Scientific Rigor.

FDA-Registered | cGMP-Compliant | Part 11 Compliant

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A Strong Regulatory Foundation

All analytical services are performed within a strict **cGMP quality system** regulated by the FDA. We ensure every test is defensible and inspection-ready.

⚖ Operations Aligned With:

- **21 CFR Part 210:** cGMP for Manufacturing
- **21 CFR Part 211:** cGMP for Finished Pharma
- **21 CFR Part 11:** Electronic Records

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Electronic Systems & Data Integrity

Our lab operates a fully electronic, validated quality system compliant with 21 CFR Part 11, reducing human error and strengthening data integrity.

Electronic QMS

Integrated Quality Management System for controlled documentation.

ELN System

Electronic Laboratory Notebook for secure digital data capture.

CRM System

Client Relationship Management for transparent communication.

LIMS Controller

Central workflow controller ensuring sample tracking and audit trails.

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Data Integrity: ALCOA++

We apply ALCOA++ principles to every activity to ensure data is trustworthy.

Attributable	Legible	Contemporaneous	Original	Accurate
Linked to analyst	Readable & permanent	Recorded instantly	True primary record	Scientifically sound

PLUS:

- ✓ **Complete:** All data, including repeats, retained.
- ✓ **Consistent:** Logical sequencing with time stamps.
- ✓ **Enduring:** Securely stored and protected.
- ✓ **Available:** Readily retrievable for audits.

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Audit Support

- Support during FDA & global inspections.
- Analytical investigations & root-cause analysis.
- Regulatory-ready documentation for submissions.
- **Virtual Audit Capability:** Efficient remote review.

Contact Quality

To request information or schedule an audit:

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