nuvalore

Analytical & CMC Solutions for Biopharma Startups & SMEs

Access the expertise you need without building every capability in-house.

BUILDING THE FOUNDATION

nuvalore provides flexible analytical and CMC support to build a strong foundation for your program, from early development through IND-enabling studies.

1

EARLY DEVELOPMENT

KEY SUPPORT

- Molecule Characterization
- Developability Assessment
- Analytical Strategy
- Formulation Screening
- Compatibility Studies
- Forced Degradation Studies
- QbD & DoE Support
- Investor Due Diligence Gap Analysis



OUTCOME

Faster decisions, reduced development risk, and greater investor readiness.

2

CMC & IND ENABLING

KEY SUPPORT

- Analytical Method Development
- Method Qualification
- Reference Standard Characterization
- Stability Protocol Design
- Analytical Risk Assessment
- CMC Documentation Support
- Transfer-ready Methods



OUTCOME

Build a clinical-ready analytical foundation aligned with regulatory expectations.

One Partner. Every Step of the Way.

nuvalore integrates seamlessly with your team, providing flexible, scalable support as your program progresses through each stage of development.

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ADVANCING YOUR PROGRAM

nuvalore provides the analytical and GMP support you need to progress through clinical development and toward commercial readiness.

3

CLINICAL DEVELOPMENT



KEY SUPPORT

- Method Validation (ICH Q2 (R2), Q14)
- Stability Studies
- Batch Release Testing
- OOS Investigations & Support
- Analytical Comparability
- Method Transfer Support
- Vendor and CRO Oversight

OUTCOME

Reliable GMP-compliant analytical data supporting Phase I–III clinical milestones.

4

COMMERCIAL READINESS



KEY SUPPORT

- GMP Quality Control Testing
- Product Release Support
- Ongoing Stability Programs
- Method Lifecycle Management
- Change Control & Regulatory Support
- Inspection & Audit Readiness

OUTCOME

Sustainable quality and regulatory compliance for commercial launch.

WHY PARTNER WITH NUVALORE

- **GMP-Certified Laboratory**
- **ICH Q2(R2), Q14 & QbD Expertise**
- **Analytical & CMC Expertise**
- **Flexible & Scalable**
- **Fast Turnaround**

GET IN TOUCH

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