INFOGRAPHIC

5 Benefits to Outsourcing Your Stability Studies to a Trusted CRO

Stability studies are a fundamental part of biopharmaceutical development. Since proteins are sensitive to environmental factors, changes in biopharmaceutical stability due to aggregation, degradation, chemical, or physical instability can alter protein folding and structure. These changes can affect the quality, safety, efficacy, and biologic activity of the molecule. Therefore, an early assessment of biopharmaceutical stability is of prime importance. We offer stability programs according to the ICH Q1A(R2), Q1B, and Q5C guidelines and expanded programs tailored to the client's needs.

Why We Recommend This Approach

1
Access to experts in the field of GMP analytics and a devoted team of project managers

2
State-of-the-art analytical instrumentation

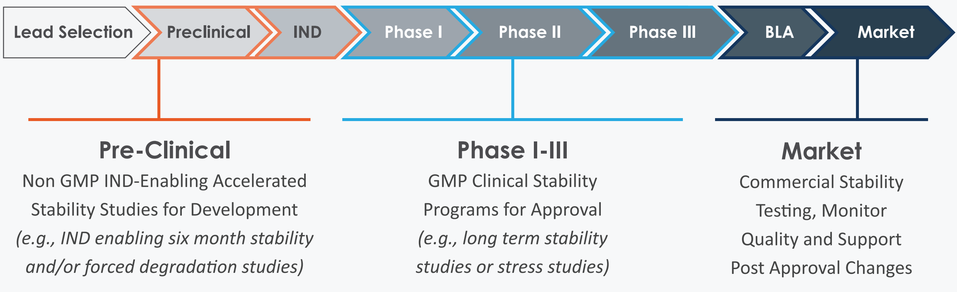
3
Provides qualified GMP/ICH environmental chambers for stability studies

4
Offers a solution for on-site storage capacity

5
Significant support for all major milestones in the development stages

Stability programs are most often multi-year programs. All analytical techniques must be robust to prevent out-of-specification (OOS), out-of-expectation (OOE), or out-of-trend (OOT) results which would put the study or a potential product release at risk. We implement and validate all applied methods, including a comprehensive robustness assessment for critical methods, e.g., DoE approaches.

With over 20 years of experience, we use mass spectrometry to assess degradation pathways and biochemical modifications that may occur during a stability study.



Pre-Clinical
Non GMP IND-Enabling Accelerated Stability Studies for Development
(e.g., IND enabling six month stability and/or forced degradation studies)

Phase I-III
GMP Clinical Stability Programs for Approval
(e.g., long term stability studies or stress studies)

Market
Commercial Stability Testing, Monitor Quality and Support Post Approval Changes

Enabling Tomorrow's Therapeutics

Contact our team to learn more about our stability programs and how we can achieve major milestones together.

Contact Us

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