Alcami Advantage
Capabilities: Stability

Alcami has the facilities, expertise and experience to ensure your stability studies to execute your stability study whether it is a project to support global registration, a change to a commercial product, or the pre-clinical API stability study to support an IND.

API and pharmaceutical product stability studies are performed throughout all phases of drug development and then carried on through the lifetime of the pharmaceutical product. While stability studies are required by 21CRP211.164, the purpose of the studies is to assure APIs and drug products maintain the safety and efficacy over time from pre-clinical to commercial.

The choice of right CRO to perform a stability study is crucial to the success of a product development program. Once a stability program is started, moving a program to a different laboratory is costly and can affect the timeline to file INDs, NDAs, or annual updates. Therefore, the choice of the CRO laboratory to perform the stability study cannot be taken lightly.

Attributes of the right stability-testing CRO laboratory:

Compliance Track Record:
The laboratory must have an established track record with regulatory agencies. New laboratories that have not been inspected are risky as they may have compliance gaps that are not readily detected during typical qualification audit.

Stability Chamber Capacity:
CRO stability testing laboratories need to have adequate chamber capacity at all times and must track the capacity utilization levels of each chamber. Given that new chamber capacity takes months to bring on-line from order to release, having sufficient capacity at all times at your CRO is vital for success of stability programs.

Years of Experience in the Laboratory and Designing Stability Programs:
Stability studies must be first time right. Leveraging an experienced stability protocol design team at a CRO can prevent INDs clinical holds or NDA's approval delays by ensuring your stability program comprehensive and complete.

Timely Testing and Reporting:
Stability testing must occur within days of the stability pull to ensure the results reflect the condition of the sample at the designated pull time. This is especially true for samples from accelerated conditions at early time points. The right CRO will have SOP(s) on the timing of the testing of stability practices and should have sound processes to track the status of the testing from pull to report.

Timely and Comprehensive OOS/OOT Investigations:
The right CRO must have a comprehensive OOS/OOT investigation SOP designed to determine the root cause of the OOS/OOT results in a timely fashion.

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Established Disaster Recovery Plan:
No geographical location or facility is immune from power interruption to natural or man-made causes. The right stability facility will have automatic back up utilities and a comprehensive disaster recovery plan to ensure the continuity of the studies.

The Benefits of Using Stability Services at Alcami

- The Alcami Stability Sites in Wilmington, St. Louis, and Edison, NJ have had dozens of audits from the FDA, EMA and other regulatory bodies with no findings.
- Walk-in chambers for ICH zones I, II, III, and IV conditions along with reach in chambers for stress conditions, -20°C, -70°C and photostability (Option 1 and 2).
- On-site redundant storage capacity at all accelerated, intermediate and long term ICH conditions. As well as off-site storage at other Alcami sites for disaster recovery storage.
- Alcami has a team of protocol writers with a combined 30 years of experience in writing stability protocols. This team is supported by a leadership team with decades of stability program experience. Alcami utilizes a Part 11 compliant stability protocol creation application to ensure all required study parameters are addressed in each protocol. This same system seamlessly creates the pull schedule, testing schedule and is linked to the electronic inventory of each lot of product.
- Chamber mapped with 24 probes are released by an independent quality team prior to use.

- State of the Art around-the-clock monitoring of chambers with automated call system that has multiple back-up systems to ensure all data is captured and all excursions result in alarms.
- Rigorous preventative maintenance program in place to ensure the chambers function as designed.
- Stability facility requiring two level of security for entry and off-hours security personnel and intrusion alarms to local authorities.
- Modern, well organized laboratories are staffed with fully trained analytical groups with a primary focus on stability testing. Same day testing of stability samples is available as needed by the studies.

Alcami has three North American sites with stability chambers; Wilmington, NC, St. Louis MO, and Edison, NJ. Back up samples can be held at different geographical locations to provide that insurance that your stability study would remain intact in case of a natural disaster at one of our locations.

Alcami has storage for all major ICH conditions Zone 1, 2, 3, and 4. While at the same time leverage our years of experience in the study design, data interpretation, and trend analysis.

Let Alcami be the CRO that provides you the insurance that you need to ensure the safety and compliance of your stability studies.