

TOP 5 CONSIDERATIONS FOR OUTSOURCING STABILITY STORAGE

WHAT SHOULD YOU EXPECT FROM YOUR OUTSOURCING PARTNER?

- ✓ Clear guidance on the design and execution of your stability program
- ✓ High level of end-to-end control over samples with each stability unit locked with access control and fully validated system for assigning and tracking removal dates ensuring samples are handled as per the client requirements
- ✓ Full product testing capability to GMP via a competent analytical laboratory network
- ✓ Sample distribution to global locations using Good Distribution Practice (GDP) accredited couriers
- ✓ Clear procedures for documenting deviations, storage excursions and disaster recovery, with clear communication and quick transmission of the information to the client when these situations arise



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Total Quality. Assured.

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Intertek Melbourn have provided GMP stability storage services since 2004. Our Stability team are currently coordinating over 200 stability studies for more than different 30 clients from across all global territories. We offer over 375,000L of capacity over various conditions, including ICH and bespoke conditions.

WHAT DOES YOUR OUTSOURCING PARTNER NEED FROM YOU?

- ✓ Input for protocol generation and approval: batch references, sample numbers, storage orientation, packaging etc
- ✓ Confirmation of requirements for sample removal/testing/distribution
- ✓ Understanding of hold and distribution conditions
- ✓ Timely notification of any changes to testing methods, specifications or other changes to the protocol throughout study duration
- ✓ Confirmation for disposition of residual samples upon study completion



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