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SAMPLE STABILITY & BIOREPOSITORY STORAGE BEST PRACTICES GUIDE

Access Our Best Practice Guide

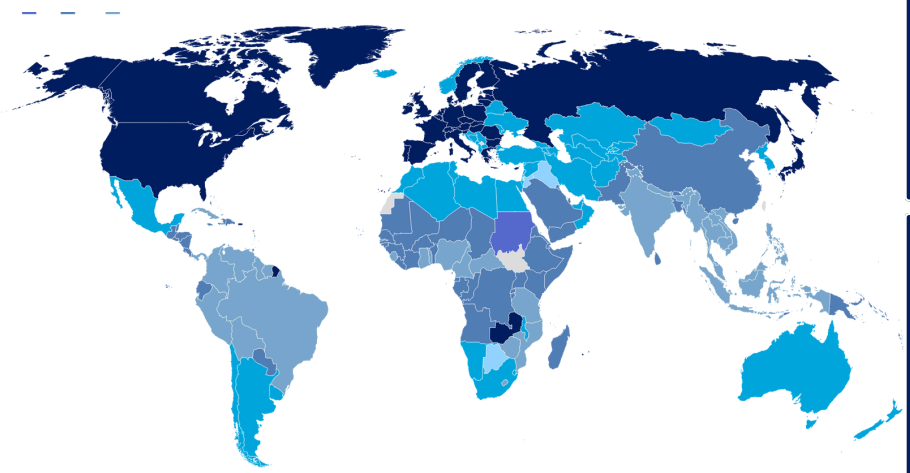
From proof-of-concept to commercialization, every new regulatory approved drug and device requires ~1 million samples to be stored along the R&D pipeline through patent expiration.

Pre-Clinical Research → Clinical Research → Drug Manufacturing → Drug Products

- Animal Samples
- Reagents/Chemicals
- Drug API & Excipients
- Drug Products/Packaging
- Bionalalytical Stability & Biological Samples
- Biologics & Substances
- Medical Devices

KNOW YOUR ICH STABILITY ZONE

- Zone I — Temperate zone
- Zone II — Mediterranean/subtropical zone
- Zone III — Hot dry zone
- Zone IV — Hot dry zone
- Zone IVa — Hot humid/Tropical zone
- Zone IVb — ASEAN testing conditions hot/higher humidity



Accelerated & Intermediate Testing Conditions

Climatic zone	Temp.	Humidity	Min. Duration
Accelerated Ambient	40°C ± 2°C	75% rH ± 5% rH	6 months
Accelerated Refrigerated	25°C ± 2°C	60% rH ± 5% rH	
Accelerated Frozen	5°C ± 3°C	No Humidity	
Intermediate	30°C ± 2°C	65% rH ± 5% rH	

Long Term Testing Conditions

Climatic zone	Temp.	Humidity	Min. Duration
Zone I	21°C ± 2°C	45% rH ± 5% rH	12 months
Zone II	25°C ± 2°C	60% rH ± 5% rH	
Zone III	30°C ± 2°C	35% rH ± 5% rH	
Zone IV	30°C ± 2°C	65% rH ± 5% rH	
Zone IVb	30°C ± 2°C	75% rH ± 5% rH	
Refrigerated	5°C ± 3°C	No Humidity	
Frozen	-15°C ± 5°C	No Humidity	

MASTERING STABILITY: BEST PRACTICES FOR ICH Q1A & Q1B COMPLIANCE

- ☑ Select batches representative of final formulation
- ☑ Perform photostability per Q1B using D65-equivalent light sources
- ☑ Document excursions & maintain full audit trails
- ☑ Store in validated chambers with real time monitoring
- ☑ Apply forced degradation studies to stress-test molecule integrity

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The sample types listed are a representation of the many samples stored by Astoriom. **Use the QR code to access a more complete version of our best practices guidelines.**

Sample Type	Temperature	Best Practices
Whole blood (Biorepository)	• 4°C (Refrigerator) ≤24–72 hours • -80°C (Ultra-low freezer) Months to years	• Avoid temperature fluctuations to preserve sample integrity • Document all storage conditions for traceability and quality control • Use temperature-monitored freezers with alarms
Whole Blood (Stability Studies & DNA/RNA analysis)	• -80°C (Ultra-low freezer)	• Minimize the number of freeze-thaw cycles • Store samples in secure, access-controlled facilities • Implement regular monitoring of storage conditions
Cells / Stem cells PBMCs, DNA/RNA	• 2°C to 8°C (Refrigeration) Use: Transport/holding before processing • -80°C Use: Short-Term: (hours to few days) • −135°C to -196°C (Liquid nitrogen vapor or liquid phase) Use: Years to decades	• Minimize refrigeration time to avoid reduced viability • For clinical-grade stem cells, follow GMP-compliant protocols and use validated cryobags or vials • Minimize freeze-thaw cycles, which damage cells • Store in liquid nitrogen vapor phase (−150°C to −196°C) to reduce contamination risk compared to immersion in liquid phase
FFPE Tissue	• 18°C - 25°C Use: Short-Term (weeks) • 2°C - 8°C (Incubator) Use: Medium-Term (several months) • -20°C to -80°C (Freezer or Ultra-low freezer) Use: Long-Term (months to years)	• Humidity: Low humidity (<30%) is ideal to prevent paraffin block degradation • Light: Store in the dark or in opaque containers—UV exposure can degrade nucleic acids • Avoid Fluctuations: Temperature cycling can accelerate degradation
FFPE Blocks	• Room temperature (18–25°C) Use: dry, temperature-stable environment (10-20 years)	• Avoid direct sunlight, excessive heat, or fluctuating temperatures • Humidity: Keep relative humidity <60%
Drugs / API - Vaccines	• 2–8°C - Refrigerated vaccines; • -15°C to -50°C – Frozen vaccines • -60°C to -80°C – Ultra-cold vaccines	• Monitor with continuous digital temperature loggers • Avoid freezing inactivated protein subunit • For Ultra-cold, use specialize freezer or thermal shippers
Drugs / API – Solids	• 15–25°C (controlled room temp)	• Stability testing per ICH Q1A (R2) required for shelf-life assignment • Monitor temperatures with calibrated GxP-compliant systems
Medical Devices	• 2-40°C depending on depending on kit, reagent and device	• Documentation - Maintain storage data logs for regulatory inspections (FDA, EMA, ISO) • Stability Testing - Conduct per ISO 11607, ICH Q1A, and simulate real-world transport/storage conditions

BECAUSE SAFEGUARDING EVERY SAMPLE MATTERS

- ICH, cGMP, MHRA, FDA, CAP accredited and ISO 9001 certified
- Global leader in regulatory compliant sample stability & biorepository storage
- Dedicated disaster recovery and protection planning solutions
- Experts in sample storage design with engineered services and validation solutions