

Outsourcing stability storage: A cost-effective and quality-driven approach for pharmaceutical and medical device companies

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Introduction

Stability storage is a vital part of the quality assurance process for pharmaceutical and medical device products, as it ensures that products meet the required standards and regulations throughout their shelf life. However, conducting stability storage in-house can be a complex and costly undertaking, requiring dedicated facilities, equipment, personnel, and resources. That is why many companies are opting to outsource their stability storage needs to a trusted and experienced partner that can offer them high-quality, flexible, and cost-effective stability storage solutions.

In this whitepaper, you will discover:

- ✓ How outsourcing stability storage can benefit your company by reducing operational costs, increasing efficiency and productivity, enhancing innovation and compliance, and accelerating time to market.
- ✓ Real-life case studies using leading pharmaceutical and medical device companies that have successfully leveraged outsourcing partnerships to achieve their stability storage goals and overcome their challenges.
- ✓ How Q1 Scientific, a Cambrex company, is transforming the way companies store their products, enabling faster drug launches to market, and saving companies the expense of building and monitoring their own storage chambers.

Outsourcing stability storage: A strategic solution

Stability storage is a vital component in drug and regulated product development for the pharmaceutical and medical device industry and contributes to the advancement of public health and well-being. The potential risks of a poorly managed stability programme are product recalls, adverse reactions, or lawsuits that could result from using an unstable or degraded drug or product.



About Cambrex

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance development and manufacturing across the entire drug lifecycle, as well as comprehensive analytical and IND enabling services.

With over 40 years of experience and a team of 2,000 experts servicing global clients from North America and Europe, Cambrex offers a range of specialized drug substance technologies and capabilities, including continuous flow, controlled substances, solid-state science, material characterization, and highly potent APIs.

About Q1 Scientific

If you are looking for a secure, reliable and cost-effective way to store your pharmaceutical and medical device products under any ICH or custom temperature and humidity condition, you need Q1 Scientific, the leader in outsourced stability storage. Operating from state-of-the-art facilities in Ireland, Belgium and the US, with walk-in rooms and reach-in cabinets that are fully validated and monitored 24/7, Q1 Scientific can store your samples at conditions ranging from -80 °C ultra-low freezer storage to over 50 °C.

Pharmaceutical and medical device companies often rely on in-house storage from old or used equipment for initial cost-savings, yet invariably end up with additional costs to manage equipment failures, routine maintenance, regulatory compliance and stability infrastructure to avoid missing scheduled time points.

Outsourcing stability storage is a strategic solution that can help pharmaceutical and medical device companies achieve stability programme excellence and gain a competitive edge in the global market.

The costs and risks associated with in-house stability storage

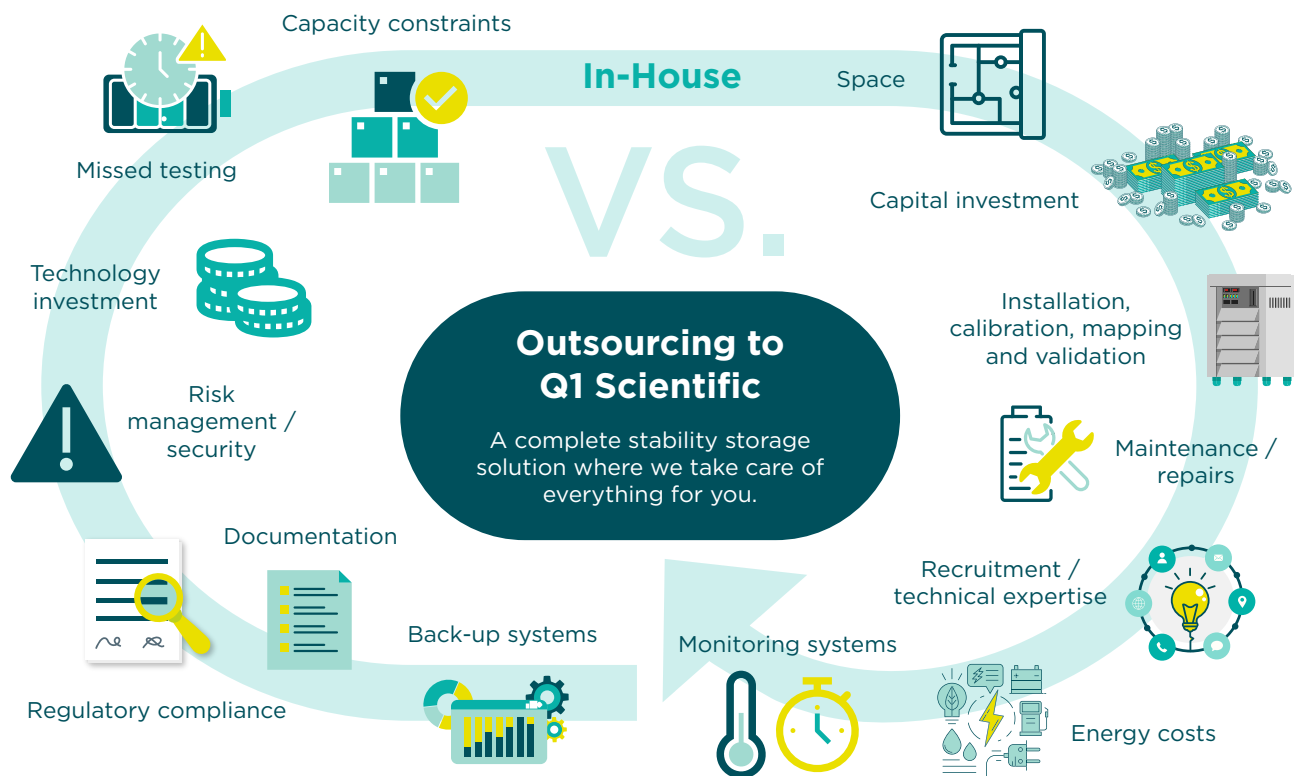
Performing stability storage in-house can entail significant costs and risks for pharmaceutical and medical device companies. Some of the costs and risks associated with in-house stability storage are:

Capital expenditure: Purchasing, installing, and validating stability chambers or cabinets requires a large initial investment, as well as ongoing maintenance and calibration costs. Stability chambers or cabinets also occupy valuable space and resources that could be used for other purposes.

Operational expenditure: Operating and managing stability chambers or cabinets incur additional costs, such as electricity, water, personnel, etc. Stability chambers or cabinets also consume energy and generate heat and noise, which can affect the working environment.

Compliance risk: Maintaining and monitoring stability chambers or cabinets poses a compliance risk, as companies need to adhere to the strict regulatory guidelines and standards for stability storage. Stability chambers or cabinets can malfunction or fail due to various reasons, such as power outage, mechanical breakdown or human error, which can compromise the integrity and safety of the stability samples and data.

Figure 1: The costs and risks associated with in-house stability storage



Key attributes to look for in an outsourcing partner

Choosing the right outsourcing partner for stability storage is a critical decision, as it can have a significant impact on product quality, regulatory compliance and market success. Therefore, it is important to identify and look for several key attributes in an outsourcing partner, such as:

GMP Compliance



Expertise and experience to ensure that their stability storage facilities and equipment meet the highest standards of Good Manufacturing Practice (GMP) and comply with the relevant regulatory guidelines and standards for stability storage.

Capability to perform validation, calibration, maintenance and monitoring of their storage chambers and systems.

Documentation and reports to demonstrate GMP compliance and support your audits and inspections.

Capacity



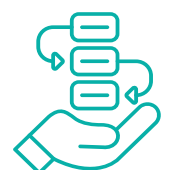
Capacity to accommodate various types of stability studies and products, ranging from small-scale to large-scale, from short-term to long-term, and from ambient to more extreme conditions.

A wide range of storage conditions, such as 25 °C/60% RH, 40 °C/75% RH, 5 °C, -20 °C, -80 °C, photostability, etc.

Customized solutions for non-standard, specialized requirements.

The ability to handle storage of a wide variety of pharmaceutical and medical device products.

Flexibility



Flexibility to adapt to your changing needs and demands.

On-demand access to stability storage and services, allowing you to start, stop or modify stability studies at any time.

Scalable solutions that can grow or shrink according to your product development and market strategies.

The ability to respond quickly and efficiently to any issues or challenges that may arise during the stability storage process.

Quality



Quality systems and controls to ensure that their stability storage services are reliable and consistent.

Staff and resources to perform regular quality checks and audits on storage facilities and equipment.

Technology and software to monitor and record the environmental parameters and alarms of their storage chambers and systems.

Technology for tracking and managing all samples.

Data access and visibility to you through secure online portals or platforms.

Guarantee the integrity and safety of your products throughout the stability storage process.

Efficiency



Efficiency to deliver your stability storage services in a timely and cost-effective manner.

Infrastructure and logistics to facilitate the transportation and handling of your products from your sites to their storage facilities and vice versa.

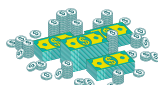

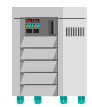













Communication and collaboration tools to coordinate with you and provide you with regular updates and feedback on your stability storage.

They ultimately should help you save time and money by eliminating the need for investing in or maintaining in-house stability storage facilities and equipment.

Why outsourcing?

Outsourcing stability storage to Q1 Scientific can help pharmaceutical and medical device companies save costs and resources, as well as improve their quality, efficiency, and innovation.

Figure 2: Q1 Scientific, a Cambrex Company: A trusted partner for outsourcing stability storage

In-House	Outsource
 <p>Requires large initial investment and ongoing maintenance costs for stability chambers or cabinets</p>	 <p>Eliminates the need for investing in or maintaining in-house stability chambers or cabinets</p>
 <p>Consumes valuable space and resources that could be used for other purposes</p>	 <p>Frees up valuable space and resources that could be used for other purposes</p>
 <p>Poses a compliance risk due to the strict regulatory guidelines and standards for stability testing</p>	 <p>Ensures the quality and compliance of stability samples and data by relying on the expertise and experience of Q1 Scientific</p>
 <p>Delays the product development and approval process due to the limited capacity and turnaround time for stability testing</p>	 <p>Accelerates the product development and approval process by providing immediate access to the required storage conditions and capacities</p>
 <p>Distracts from the core competencies and strategic goals of the company</p>	 <p>Enables the company to focus on its core competencies and strategic goals, rather than on the operational aspects of stability storage</p>
 <p>Lacks the flexibility and scalability to adapt to the changing needs and demands of the company</p>	 <p>Provides flexible and scalable solutions that can adapt to the changing needs and demands of the company</p>
 <p>Misses out on the knowledge and insights of the outsourcing partner, who can provide customized solutions, best practices, and market trends</p>	 <p>Benefits from the knowledge and insights of Q1 Scientific, who can provide customized solutions, best practices, and market trends</p>
 <p>Faces the risk of stability chamber or cabinet malfunction or failure, which could compromise the integrity and safety of stability samples and data</p>	 <p>Mitigates the risk of stability chamber or cabinet malfunction or failure, which could compromise the integrity and safety of stability samples and data</p>

Case Study: Optimized Stability Storage

Facing space constraints and regulatory pressures, a healthcare manufacturer turned to Q1 Scientific. By outsourcing stability storage to Q1 Scientific, they reduced costs, maintained quality standards, and concentrated on their core competencies — all while benefiting from Q1 Scientific's expertise.

Challenge

A leading healthcare manufacturer was running out of stability storage space at their site due to the prioritization of space for manufacturing operations. A decision was made to move the stability storage to leasable temporary units outside of their building that included three walk-in storage chambers at ICH conditions, costing them roughly €250k annually. Due to the stability storage chambers being outside the building in temporary units difficulty maintaining ICH conditions was exacerbated in the heat of summer and cold of winter. These stability storage chambers were frequently alarming due to being out of specification, often outside of regular work hours. The healthcare company wanted to avoid a regulatory headache down the road and find a more secure, reliable and cost-effective stability storage solution.

"Q1 Scientific offers direct contact with qualified people who know what is required. This ensures the project is straightforward from start to finish. A pull date schedule is prepared, provided, and adhered to, with email notice of sample dispatches which assists with planning the analysis regimen. The monthly billing structure is helpful and means that in the event of a product not performing as expected, the study is cancelled with minimum expense. It was a pleasure to deal with the Q1 staff who carried out their duties in a friendly and efficient manner."

Technical Manager, Healthcare Manufacturer

Solution

The healthcare company partnered with Q1 Scientific after seeing the benefits of outsourcing to an industry leader in storage with 24/7 monitoring, integrated backup systems and an expert team delivering secure, reliable and cost-effective stability storage solutions. The customer transferred all their stability samples to Q1 Scientific and saved significant costs in the process, turning CAPEX into OPEX.

Outcome

By outsourcing its stability storage to Q1 Scientific, the healthcare manufacturer:

- Eliminated the need for purchasing, installing or validating new stability chambers or cabinets, saving time and money.
- Ensured that their stability samples were stored and handled in accordance with the highest standards of Good Manufacturing Practice (GMP) and the relevant regulatory guidelines and standards.
- Mitigated the risk of stability chamber or cabinet malfunction or failure, which could compromise the integrity and safety of stability samples and data.
- Freed up valuable resources at their site that could be used for other purposes.
- Focused on their core competencies and strategic goals, rather than on the operational aspects of stability storage.
- Accessed the expertise and experience of Q1 Scientific to provide them with customized solutions, best practices and market insights for their stability storage needs.



Case Study: Disaster Recovery

During an ICH stability study crisis, a pharmaceutical company activated their Q1 Scientific disaster recovery plan. Samples were saved, timelines remained intact, and quality assurance was maintained thanks to a seamless sample transfer and expert support from Q1 Scientific.

Challenge

A pharmaceutical company was conducting stability testing on a new drug product intended to treat a rare, life-threatening disease. The product was in the final stage of development and on track to be submitted for regulatory approval. At one point in their ICH stability study, the company discovered that one of its stability chambers had malfunctioned due to a faulty sensor that caused the temperature and humidity levels to fluctuate erratically. The malfunction continued unnoticed for several hours, affecting hundreds of samples. The pharmaceutical company was unable to leverage its own in-house backup equipment, as all redundant chambers were already at full capacity. The pharmaceutical company faced the risk of losing valuable data and samples, delaying its regulatory filing, and compromising its product quality and patient safety.

"Q1 Scientific has provided us with an excellent resource for stability storage. The staff are very knowledgeable and friendly and show a great interest in our business. The security provided for critical samples is first class and allows us to know that our samples will be kept at the required conditions for the duration of our stability studies"

Leading Pharmaceutical Company

Solution

The pharmaceutical company was already an existing Q1 Scientific client and had space reserved in the event of an emergency to transfer samples within a 24-hour timeframe of the condition failure, remaining in compliance with ICH guidelines. This proactive approach of the customer reserving emergency backup storage space at Q1 Scientific is an example of many of our clients' risk mitigation strategies, highlighting the benefits of having a disaster recovery plan that includes a contingency agreement with industry leaders who offer a reliable and compliant stability storage service. As a result of our partnership and successful sample transfer to Q1 Scientific, the company was able to continue its stability testing program without interruption or deviation.

Outcome

By having a disaster recovery plan that involved Q1 Scientific as their backup/disaster recovery stability storage provider, the pharmaceutical company:

- Saved significant time and cost resources by avoiding the need to repeat or extend the stability testing program.
- Kept their regulatory filing on track, bringing the product to market as planned.
- Ensured the integrity and safety of their stability samples and data.
- Maintained their product quality and patient safety standards.



Case Study: Strategic Space Management

When storage space dwindled, a pharmaceutical company made a strategic move: outsourcing reference samples to Q1 Scientific. The result? Cost savings, efficiency gains, and continued regulatory compliance — all while unlocking valuable in-house resources.

Challenge

A leading pharmaceutical company with a portfolio of drug products in various stages of development, ranging from pre-clinical to post-marketing, was actively conducting stability testing on-site at their state-of-the-art facility in mainland Europe. However, they were facing a major problem of running out of storage space at their facility for samples on stability, risking potential delays to their development and regulatory filing timelines. The company had two types of stability samples in storage: reference samples (retained samples of each batch of drug product used for comparison and verification) and critical samples (drug products that are subjected to accelerated or long-term stability testing to determine their shelf life and expiration date). The company wanted to find a way to optimize its storage space and operational efficiency without compromising its product quality or regulatory compliance.

Solution

The company decided to outsource the storage of the reference samples to Q1 Scientific, a trusted provider of stability storage services. The benefits of this approach

included reduced operational costs, improvement of operational efficiency and accelerated development activities to drive more products to the market faster. However, they needed assurance of quality, regulatory compliance, communication, sample coordination and security to make the change. Following a tour of the Q1 Scientific facility, the pharmaceutical company was impressed with the team, infrastructure and approach to managing stability storage. They decided to move all their reference / retain samples to Q1 Scientific, which offered them 24/7 monitoring, integrated backup systems, GMP compliance, documentation and reports, transportation and logistics handling, and customized solutions for their stability storage needs.

Outcome

By outsourcing their reference sample storage to Q1 Scientific, the pharmaceutical company:

- Saved up to 40% of their operational costs with stability storage on-site by eliminating the need for purchasing, installing or validating new stability chambers or cabinets.
- Reduced the time associated with stability testing by up to 20% with the added efficiency gains from trusting the Q1 team to manage their samples.
- Freed up valuable space at their facility for storing critical samples that required in-house testing and monitoring.
- Ensured the integrity and safety of their reference samples and data by storing them in accordance with the highest standards of GMP and the relevant regulatory guidelines and standards.
- Accessed the expertise and experience of Q1 Scientific to provide them with customized solutions, best practices and market insights for their stability storage needs.

"We have worked with Q1 Scientific for a while now and we are always impressed with their knowledge, professionalism, and ability to assist with our requirements, often at short notice. No study is too small or too large, and atypical storage requests are always handled with the same care as large routine stability studies. I would highly recommend Q1 as a stability storage facility"

European Pharmaceutical Company

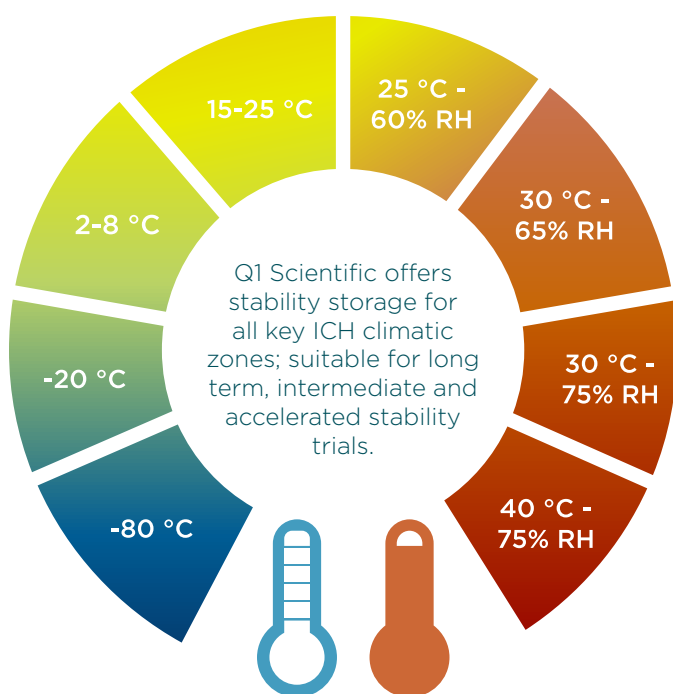


Working with Q1 Scientific

If you are looking for a secure, reliable and cost-effective way to store your pharmaceutical and medical device products under various environmental conditions, you need Q1 Scientific, the leader in outsourced stability storage. Operating from state-of-the-art facilities in Ireland, Belgium and the US, Q1 Scientific helps improve the speed of new drugs and medical devices reaching the marketplace along with saving companies the expense of building and monitoring their own storage chambers. With full equipment validation, tightly controlled conditions and continuous sample monitoring, Q1 Scientific is not just a storage provider, it is your trusted partner for stability storage excellence.

At Q1 Scientific, we store samples from -80 °C to +50 °C with a full range of humidity control working to standard ICH and custom conditions for R&D. Stability storage is available for all key ICH climatic zones; suitable for long-term, intermediate and accelerated stability trials with companies having a choice of shared or exclusive walk-in rooms and reach-in cabinets at these ICH or custom conditions:

Figure 3: Q1 Scientific stability storage for all key ICH climatic zones








Facilities overview

Waterford, Ireland

-  **30,000** sq ft facility
-  **40** walk-in stability storage chambers
-  **31** ultra-low freezers
-  **5** reach-in stability storage units
-  **3** reach-in freezers
-  **1** photostability unit
-  **1** thermal cycling unit

Liege, Belgium

-  **20,000** sq ft facility
-  **6** walk-in stability storage chambers
-  **4** ultra-low freezers
-  **1** reach-in stability storage units
-  **1** photostability unit

Durham, North Carolina

-  **7,000** cubic feet
-  **7** walk-in stability storage chambers
-  Reach-in units and ultra-low freezers available upon request

Conclusion

Throughout this whitepaper, we have presented the value and benefits of outsourcing stability storage. We hope that you have gained a deeper understanding of how outsourcing stability storage can help you overcome your current and future challenges, and how you can leverage the expertise and experience of Q1 Scientific to optimize your stability storage needs.

There are many reasons pharmaceutical, medical device and life science companies look to outsource their storage and stability needs. Whether you need storage of bulk materials taking up valuable in-house space, management of samples on ICH stability studies, access to specialized conditions e.g. photostability or establishing emergency off-site backup storage, trusting the right partner for your needs is crucial. At Q1 Scientific, a Cambrex Company, we provide our clients with peace of mind and instill confidence that samples are managed by experienced industry professionals with all the right tools for success.

Companies often rely on in-house storage from old or used equipment for initial cost-savings, yet invariably end up with additional costs to manage equipment failures, routine maintenance, regulatory compliance and stability infrastructure to avoid missing scheduled timepoints.

Our facilities offer:

- The full suite of ICH stability conditions compliant with ICH guidelines, in addition to non-standard and custom conditions by request.
- Walk-in and reach-in chambers that are mapped, fully qualified and maintained with continuous monitoring, backup data and power.
- A proprietary sample management system.
- A dedicated team of professionals who are renowned for excellence in the management of stability programmes, having a 100% success rate for stability pulls.

Q1 Scientific, with over a decade's worth of expertise, combined with over 40 years of experience by Cambrex, is transforming the way companies store their products, enabling faster drug launches to market, and saving companies the expense of building and monitoring their own storage chambers.

Contact us

If you are interested in learning more about how outsourcing your stability storage to Q1 Scientific can help you save time and money, while minimizing risk with our secure, reliable, and cost-effective stability storage solutions, please visit our website or contact us today at q1scientific.com.

