



SAMPLE STORAGE FOR THE PHARMACEUTICAL INDUSTRY

ARCHIV SERVICES

YOUR ADVANTAGES

- GLP- and GMP-certified security archives
- Experience with takeovers worldwide, including from CROs
- Personnel trained for GxP services
- Experience in handling of hazardous and temperature-controlled goods
- Protection from fire and water damage, redundant power supply
- Full air conditioning, firefighting and air monitoring systems
- Business continuity management (including disaster recovery)
- ISO 9001 and ISO 27001 certification
- Validated archive software in conformity with GAMP-5
- Fast, professional delivery of preservation items
- Transparency on all preservation items
- Access control and documentation
- Destruction and disposal within the Rhenus Group
- Labour for refilling and diagnostics

With Rhenus, the complete spectrum of custody, administration and destruction of pharmaceutical industry preservation items is all handled by just one contact partner. We assure you of a seamless track & trace for samples and documents.

Our services are comprehensive and global - and individually tailored to your needs.

THE COMPANY

Z.A.S. Zentral Archiv Services GmbH is operating GxP-compliant processing and archiving facilities for over 100 million preservation items for the pharmaceutical industry. Whether it is the fixed sample originating from animal studies or the file from the production documentation: Everything is stocked in GLP- and GMP-certified security archives in Germany and a few other European countries where they are retained in air-conditioned, especially protected areas.

Z.A.S. is a member of the Rhenus group. In the field of document and information logistics, Rhenus has responsibility for over 10 billion documents and works for over 15,000 customers at home and abroad. As regards the pharmaceutical industry, Rhenus is operating mailrooms for handling the incoming and outgoing physical and electronic mail, scanning stations for the GxP-compliant digitisation of paper-based documents, and facilities for mobile and stationary file and data carrier destruction. Rhenus is additionally providing digital archiving solutions.

Z.A.S. Zentral Archiv Service GmbH

Justus-von-Liebig Str. 7
17033 Neubrandenburg
Germany

Telephone: +49 (0) 395/570 51 00
Email: info@zas-archiv.de
Internet: www.zas-archiv.de



Good manufacturing practice (GMP)

A good manufacturing practice (GMP) is a production and control system that helps to ensure a quality product. Many countries have legislation and medical device companies must follow their legislation. These GMP guidelines remain more or less similar to the ultimate health of the patient as well as producing good quality medicinal products. In the U.S. a drug may be marketed if it has passed all of the specifications tests but is found to be manufactured which violates current good manufacturing guideline. The GMP is a mandatory aspect in pharmaceutical manufacturing. Although there are a number of them, all guidelines follow the same principle. Manufacturing processes are clearly defined and controlled to ensure consistency and compliance.



YOUR CHALLENGE

The keeping of preservation items such as sample material and retention samples in conformity with GLP, GCP or GMP specifications, and also raw data of the pharmaceutical or chemical industry, compels businesses to comply with special requirements that go far beyond the normal official regulations relating to the archiving of documents. It applies to all phases of the sample life cycle, from the receipt of samples at the archive location, to maintenance and monitoring of the specified storage conditions, long-term quality assurance of the preservation items, and also professional destruction and disposal.

In recent years, the volume of items in the GxP-regulated sector that are subject to retention requirements has increased constantly, and alongside the long-term preservation of the corresponding documents meanwhile constitutes a branch of archiving in its own right. It should be noted in this context that the preservation items must be archived separately from one another, with access restricted to appropriately qualified personnel.

OUR SOLUTION

We offer our pharmaceutical industry customers GxP-compliant, temperature-controlled and monitored archiving solutions for their preservation items resulting from diagnostics or (pre-)clinical research, in addition to their study and product licensing records. In the case of worldwide deliveries by CROs or clinical investigators, our service already begins before takeover of the items concerned with the organisation of professional transport, any import permits that may be required, as well as transfer agreements. Each preservation item is bar-coded at the time of takeover of your stocks of samples and/or files and captured in our archiving system, for example on a study base. Each move from the takeover through to ultimate destruction is recorded in the archiving system. Our online portal via which also the return of preservation items can be requested, gives you an all-time transparent overview of the stocks. Our service only ends with professional destruction and disposal in strict compliance with statutory regulations within the Rhenus Group. The portfolio of items we can archive includes:

- Wet tissues, preclinical organic material that has undergone fixation
- Paraffin blocks, microscope slides and x-ray images
- Sample material and retention samples to be preserved isothermally, e.g. at -20°C to -196°C
- Retention samples and active substances at room temperature or in temperature-controlled stability storage between 5°C and 40°C
- Electronic raw data in the shape of data carriers or digital data for long-term archiving

We also offer additional services, such as refilling of wet tissues or microscope diagnosis, in the microbiology laboratory that forms part of our archive. We accompany audits and inspections. We preserve our customers' documents in a GxP-compliant manner and destroy them professionally.

YOUR GAIN

The Rhenus solution allows you to archive your preservation items securely, reliably and cost-efficiently. Given that each preservation item is bar-coded and captured, we ensure absolute transparency over your stocks of samples and files. With its security archives, Rhenus has focussed on the pharmaceutical industry for many years and employs industry specialists as contact persons who can advise you on all matters relating to archiving.

Rhenus will organise and administer the complete sample life cycle of your preservation items on your behalf at global level, regardless of whether they originated from you or your service providers. The archives are equipped with all necessary safety features, including CO₂-based firefighting systems and full air conditioning. As with documents, the status of the individual preservation items is documented by the system in an audit-proof manner.

