

DISCOVER  
OUR SEGMENT

# GLP AND REGULATORY ARCHIVING



SCC

WE CARE FOR YOUR SUCCESS





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Head of GLP and Regulatory Archives  
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## Our focus

**With more than three decades of experience in the storage of regulatory and scientific data, we know precisely what counts most in the field. Both in scientific archiving and data storage in compliance with Good Laboratory Practice (GLP), we offer our customers sustainable overall concepts for all their regulatory needs.**

Our clients benefit from a European and global central archive that provides suitable, efficient and perfectly safe storage for their diverse archive materials.

We ensure regulatory compliance with secure data retention requirements, as well as reliable accessibility and availability in case of short-term requests.

Using our professional archiving solutions is the best and easiest way to protect, preserve and manage your data.

Benefit from our professional storage and our experience and expertise in data management by exploring our archiving possibilities in greater detail.

# GLP archiving services

With a vast of experience in the handling of GLP studies, SCC's experts archive your raw GLP data in a way that provides security and convenient access at the same time.

In 2004, we were certified by the German authorities as the first GLP contract archive in Germany. Since then, SCC has successfully passed further official reinspections, which are scheduled by the authorities at regular intervals.

## What we offer:

- Comprehensive GLP-compliant archiving concepts for all regulatory needs
- A European and worldwide central archive with the option of establishing separate customer archiving areas
- State-of-the-art technology and fully equipped archives, in line with official requirements
- Security monitoring 24/7
- Immediate reviews and re-evaluations of GLP study raw data by SCC scientists in response to inquiries from authorities



## The GLP Archive Management System has been developed, designed and proven as a valid GLP administration system with:

- Precise, immediate and easy retrieval of individual units of archived data and materials
- Complete audit trail of all entries or changes of records guaranteed
- Risk elimination through regular back-ups of the database

Our system ensures dependably safe and quickly accessible storage. Access to and movement of records and materials is carefully monitored and documented.

Let us be your reliable and high-quality partner for all GLP-related archiving issues.



## Regulatory archiving services

Our portfolio of tailor-made archiving services contains highly efficient solutions for your regulatory and scientific archiving needs. Our proprietary Electronic Document and Dossier Management System (EDDMS) ensures quick access to all regulatory information, including electronic documents and submission details, at all times and from any location.

**Proven and tested over decades**, EDDMS has established itself as our universal regulatory dossier management system.

With the help of **EDDMS**, our scientific and archiving experts have successfully managed **hundreds of dossier preparations** and international submissions.

**EDDMS** will simplify your day-to-day business operations and save you time and money during dossier preparation.



## Regulatory archiving services

### The benefits of using EDDMS:

- Particularly efficient in **data management for task forces** – from individually defining access rights for different client users to calculating study costs and cost compensations.
- **A convenient combination of versatile tools** for data administration, data presentation, tracking of studies and regulatory submissions.
- **Quick and easy dossier generation** (e.g. in the **CADDY** format) thanks to the automatic import function for reference lists, submitted electronic files and study headers.
- **Enables detailed searches** for available data in the entire data stock via a specially developed **index system**, which guarantees authorised users fast and reliable access to archived regulatory and scientific information from any part of the world.



# Who we are

SCC – Scientific Consulting Company – was founded in 1989 by Dr Friedbert Pistel. Since then, we have risen to become one of Europe's largest privately owned and independent scientific consulting companies, supporting global customers in the regulatory affairs business.

Our headquarters are located in Germany in the culturally rich Rhein-Nahe region, less than one hour's drive from Frankfurt Airport.

We have a second German office in Berlin, opened in 2014, and in 2018 also established SCC Japan in Tokyo, after 10 years of running a liaison office in Japan.

At SCC, you will find an open-minded, innovative entrepreneurial spirit backed by the expertise and commitment of a strong team. This winning combination has played a significant role in the rapid development of the company. We offer our customers high quality, flexibility, reliability and versatility, coupled with vast knowledge and a wealth of experience. Their success is what drives us forward.



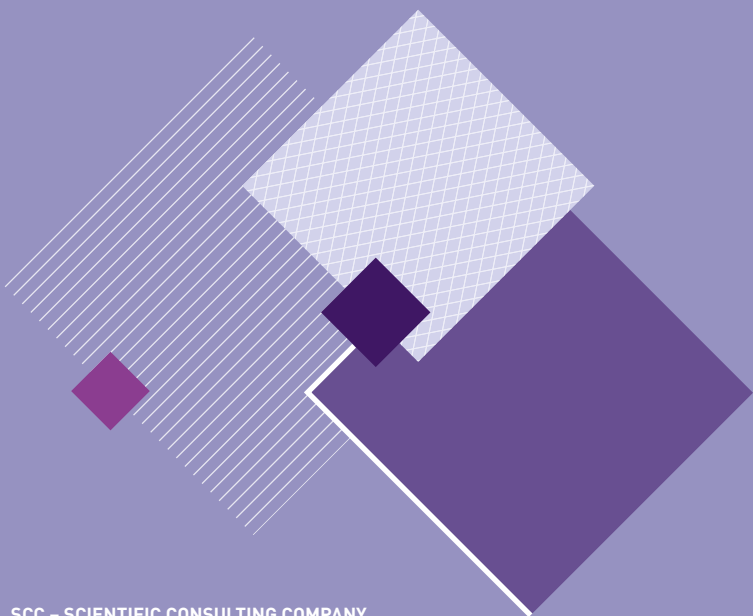
**85%**  
with a university  
degree

in  
**19**  
different  
disciplines

from  
**10**  
nations

**130**  
SCC employees





**SCC – SCIENTIFIC CONSULTING COMPANY**  
Chemisch-Wissenschaftliche Beratung GmbH

**HEADQUARTERS**  
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