
GCP compliance audit services
Health Inspired,
Quality Driven.
SGS

# About SGS Clinical Research

With over 40 years of experience as a CRO, SGS provides expert support for every stage of your clinical development, including oversight of quality.

At SGS, we understand that ensuring compliance is not just a regulatory obligation. It is also a commitment to the success of your clinical trials. Our audit services go beyond preventing trial delays – they provide a robust framework for ensuring oversight and maintaining unwavering compliance with regulatory standards. Partnering with SGS offers you the peace of mind and reliability that are essential for the seamless progression of your clinical trials. When you need to be sure, choose SGS.

"Our audit services aren't just about compliance – they're a testament to our unwavering passion for ensuring your clinical success."

**ISABELLE LENAERTS**
SGS QUALITY ASSURANCE DIRECTOR

# Benefits of GCP Compliance Audits

Audits, integral to ensuring Good Clinical Practice (GCP) compliance, involve systematic reviews of processes, documentation, and adherence to established principles. Their significance lies in the identification of areas for improvement, the assurance of data quality, and the upholding of regulatory and ethical standards in clinical research.

## Regulatory alignment

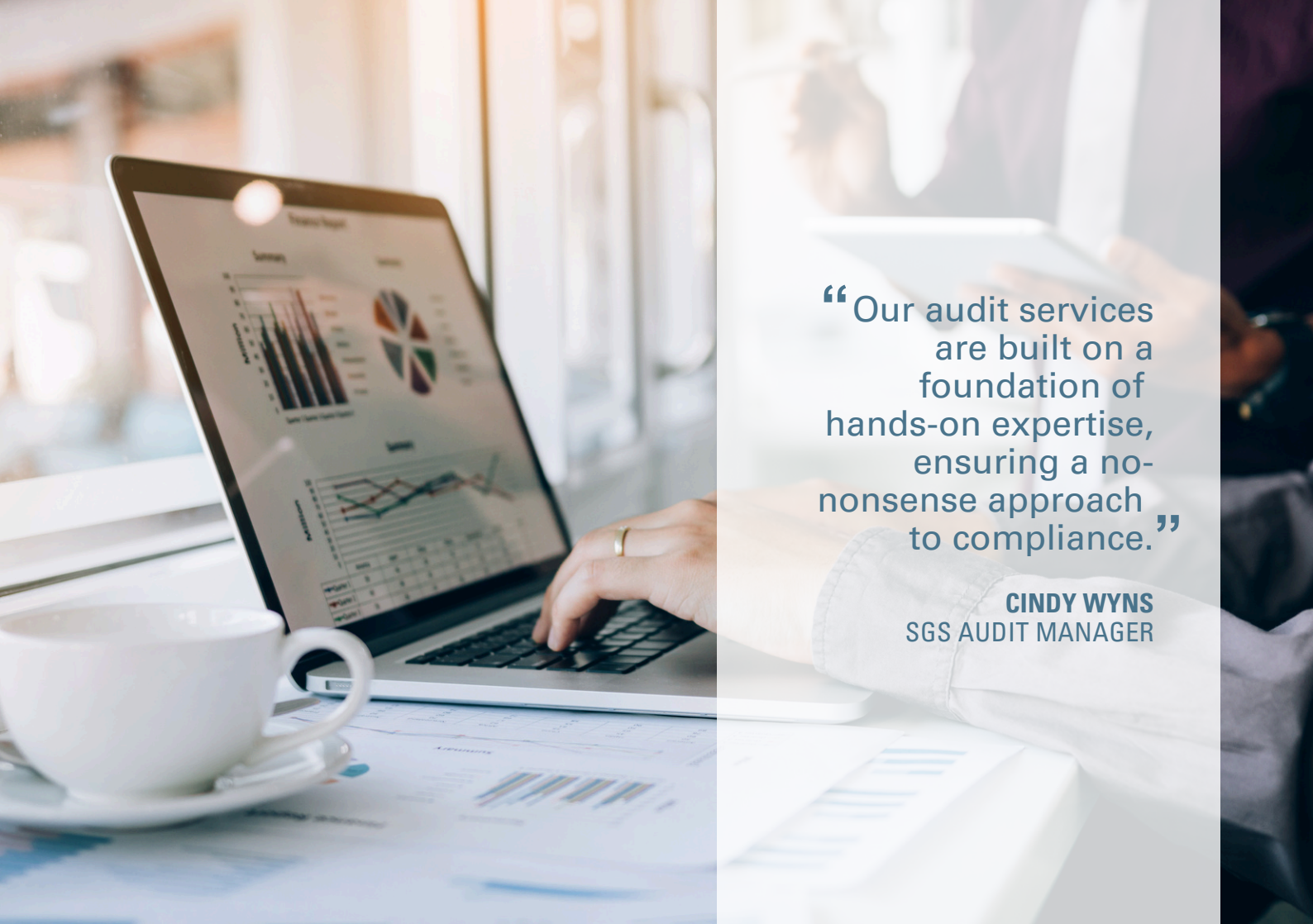
Ensures adherence to applicable laws and regulations.

## Impartial assessment

Independent audits provide an impartial and objective evaluation of an organization's risk and compliance, uncovering areas that might be overlooked internally.

## Preventive measures

Identifies potential issues proactively, allowing for timely corrective actions and preventing delays in reaching compliance. This ensures continuous preparedness.



"Our audit services are built on a foundation of hands-on expertise, ensuring a no-nonsense approach to compliance."

**CINDY WYNS**
SGS AUDIT MANAGER

# Our Audit Services

Our audit services - supporting Phase I-III clinical trials - provide enhanced quality standards, optimize clinical trial effectiveness and minimize regulatory risk. Whether you need support with study audits or qualification audits, we've got you covered.

# What to expect during the audit

### AUDIT REPORT | AUDIT CERTIFICATE

A comprehensive final report and audit certificate are delivered.

### AUDIT CONDUCT

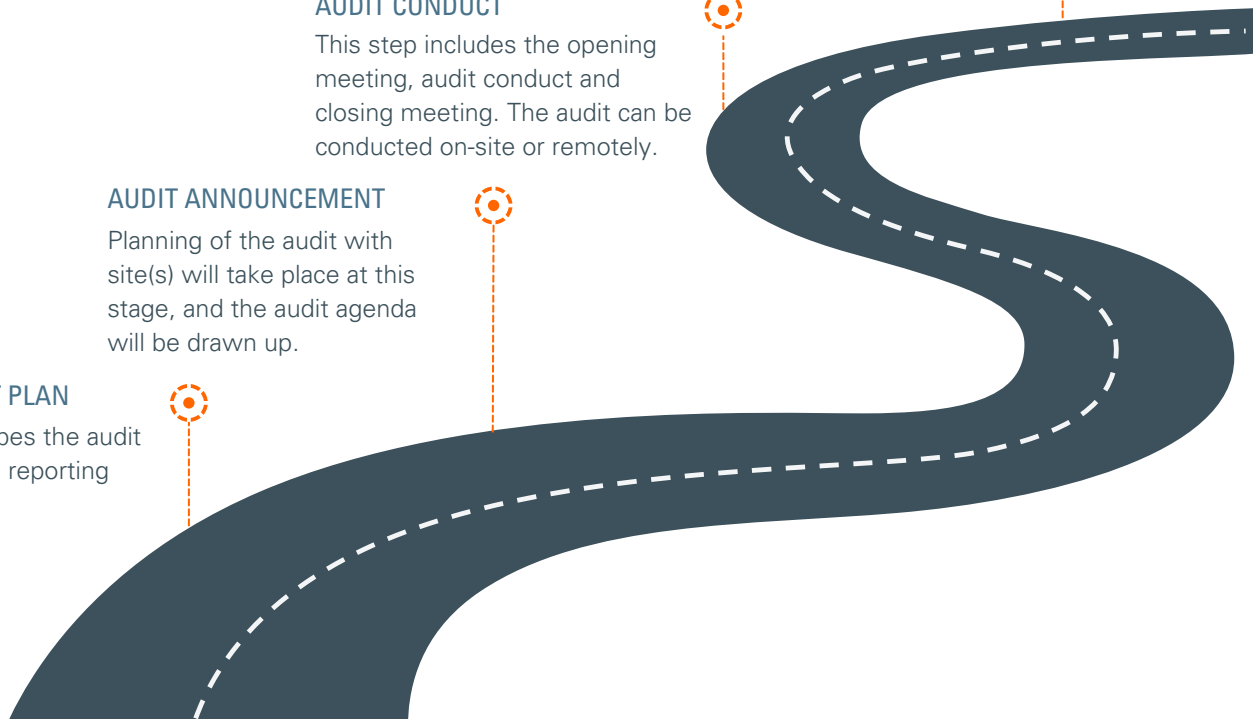
This step includes the opening meeting, audit conduct and closing meeting. The audit can be conducted on-site or remotely.

### AUDIT ANNOUNCEMENT

Planning of the audit with site(s) will take place at this stage, and the audit agenda will be drawn up.

### AUDIT PROJECT PLAN

This plan describes the audit strategy, scope, reporting and follow-up.



# Benefits of outsourcing

Outsourcing GCP compliance audits to SGS offers distinct advantages, allowing you to concentrate on your core activities while an impartial assessment of the processes or study in scope is being performed. We help you to identify the non-compliant areas and where to focus remedial actions if needed.

## Specialized knowledge and objectivity

Significant domain knowledge and expertise in GCP regulations gives SGS a thorough understanding of your compliance, while providing an unbiased perspective to minimize internal biases and conflicts of interest.

## Guidance and advice

This expertise allows SGS to offer valuable advice on addressing audit findings, facilitating effective implementation of corrective actions and maintaining an effective quality control program.

## Cost-effective solutions

Outsourcing GCP compliance audits proves cost-effective compared to maintaining an in-house audit team.

## Efficient compliance assurance

Conduct risk-based audits efficiently, focusing on potential non-compliance areas to save organizational resources and ensure adherence to regulations. This helps organizations to maintain a state of preparedness, reducing the risk of regulatory issues.

> “By focusing on the most significant risks, GCP audits can ensure proactive quality management, identifying potential issues before they impact trial outcomes.”

**ANN ENGELS**
SGS SENIOR QUALITY ASSURANCE AUDITOR

# Auditor team

Our experienced audit team offers broad European coverage, conducting thorough audits across study phases. With primary expertise in GCP, along with experience in GXP fields like GCLP, GMP and GAMP 5, our team excels in qualifying for study participation and evaluating compliance for both sites and vendors.

Several auditors on the SGS team have an operational background in key roles such as study coordinator, data quality coordinator, and CRA. This enhances their proficiency in executing effective and thorough audits. With access to a broad range of subject matter experts in clinical research, we ensure a comprehensive approach.

# Meet Dilan Könes

## SGS QUALITY ASSURANCE AUDITOR

With about 7 years of experience in clinical research and GCP, I have held various roles across the clinical research landscape ranging from clinical study site coordinator at an investigator site to positions supporting quality assurance on both the CRO and sponsor side. As a QA professional specializing in GCP auditing, I conduct a wide range of audits, including investigator site, system and vendor audits.

Each audit sparks my excitement as I navigate different protocols and processes, engage with stakeholders and delve into various processes.

# Pharma

## Health Inspired, Quality Driven.

## Contact us


clinicalresearch@sgs.com

sgs.com/pharma

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SGS

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