

**Expertise,  
Compliance,  
Performance**



# GCP Quality Audits

*Your expert partner for clinical trials meeting  
the highest standards*



OPTIMED

For over 35 years, Eurofins Optimed has been supporting healthcare stakeholders in conducting high-quality clinical studies, combining scientific rigour, innovation and operational excellence.

Thanks to our integration within the **Eurofins Scientific** Group, a global leader in analytical services present in over 55 countries, we are able to guarantee **international quality standards** to our clients while maintaining operational flexibility tailored to each project.

Our Quality & Audits department supports sponsors and partners in managing risks related to the conduct of clinical studies. Thanks to **our experienced Quality expert**, we offer tailored audits designed to meet your specific context.

**Our objective:** to help you ensure compliance, secure your data and anticipate deviations in order to strengthen the reliability and credibility of your clinical projects.

## Our audit services

### Qualification audits

Comprehensive assessment prior to the start of clinical studies.

### Preparation for regulatory inspections

Dedicated support and tailored guidance to ensure a smooth inspection process.

### Subcontractor audits

Comprehensive quality assurance of external service providers.

### Routine audits

Audits conducted to verify compliance of activities within an ongoing study.

## Why choose us?



Proven experience: successful audit track record, with four ANSM inspections confirming the robustness of our expertise.



Flexibility and responsiveness: interventions tailored to your operational constraints with short turnaround times.



Detailed post-audit follow-up: comprehensive reports, pragmatic recommendations and operational post-audit support.

## A strong and proven auditing expertise

- ◆ **30+ audits** of GCP, GMP and GLP facilities,
- ◆ **10+ audits in data security** and data management,
- ◆ **10+ audits of investigator sites**,
- ◆ Inspected by the **ANSM** as part of regulatory inspections,
- ◆ Experience covering **Phase I and II**, in both national and international environments,
- ◆ Strong knowledge of **ICH E6 (R3)**, EU Regulation **536/2014**, **GCP, GMP, GLP**,
- ◆ Expertise across the entire **quality system in clinical research**, with a strong focus on data security and integrity,
- ◆ **International** experience and **adaptability** to various regulatory environments,
- ◆ Recognised expertise in **CAPA management** and **continuous improvement**.

### *Lyes BOUZOUAGH (Lead auditor)*

- ◆ **PharmD** (Doctor of Pharmacy),
- ◆ Quality Assurance Manager,
- ◆ 5 years' experience in **GCP** quality audits,
- ◆ 2 years' experience in **GMP** quality audits.

Strong expertise to ensure the compliance and quality of your clinical trials.



# Contact

*For further information or to schedule an audit:*



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