Clinical Trials Center

ISO 9001 CERTIFIED 2015

Audits and Preparation for Inspections

USZ Universitäts Spital Zürich

Services
for Clinical Research

Head Quality Assurance

Claudia Hermann, PhD

Services

- Independent audits to optimize the quality of your projects
- Preparation for inspections by authorities or for external audits

GCP Audit

A GCP audit evaluates the conduct of clinical trials and research projects. The focus is on the verification of quality and integrity of recorded data, and of the procedures to ensure the rights, safety and well-being of trial subjects.

GMP/GDP Audit

A GMP/GDP audit is conducted at manufacturing sites of drugs and biologicals and bulk suppliers to verify the quality of active pharmaceutical ingredients (API) and drugs.

GCLP Audit

GCLP audits evaluates the compliance with quality standards for the handling and analysis of biological samples collected in clinical trials.

PV Audit

Pharmacovigilance (PV) describes the recording, monitoring and evaluation of adverse drug reactions. The purpose of an independent PV audit is the verification of compliance with regulatory requirements and operating procedures.

System Audits or Project Related Site Audits

The audit is conducted to evaluate the entire quality system (concept, requirements, implementation) or the trial/project specific procedures and the respective documentation (completeness, traceability).

Announced Inspection by Authorities or External Audit?

On request we conduct a mock audit or a mock inspection to help you preparing an audit or an inspection.

Tariff

Please ask for a quotation

How to find us

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