Dr. Dagmar Chase
Managing Director
GCP Advisor
dagmar.chase@clinrex.com

Clinrex GmbH

Rosenkavalierplatz 12
81925 Munich, Germany

Tel. +49 89 92 92 87 0
Fax +49 89 92 92 87 50

info@clinrex.com
www.clinrex.com

BVMA member since 2008
Audits passed in 2008, 2011
and 2015

Clinrex GmbH
your clinical research experts

HISTORY AND MISSION

Clinrex was founded by Dagmar Chase in 2004 to offer consulting services and training in the areas GCP and Project Coordination for clinical trials. Before Clinrex, Dagmar Chase accrued more than 20 years of knowledge in the respective fields through building a full service CRO. Besides growing the company, she always focussed on the quality management aspect of clinical trials. Now, as a consultant and trainer, passing on knowledge and experience is her mission.

HIGHLIGHTS

Since 2006, Clinrex is offering at its premises seminars under the slogan Smart Training®, meaning that the training is performed exclusively for small groups. Topics and questions can be discussed individually. The concept has proven to be highly effective for the participants. Certificates are issued.

In 2007, Clinrex started to offer the management of DSMBs/DMCs. Clinrex is able to build the internet platform to share information between the sponsor and the DSMB/DMC (open area) and between board/committee members only (closed area). All communication is channelled via Clinrex in order to ensure independence of the board/committee from the sponsor company which is an important factor for ECs and authorities.

SERVICES

GCP/Quality Management Consulting
- ▷ Assessment of systems or studies regarding GCP compliance
- ▷ Inspection preparedness
- ▷ SOP development/SOP streamlining
- ▷ GCP gap analyses
- ▷ Interface sponsor/CRO (CRO selection and oversight)
- ▷ Investigator Initiated Trials

Training
- ▷ Customised in-house training for sponsor companies and CROs
- ▷ Training for investigators and/or study nurses at hospitals or office based
- ▷ Smart Training® (see Highlights)

Project Coordination
- ▷ Identifying the right partners (third parties) for sponsor companies
- ▷ Third party management and oversight, link to sponsor companies
- ▷ Setting up investigator meetings

DSMB/DMC/Steering Committee
- ▷ Writing the charter
- ▷ Setting up an internet platform for shared documents
- ▷ Upload data/information as defined in the charter
- ▷ Expert Identification / Setting up the board/committee
- ▷ Management of boards/committees (facilitator role) (see Highlights)

Presentations
- ▷ How to avoid GCP inspection findings? (e.g. during Investigator Meetings)
- ▷ Investigator Initiated Trials
- ▷ EU Clinical Trials Regulation (EU) No 536/2014