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

Clinrex GmbH
your clinical research experts

HISTORY AND MISSION

Clinrex was founded in 2004 by Dagmar Chase to offer Quality Management consulting services, training and audits in the area of GCP. Before Clinrex, Dagmar Chase accrued more than two decades of knowledge in the respective fields through starting-up and growing a full service CRO. Dagmar Chase builds on over 30 years of experience when offering her services. Now, as a consultant and trainer, passing on knowledge and experience, is her mission.

HIGHLIGHTS

Since 2006, Clinrex is offering seminars at their premises 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 has 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 ethic committees and authorities.

SERVICES

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

Training
- ▷ Customized in-house training for sponsor companies and CROs
- ▷ Training for investigators and site personnel
- ▷ Smart Training® (see Highlights)
- ▷ Training Focus: ICH-GCP (R2), EU Clinical Trials Reg. 536/ 2014, AMG, Non-interventional Studies (NIS), IITs, Project Management / Working with CROs

DSMB / DMC / Steering Committee (see Highlights)
- ▷ Member identification / setting up the board/committee
- ▷ Writing the charter
- ▷ Setting up an internet platform (open / closed area)
- ▷ Upload data/information as defined in the charter
- ▷ Management of board/committee meetings (facilitator role)

Presentations
- ▷ How to avoid GCP inspection findings? (e.g., during Investigator Meetings)
- ▷ Investigator Initiated Trials
- ▷ Regulatory framework for clinical trials (e.g., ICH-GCP (R2), EU Clinical Trials Regulation 536/2014, AMG)
- ▷ Non-interventional Studies (NIS)