Biofrontera
Deep in dermatology

# Clinical Research Associate

## Job Purpose/Summary

The Clinical Research Associate is responsible for the processes and activities required in the initiation, execution and termination of clinical trial sites. Part of an international team, the position will have a focus on ongoing as well as planned trials in the United States and is expected to participate in trials internationally as required. The Clinical Research Associate will interface with investigators and site personnel for the successful execution of trials. All activity will be conducted in accordance with the applicable laws, rules and regulations and GCP.

## Duties/Responsibilities

- Will have primary responsibility for the initiation and execution of company sponsored clinical trials according to the specifications of Good Clinical Practice (ICH-GCP), the "Declaration of Helsinki" and the corresponding laws and regulations of the individual countries (e.g. 21CFR 312, 21CFR 812) where the clinical trial is being conducted
- Act as a part of the team to identify and perform site qualification visits
- Prepare site initiation packets and train site personnel on trial protocols and reporting requirements
- Perform periodic site monitoring according the established schedules
- Assist site audits and provide follow up to ensure corrective actions; provide follow up to ensure issues are corrected and trials proceed according to protocol
- Act as a resource to investigators and site personnel with regards to questions and EDT system issue
- Interface with internal and external employees or service providers to comply with the study protocol and respective Biofrontera SOPs
- Documentation of the process and the results of a clinical trials
- Support creation and maintenance of study specific trial master files as assigned
- Support in archiving of study-specific documents
- Ensure corporate and regulatory compliance for government for all marketed products
- Demonstrate compliance, company values and required competencies on a consistent basis
- Perform other related duties as requested

## Qualifications and Experience Required:

- Bachelor's degree from an accredited college or university in the life sciences or related field
- 3+ years of experience with clinical trials, preferably with direct monitoring experience
- Demonstrated knowledge of the regulations and guidelines laid down in the Declaration of Helsinki, in the ICH-E6 (GCP), especially the responsibilities provided in ICH-E6 section 5 (Sponsor), and in the respective local and international laws (e.g. FDA Regulations Relating to Good Clinical Practice and Clinical Trials, European Clinical Trial Regulation)
- Previous experience with data collection software utilized in clinical settings

## Key Attributes:

- Self-directed and confident
- Ability to work as a remote member of an international team
- Demonstrated ability to build teamwork centered on shared commitment and goals