senior clinical research associate

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Education / Clinical Research

2007 - 2008:	Module: Subject Specialist Clinical Research at the „FORUM Institut für Management GmbH“
2004:	Examination regarding expert knowledge in retail trade with over-the-counter-drugs according § 50 German Drug Law
1992 - 1993:	Vocational training as Clinical Research Associate at the „Institut für Klinische Pharmakologie Bobenheim, Prof. Dr. Lücker GmbH“ in Grünstadt, FRG with the examination result “excellent”

Career / Clinical Research

Since 06/1997:	Freelance Senior Clinical Research Associate
1995 - 1997:	Clinical Research Associate and Clinical Project Leader at the company “Orion Pharma GmbH” in Hamburg, FRG January 1996: Senior CRA, Head of Monitoring
1992 - 1995:	Clinical Research Associate and Clinical Project Leader at the „Institiut für Klinische Pharmakologie Bobenheim, Prof. Dr. Lücker GmbH“ in Grünstadt, FRG

Key Experience

- Budget planning and tracking
- Coaching as well as mentoring of trial sites and CRAs
- Co-Monitoring and QC Co-Monitoring
- Clinical trials of medical devices
- CRA training
- Electronic CRF
- Ethic and authority submission
- ICH GCP training
- Lecturer (retail trade with over-the-counter drugs)
- Monitoring of several multicenter and multinational studies phases I-IV
- Preparation and realization of investigator meetings
- Preparation of audits/inspections as well as participation and follow-up
- Project management of several multicenter and multinational studies phases I-IV
- Selection of investigational trial sites
- Set up a department “Clinical Research”
- Trial Master File review at sponsor

Therapeutic Experience

- AIDS
- Allergology
- Cardiology
- Dermatology
- Diabetology
- Endocrinology
- Gastroenterology
- Gynaecology
- Hematology
- Hyperhidrosis
- Immunology
- Infectious diseases
- Intensive Care
- Neurology
- Nutrition
- Obesity
- Oncology
- Ophthalmology
- Orthopedy
- Pain
- Pneumonology
- Psychiatry
- Reproduction
- Transplantation

Professional Training (Clinical Research) of the last 10 years

- Symposium „Audits & Inspektionen", DGPharMed, 01/2024
- Refresher Training GCP and Regulations, eurofins bioskin, 12/2022
- GCP-Refresher-Schulung, GCP-Service International Ltd. & Co.KG, 04/2022
- MPG Refresher/GCP Refresher, ARTIMED, 07/2021
- Workshop „Applied Course in Data Management", AGAH e.V., 06/2021
- MDR-Update-Schulung, GCP-Service International Ltd. & Co.KG, 11/2020
- GCP-Refresher-Schulung, GCP-Service International Ltd. & Co.KG, 04/2020
- Conference „5th European Conference on Clinical Research: Science, Technology and Regulations Coming Together for Better Patients´ Health", EUCROF, 02/2020
- Seminar „Das neue Monitoring-Konzept für klinische Prüfungen", FORUM, 09/2019
- MPG (Medicinal Devices Act) Refresher, FORUM, 11/2018
- Training „Klinische Prüfung von Arzneimitteln GCP Update Kurs 2018", S. Zeller for bios-kin GmbH, 11/2018
- Conference „4th European Conference on Clinical Research; Clinical Research in Europe: Are you ready to embrace the changes?", EUCROF, 02/2018
- Symposium „Audits & Inspektionen; Qualitätsmanagment at its best", DGPharMed, 09/2017
- Conference „3rd European Conference on Clinical Research; Flying to 2020: Managing Turbulences of Innovation and Change", EUCROF, 10/2016
- Refresher GCP-Prüfarztschulung, GCP-Service International Ltd. & Co.KG, 10/2016
- Course „Pharmaceutical Legislation Update", NSF Health Sciences, 10/2015
- Symposium „Audits & Inspektionen; Inspection Readiness – Akteure, Partner & Prozesse", DGPharMed, 01/2015
- Workshop „Was ändert sich mit der EU-Verordnung zu klinischen Arzneimittelprüfungen? Viele Fragen - Welche Antworten?", AGAH e.V., 06/2014
- MPG (Medicinal Devices Act) - Prüferkurs, ARTIMED, 05/2014

Status: January 2024