

## Marion Wendt

## CURRICULUM VITAE

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### Education / Clinical Research

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- 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. Lückner GmbH“ in Grünstadt, FRG with the examination result “excellent”

### Career / Clinical Research

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- 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 „Institut für Klinische Pharmakologie Bobenheim, Prof. Dr. Lückner GmbH“ in Grünstadt, FRG

### Key Experience

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- 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

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

## Professional Training (Clinical Research) of the last 10 years

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- MPDG-Refresher-Training, GCP-Service International Ltd. & Co.KG, 04/2024
- GCP-Refresher-Training, GCP-Service International Ltd. & Co.KG, 04/2024
- Symposium „Audits & Inspektionen“, DGPharMed, 01/2024
- Refresher Training GCP and Regulations, eurofins bioskin, 12/2022
- GCP-Refresher-Training, 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-Training, GCP-Service International Ltd. & Co.KG, 11/2020
- GCP-Refresher-Training, GCP-Service International Ltd. & Co.KG, 04/2020
- Conference „5<sup>th</sup> 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 bioskin GmbH, 11/2018
- Conference „4<sup>th</sup> European Conference on Clinical Research; Clinical Research in Europe: Are you ready to embrace the changes?“, EUCROF, 02/2018
- Symposium „Audits & Inspektionen; Qualitätsmanagement at its best“, DGPharMed, 09/2017
- Conference „3<sup>rd</sup> European Conference on Clinical Research; Flying to 2020: Managing Turbulences of Innovation and Change“, EUCROF, 10/2016
- Refresher GCP-Prüfarzt Schulung, 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

Status: January 2025