Wolfgang Oestreich, MD
Managing Director
opinfo@oandp-cro.com

Brian S. Raftery
Managing Director
opinfo@oandp-cro.com

Dr. Oestreich + Partner GmbH
Research+Marketing in Medicine+Pharmacy

Venloer Str. 47-53,
50672 Köln, Germany

Tel. +49 221 91287 10
Fax +49 221 91287 11

www.OandP-CRO.com

BVMA member since 2012
Audits passed in 2012 and 2015

DR. OESTREICH + PARTNER
Contract Research Organisation

HISTORY AND MISSION

DR. OESTREICH + PARTNER has been providing for over 20 years full service CRO capabilities including EDC software development to the clinical research community. We have experience in Pharma, Medical Device, Nutrition, Cosmetic industry and with health care institutions. Our philosophy is the synergy of the project´s research and commercial aspects giving an optimal return to the client´s investment. Project team building and its continuity is a critical criterion for success.

HIGHLIGHTS

»From experts for experts«. Since 1998 an in-house development of a 21 CFR 11 core compliant EDC system including high adaptability project orientation, user intuitive workflow interfacing and ongoing analysis of key metadata to support multilevel study optimisation and user resouce management (e.g. risk based monitoring).

»No marketing without research, no research without marketing«. However beneficial your health care product may be for the consumer, in the final equation it is the turnover and the profit to your company that count. **We offer consulting and implementation with competence and longstanding experience**.

»Pleasure in the job puts perfection in the work.«
Aristotle

SERVICES

Pharma

- Consulting: Medical, statistical and commercial support to product development
- Clinical trials: phases II-IV, NIS, pharmacoeconomic and observational studies
- Project management: site recruitment and qualification, ICH-GCP compliant On-site monitoring / On-line monitoring (EDC), study material management
- Data management: eCRF / pCRF, data cleaning, coding and reporting, customised software solutions, hosting and administration of product registries
- Biostatistics: case no. calc., randomisation, methodology, analysis, reporting
- SMO: providing professional personnel support for sites
- Multidisciplinary expert group to manage tasks with Authorities
- Medical Writing: study protocol, investigator brochures, study reports, DSUR, PSUR, literature search, publications
- Pharmacovigilance: E2B, NIS, PASS, PAES, SAE/ADR management, study / safety database reconciliation.
- Quality management based on ISO 9001, SOP creation and training, audits

Medical Devices

- **Pre-market:** Determining essential requirements, classification of medical devices and borderline products; risk management (ISO 14971); consulting on pre-clinical studies; conformity assessment procedure based on risk in combination with ISO 13485; clinical investigations in compliance with ISO 14155 guidances and ICH-GCP; services for non EU established companies; literature research and Clinical Evaluation Report preparation
- **Placing on the market:** Verification of classification and essential requirements; review of conformity assessment procedures; preparation of Technical Documentation; choice of an appropriate Notified Body
- **Post-market:** Implementation of post-market Medical Device vigilance system; clinical follow-up studies to demonstrate: essential requirements compliance, efficacy and cost effectiveness; handling and reporting of events and call-backs; storage and online access of Technical Documentation.