

Kernteam:

Anette Skowronsky

Managing Director MedConCap GmbH

Pharmacist; 22 years of experience in regulatory affairs, quality management systems, GMP, class I to III medical devices, clinical evaluation and communication with various professional groups in the healthcare sector.

The implementation of medical device-specific directives such as MDR, various MEDDEV and guidance documents is part of her daily business. She specializes in material medical devices and wound dressings.

She is also active as a 1st and 2nd party auditor in Germany and abroad, a sought-after moderator and author of specialist books.

Assumption of PRRC tasks in accordance with Art. 15 MDR.

Prof. Dr. Christine von Reibnitz

EBC Hochschule Berlin, Health Management, Master of Public Health

Many years of experience in the medical device industry with a focus on clinical evaluation, reimbursement and prescribability, health economics.

Prof. Dr. von Reibnitz also develops further education and training concepts.

She is also a renowned author of specialist books, a sought-after speaker and regularly publishes in various specialist journals.

Susanne Mays

Quality Management Officer and Regulatory Affairs Officer at MCC, Data Protection Officer and Auditor, Coach and Mediator.

Ms. Mays is also available as a multilingual team assistant.

Fredi Skowronsky

Data manager and Data Protection Officer, IT officer.

Supporting-Team:**Development and Supply Chain Management****Dr. Petra Hertel**

Many years of experience in research and development as well as production of medical devices in accordance with DIN EN ISO 13485. Further key areas are project management (planning, analysis, implementation, problem solving, time line, budget and customer management), acquisition and development of suppliers, supply chain management, establishment and further development of quality controls.

Extensive knowledge of risk management and biocompatibility standards rounds off her expertise. Assumption of tasks according to Art.15 MDR.

Project Management**Stefan Bergmann**

Long-standing project manager with experience in international projects in the medical and medical technology sector. Our colleague cooperates with national and international wound centers and clinics in the field of training. He sets up wound centers and develops curricula for training courses in the wound area. As a networker and communication fan, he opens us up to digital applications for clinical studies, wound documentation and training.

Clinical evaluations, clinical studies, data analysis, biostatistics and accompanying scientific research**Prof. Dr. Alexander Hodeck**

Sports scientist at the EBC University of Applied Sciences in Berlin and research assistant in the field of sports management at the Faculty of Sports Science at Leipzig University. Head of the Department of Sports Sociology at the TU Chemnitz.

Dr. med. Alper Erkin

Specialist in cardiac surgery and wound specialist. Head of the Department of Cardiac Surgery and Director of the Wound Clinic at Sakarya University in Turkey. The wound clinic is a model clinic in the region. Lecturer at Sakarya University, numerous publications in the field of wound care. Well-connected internationally in the field of wound healing and wound care, Dr. Erkin conducts clinical studies.

Prof. Dr. med. Ojan Assadian

Specialist in hygiene and microbiology, President of the Austrian Society for Hospital Hygiene. His work focuses on experimental and clinically applicable diagnostic and therapeutic methods for the treatment of infected wounds. Preparation of delimitation reports, various publications and author of specialist books.

Prof. Dr. med. Gerd Meißner

Specialist in surgery with many years of experience as Medical Director of the Saalekreis Emergency Medical Services, now a surgeon in private practice. He is a medically appointed expert witness for all courts, honorary judge of the Saxony-Anhalt Medical Association, member of the Society for Surgery, Emergency Medicine and Lymphology, member of the BDC. Various publications and lectures round off his expertise.

Questions on medicinal products, pharmaceutical law and the Qualified Person §14 AMG)

Dr. rer. nat. Monika Boos

Medical doctor specializing in pharmacovigilance/vigilance, many years of experience in various therapeutic areas including substances for skin diseases. Speaker and publications. Master of Laws in Pharmaceutical Law. Focus on clinical evaluation reports, vigilance, PSUR, PMCF, classification and demarcation issues of medicinal products/medical devices/cosmetics.

Specific question

Prof. Dr. med. Christoph Trautner:

Specialist in public health, cost-benefit analyses of treatments for various diseases, evaluation of data on epidemiology and health economics, preparation of biostatistical appraisals according to MEDDEV, various publications.

Other

Law Office Dr. Fandrich / Stuttgart and Bonn

For complex legal issues.

Climedo / Munich

Collaboration on clinical studies in the database area.