Name: Markus Bütler
Address: Burgstrasse 1
5634 Merenschwand

E-Mail: markus_buetler@bluewin.ch
Phone.: 056 664 34 31
Mobile.: 079 279 10 48
Nationality: Swiss
Date of Birth: 23.03.1963
Marital Status Married

LANGUAGES

- German: Mother tongue
- English: fluent in spoken and written

REFERENCE

- On request

JOB EXPERIENCE

01.07.2023 – to date, **Vice-President Quality Management, Operations & PRRC**

- Member of CorFlow's Management Team
- Direct Reporting to the Senior Director RnD
- Responsible for the Quality Management Strategy
- Responsible for the Quality Management according EN ISO 13485, MDR 2017/745/EC, 21CFR Part 820, 801, 803, 807, 822
- Responsible Person for Regulatory Compliance (PRRC)
- Responsible for the Conformity Assessment of the Medical Devices
- Initiating and reviewing of Technical Approvals according to IEC 60601-1, ff

01.08.2019 – 30.09.2023, **Vice-President Quality Management & Regulatory Affairs**

- Member of CorFlow's Management Team.
- Direct Reporting to the COO
- Responsible for the Quality Management and Regulatory Strategy
- Responsible for the Quality Management according EN ISO 13485, MDR 2017/745/EC, 21CFR Part 820, 801, 803, 807, 822
- Responsible Person for Regulatory Compliance (PRRC)
- Supporting Life Cycle Management in the company according to the Regulations
- Responsible for the Conformity Assessment of the Medical Devices
- Initiating and reviewing of Technical Approvals according to IEC 60601-1, ff

- Responsible for the Technical Documentation (STED), Design and Technical File according to Medical Device Regulation and FDA DeNovo (510k) applications in the USA
- Monitoring of the relevant applicable Regulation and Standards for Medical Devices
- Premarket approvals 510(k) Medical Devices
- Technical support for clinical trials including submission to the governments

01.01.2017 – 31.07.2019, **Director Post Market Surveillance**

- Definition and execution of the Post Marketing Processes globally
- Implementation and execution of the Vigilance requirements according MEDDEV 2.12-1
- Handling of the reporting system to Governments
- Complaint Management
- Support of Quality Management Projects globally
- Implementation MDR (Medical Device Regulation)

01.02.2013 - 31.12.2016, **Vice-President Quality Management**

- Reporting to COO
- Responsible for the Quality Management according EN ISO 13485, MDD 93/42/EC, 21CFR Part 820, 801, 803, 807, 822
- Quality Management according ISO 9001
- Life-Cycle Management Medical Devices
- Internal and external Audits
- MDSAP Medical Device Single Audit Program Assessments
- Company Registration PMDA, Taiwan, CFDA, Brazil, US-FDA, CMDCAS etc.
- Leadership and Management of the departments: Quality Management, Quality Engineering and Quality Control

01.06.2006 - 31.01.2013, **Vice-President Quality Management & Regulatory Affairs**

- Member of Medela's Management Team
- Reporting to the CEO Medela AG
- Responsible for the Quality Management according EN ISO 13485, MDD 93/42/EC, 21CFR Part 820, 801, 803, 807, 822
- Life Cycle Management according to the Regulations
- Conformity Assessment Medical Devices
- Technical Approvals according IEC 60601-1, ff
- Responsible for the Technical Documentation (STED), Design and Technical File
- Monitoring of the relevant Standards for Medical Devices
- Certification of Products worldwide, CFDA, Brazil, Japan etc.
- Premarket approvals 510(k) Medical Devices

01.11.1994 - 31.05.2006 **Head of Quality Management & Regulatory Affairs**

- Responsible for the Quality Management according EN ISO 13485, MDD 93/42/EC, 21CFR Part 820, 801, 803, 807, 822
- Support of the top management in Quality Management & Regulatory Affairs
- Internal and external Audits
- Conformity Assessments on Medical Devices
- Certification Products worldwide, CFDA, Brazil, Australia, Japan etc
- Premarket approvals 510(k)
- Reporting system to Authorities
- Leadership and Management of the Quality Department

Schweizerischer Elektrotechnischer Verein SEV (Electrosuisse) 01.04.1987-31.10.1994
Lumpenstrasse 1 8320 Fehraltorf

01.01.1993 - 31.10.1994 **Administrator**

- Administrator process planning and engineering for testing laboratories

01.10.1990 - 31.12 1992 **Deputy Group Leader**

01.04.1987 - 30.09.1990 **Administrator Electronic-Laboratory**

- Safety Tests on consumer, equipments, medical devices and Information Technology
- Tests according IEC 60601-1 / IEC 60601-1-2

COMPUTER SCIENCE

- Word, Excel, Outlook, Powerpoint, Microsoft and Mac experiences
- GUS ERP
- Pilgrim NCR / CAPA (Complaint System)
- DotCompliance eQMS

EDUCATION MASTER DIPLOMA

- Master of Advanced Studies Lucerne School of Business/FHZ in Business Excellence qualification 2009-2010
- The Postgraduate Diploma Executive Master of Business Excellence 2001-2003

DIPLOMA / EDUCATIONS

20 years of experience in Quality Management & Regulatory Affairs, Medical Devices and Products

- Medical Device Regulation Training (EU 2017/745 09.01.2019
- Regulation (EU) 2017/745 with focus on Post-Market Surveillance and Clinical Data 27./28.11.2018
- CQI and IRCA Certified Quality Management Systems Lead Auditor Training Incorporating ISO 13485:2016 and MDSAP Requirements 02. – 06.10.2017
- MDR Introduction Training, EU Medical Device Regulations 08.11.2016
- US FDA QM Requirments according 21CFR Part 820 QSReg/GMP 17.08.2015
- Internal Auditor, Refresher 28.05.2014
- CfPA, Root Cause Investigation for CAPA 01.04.2014
- SNV, Risk-Management new Standard ISO 31000 14.05.2009
- mdrs, Application Risik-Management Medical Devices ISO 14971 10.04.2008
- TÜV Akademie, Clinical Evaluation Medical Devices and Products 13.03.2008
- SAQ Business Excellence Coach 07.03.2003
- SAQ Business Excellence Assessor 17.01.2003
- CH/IQ, Excellence Assessor EFQM /SAQ 04.-24.05.2002
- Conformity Assessment Medical Products 18.01.2001
- EOQ Quality System Manager 03.03.1999
- AAMI, Design Control Requirements and Industry Practice 20.11.1998
- SAQ-MedTech Workshop FDA 23.02.1998
- Eurospec, Risk-Analysis Medical Devices and Software 17./18.02.1998
- Diploma Quality Engineering III 31.05.1996
- SAQ Complete Diploma A 3.B Quality Engineering III 19.06.1995-24.05.1996
- SAQ Internal Quality Audits 22./23.06.1995
- KLZ Kaufmännisches Lehrinstitut Zürich Graduated Economic Diploma, 28.10.1991-31.10.1992
- KLZ Kaufmännisches Lehrinstitut Zürich Business school 30.05.1988-24.05.1989
- Professional school Brugg, apprenticeship in electronics 1979-1983

INTERESTS

- Photographer, (www.markusbuetlerphotography.ch)
- Sport; Track and Field, Mountainbiking
- General Outdoor activities and traveling