Curriculum Vitae

DICK MARCEL BOXEM

RA/QA | MDR Technical Documentation | Validation | Medical Devices

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PROFILE

Senior RA/QA and validation consultant with 30+ years of experience in medical devices, pharmaceutical API production, combination products, cleanrooms, global registrations and regulated production environments. Specialised in MDR technical documentation, product registration support, ISO 13485/9001 quality systems, process/product/software validation, audit readiness, CAPA, risk management and pragmatic project execution.

MDR REGISTRATION & TECHNICAL DOCUMENTATION FOCUS

MDR registrations	Supported 10+ successful MDR product registrations.
Technical documentation	Created complete MDR technical documentation packages according to MDR Annex II and Annex III, with Annex I / GSPR alignment.
EUDAMED / UDI	Managed EUDAMED registrations and own UDI-DI XML upload tool for efficient registration data handling.
Portfolio control	Created standard overviews for relevant products, device classes, sterilisation routes, registration strategies and registration status.
Product scope	Sterile EO and Gamma products; Class Is, Im, Ir, IIa, IIb and III; procedure packs; implants; active devices; invasive and non-invasive devices; reusable surgical instruments and measuring devices.

CORE EXPERTISE

MDR 2017/745 | PMS | CER | PSUR | SSCP	MDR Annex I, II & III Documentation	EUDAMED | UDI-DI | XML Upload Tool
ISO 13485 | ISO 9001 | MDSAP	Notified Body & Supplier Audits	Risk Management | ISO 14971 | FMEA
CAPA | Complaints | FSCA	Process Validation DQ/IQ/OQ/PQ	Cleaning & Reprocessing Validation
Sterile EO/Gamma | Packaging | Shelf Life	Software Validation ERP/CAQ/DMS/PLM	Usability | V&V | Biocompatibility

LANGUAGES & WORKING STYLE

Languages	Dutch native; German business fluent; English business fluent.
Working style	Communicative, cooperative and team-oriented; takes responsibility; performs under pressure; goal-, problem- and performance-oriented; flexible, independent and open-minded.

SELECTED VALIDATION & REGULATORY SCOPE

- Usability engineering per ISO 62366 for drug-coated devices and arterial/venous stent systems.
- Reprocessing validation for CSSD-related implants, equipment and instruments according to ISO 17664/17665 expectations.
- Cleaning validation for pharmaceutical ingredients, class III combination devices, implants, active medical devices and instruments.
- Design V&V, biocompatibility, electrical safety, functional testing, accelerated aging, shelf life, transport validation, cold chain and dose mapping.
- Global registration documentation and device master records; collaboration with notified bodies and authorities in the USA, Canada, Japan, China, Brazil, South Korea, Taiwan, Mexico, Australia, KSA and other markets.

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PROFESSIONAL EXPERIENCE

Jan 2016 - Present — Owner / Independent Consultant | BoxQM

- Provides RA/QA consulting, MDR technical documentation, validation strategy and project execution for medical device, pharmaceutical and combination-products.
- Supported 10+ MDR product registrations including complete MDR Annex II and III technical documentation and Annex I / GSPR alignment.
- Managed EUDAMED registrations and an own UDI-DI XML upload tool to improve registration consistency and upload efficiency.
- Established standardised portfolio overviews covering product groups, device classes, sterilisation routes, registration strategies and registration status.
- Supports QMS, PMS/CER/PSUR/SSCP, validation documentation, audit readiness, URS, risk analyses, SOPs, templates and user/key-user training.

Dec 2011 - Dec 2015 — RA/QA Manager (QMR) | Medical device manufacturer, family-owned company

Leading RA/QA department with budget, functional and managerial responsibility; coordinated CAPA, complaints, regulatory affairs and QC interfaces.

Achievements: Improved audit readiness and regulatory compliance across international markets by optimising the QMS, leading critical validation programs, and managing risk/FMEA, CAPA, FSCA and product registration activities for major global jurisdictions.

Jun 2011 - Dec 2011 — Head of Quality Management (QMR) | US medical device company

Leading RA/QA department with budget, functional and managerial responsibility; coordinated CAPA, complaints, regulatory affairs and QC interfaces.

Achievements: Reduced testing effort using validation results; implemented transparency-based geometrical measurement; developed a lean Gauge R&R procedure.

Apr 2009 - Jun 2011 — Validation & Calibration Manager Europe | US company, Corporate QA

Lead EU validation/calibration specialists and implemented the Global Harmonized Process Validation project across European facilities.

Achievements: Implemented harmonised process validation in Europe; restructured the Gauge R&R process.

Jul 2007 - Apr 2009 — Validation Manager | US company, Biomaterials

Created, planned and executed equipment qualifications, process validations, packaging qualifications, URS, change controls, FMEA, deviations, CAPA plans and SOP training.

Achievements: Created cleaning validation for coated class III combination-device implants; supported cleanroom production equipment planning; created cleanroom and equipment validation concepts.

Sep 1994 - Jul 2007 — Technical Manager Quality / Process Assurance | Altana Pharma AG / Byk Gulden

Established FDA-compliant quality standards, SAP-PM maintenance processesvalidation plans: DQ/IQ/OQ/PQ, PCS, CIP, technical changes, SOP/GMP/safety training and CAD documentation.

Achievements: Leading RFID/SAP-PM mobile data capture pilot; scale-up API production and new solvent tank farm with project team.

Sep 1990 - Sep 1994 — Process Operator-B / Chemical Engineer | Servo Delden GmbH

Project lead pilot-scale development and batch production of chemical specialties; performed IPC laboratory work including AAS, HPLC, argentometry, UV-Vis, KF and IR.

CERTIFICATES & TRAINING

Provider	Certificate / Training
Team-NB	MDR Clinical Training for Manufacturers
Team-NB	MDR Technical Documentation Training
TÜV Rheinland	Expert Quality Management Medical Devices International
AAMI	FDA/QSR training
DGQ	Quality Systems Auditor
PCS	Combination products; CAPA in GMP environment; qualification symposium
BG / DuPont	Safety officer; effective employee instruction; work-safety management for leadership
Concept Heidelberg	Pharma technical expert; change control management; FDA qualification and validation
Chemgineering / ISPE	21 CFR Part 11; GAMP 4; GAMP 5
TopConcept	Leadership/personnel management; conflict management; moderation; communication and presentation techniques

EDUCATION

1991 - 1993	VAPRO Process Operator (Bsc.)- chemical process engineering and process technology; chemistry, physics and mathematics - Certificate.
1982 - 1988	Technical College / Laboratory School for Chemical Engineering (Bsc.)- Analytical Chemistry - Certificate.
1978 - 1982	MAVO 4D Secondary School - mathematics, physics, computer technology, chemistry, biology, German and English.

MILITARY SERVICE

1988 - 1990	Compulsory military service, Military Engineering, Netherlands - Sergeant.

STANDARDS & REGULATORY FRAMEWORKS

Experienced with: EU MDR 2017/745, MDR Annex I/II/III/VI, ISO 13485, ISO 14971, ISO/TR 24971, ISO 20417, ISO 15223-1, ISO 10993 series, ISO 11607, ISO 11135, ISO 11137, ISO 17664, ISO 17665, ISO 14644, IEC 60601, IEC 62304, IEC 62366, IEC 81001-5-1, IEC 80001-1, ISO/IEC 16022, ISO/IEC 15415, ISO/IEC 15418, GS1 DataMatrix/UDI, FDA 21 CFR Parts 3, 4, 11, 210, 211 and 820, EU GMP Annex 11, GAMP 5, Health Canada SOR/98-282, ANVISA RDC 751/2022, China NMPA medical device registration provisions, Taiwan Medical Devices Act / TFDA regulations, TGA Essential Principles / ARGMD, Japan PMD Act / MHLW MO169 and Korean MFDS Medical Device Act / KGMP requirements.