CURRICULUM VITAE Dick Boxem

2023

Personal Data

Name	**Dick Marcel Boxem**
Address	Hauserswiesen-Ring 23, D-78187 Geisingen, Germany
Tel. private	Mobil:0163 140 69 34
Birthdate	1965, Enschede Netherlands
Web / Email	www.boxqm.de info@boxqm.de

Qualifications

Languages	German, business fluent English, business fluent Dutch, mother tongue
Validation	**Usability ISO 62366,** (Drug coated devices, Arterial and venous stent systems) **Reprocessing:** (CSSD) e.g. Implants, Equipment, Instruments,… (ISO 17664/17665) **Cleaning validation:** Pharmaceutical Ingredients, Combination Devices Class 3, Implants, active MD, Instruments,… **Process validation** (DQ, IQ, OQ, PQ) Multiple processes see attached Project List **Product validation/Verification** during development (Design V&V), Biocompatibility, usability, electrical Safety (ISO 60601-ff), functional testing, accelerated product aging, shelf life, Transport validation, Cold chain, dose mapping …. **Method validation** (Gauge R&R, ….) **Software validation** business software and their interfaces (ERP, CAQ, DMS, PLM) **Clean Room validation** Class GMP C/D resp. ISO 7/8
Consulting	Professional consulting of Quality management systems Professional consulting Regulatory Affairs(MDR 2017/745, Post Market Surveillance PMS, CER, PSUR.) Requirement-, Process-, Feasibility-,Risk-, Functional- and interface analysis conceptional problem solving Analysis of business processes
Realisation	Creating coarse and fine concepts (URS) Project responsibility (in Time - in Budget) Verification- and Validation projects Quality assurance methods Documentation Training of key user and users
Project Management	Project planning, -supervision, -controlling and -documentation
certifications	ISO 9001; ISO 13485 and 13485 MDSAP certification Analysis and documentation of business processes. Compilation of SOP´s and Forms Creation of Quality management manual Planning, conducting Management review Planning, conducting of Audits, internal /external (Supplier)

Regulatory Affairs	Planning and preparation of registration documentation and Device Master records for global Registrations. Collaboration with notified bodies and authorities worldwide. (e.g. USA, Canada, Japan, China, Brazil, S-Korea, Taiwan, Mexico, Australia, KSA,…

additional qualifications

AAMI:	FDA/QSR-Training
DGQ	Auditor Quality systems
PCS:	Combination products; CAPA im GMP-Umfeld; Symposium Qualifizierung.
BG:	Safety officer work safety ; Mitarbeiter wirksam unterweisen Grundlagen und Aufbauseminar.
DuPont:	Work safety-Management for Leadership
Concept Heidelberg:	Pharma-Technical expert; Change Control-Management; FDA Qualification and Validation.
Chemgineering:	21CFR Part 11; GAMP 4
ISPE:	GAMP 5
TopConcept:	Leadership and personell Management; conflict Management; Moderation and Presentation; communication and presentation techniques.
Personal Qualities	Well-mannered Communicative competence Team player Takes responsibility Is able to work under pressure cooperative nature goal-, problem- and performance oriented Flexible Independent and responsible open minded

Professional Experience

Date	Since 01.01.2016
Company	Owner of Box^{QM}
Date	12.2011 till 31.12.2015
Company	Medical device, Family owned Company: Instruments Production as well as Worldwide Sale of Active and Non active Medical devices class 1, 2a, 2B and 3
Department	RA/QA
Function	RA/QA Manager (QMB)
Responsibilities	- Budget, functional and managerial responsibility for RA/QA department (3 head count, CAPA, Complaints and regulatory affairs specialist) with Personal planning and personnel development - Functional responsibility for QC Team (6 head counts) - Mentoring and Optimization of QM-System (PROFIT) - Planning, conducting of Audits, internal /external (Supplier) - Supervision of Audits by Notified Body and Authorities (9001, 13485, CMDCAS, ANVISA/INMETRO/KFDA, RP,…..) - Software, Process- and Product validations (e.g. final Product cleaning, Laser welding, CNC 3 and 5 spindle) - Document change control incl. Harmonized Standards - Internal and external Contact for all Quality issues. - National and international Product registrations (DIMDI, FDA, China, Saudi Arabia, Taiwan….. - Control/Moderation of Risk analysis FMEA (ISO14971), CAPA and FSCA. - safety officer
Date	06.2011 till 12.2011

Company	US Company, Instruments Production, D-78532 Tuttlingen
Department	Quality Assurance
Function	**Head Quality Management QMB/UMB**
Responsibilities	Maintaining and optimization of the existing Quality system including the reporting to Management. Execution internal and external Audits (Supplier audits) Processing including Approval and release of Non conformances,, Complaints, Change Control and CAPAs Planning and Execution of Certification and regulatory Audits (9001, 13485 and 14001) Process- and Product validation (Molding, Vacuum hardening) Team leader: Q-Control, Document control and Test planning Acquisition and Control of Performance indexes (KPIs) Key contact for Development and Production for al quality related issues.
Major achievements	Test reduction by usage of Validation results New implemented the usage of transparencies to measure geometrical dimensions Development of a lean Gage R&R procedure
Date	04.2009 till 06.2011
Company	US Company, Corporate Function Solothurn/ Oberdorf, Switzerland
Department	Corporate Quality Assurance
Function	**Validation & Calibration Manager Europe**
Responsibilities	technical and disciplinary superior for the “Special Process Coordinator” Technical superior for all EU Validation Engineers and Calibration specialists Planning and Implementation of the Project “Global harmonized Process Validation” Key Contact during Certification and regulatory audits for all Validation and Calibration issues. QA Representative during the Definition of CAPA, FMEA and cGMP Measures within the EU facilities
Major achievements	Planning of Gage management in SAP (QM/PM) Implementation Project Global harmonized process validation in Europa Restructuring of the Gage R&R Process
Date	07.2007 til 04.2009
Company	US Company, CH-4436 Oberdorf Switzerland
Department	Biomaterials
Function	**Validation Manager**
Responsibilities	Creation, Planning and Execution of Equipment Qualifications. Creation, Checking, Planning and Execution of Process Validations. Packaging Qualifications according ISTA and DIN 11607 (Sterile Packaging) Creation, Control and Consulting of User Requirement Specifications (URS) . Creation and Execution of Document Change Controls, Quality- (GMP) and Safety Creation and Maintenance of Equipment Lists, Calibration- and Maintenance plans. Creation and Moderation of Quality- and Process-Risk analysis (FMEA). Creation and Execution of Deviations and CAPA Plans. Creation and Training of (SOPs
Major achievements	Creation and Execution der Cleaning validation for Coated Implants (Combination Device, Class3) Support at Planning and Design of Cleanroom including the Production Equipment Validation concepts created for Clean room and Equipment. Sterility Dose Audits, refurbishment and cleanliness taking the regulations in to account

CURRICULUM VITAE Dick Boxem

Date	09.1994 til 07.2007
Company	Altana Pharma AG (former Byk Gulden) Singen a Htw, Germany
Department	Pharmaceutical API Production
Function	**Technical Manager Quality /- Process Assurance**
Responsibilities	Design and Establishing of FDA compliant Quality standards. Design and Establishing, IT-Maintenance system SAP-PM with Project team as System administrator. Planning and definition of cleaning /- Process validations. Planning and Development of Process/- Safety optimizations. Control and planning of Maintenance with SAP-PM. Technical Controlling with SAP-PM and Production planning. Order and Control Maintenance of internal and external personnel Creation, Execution and Control of Qualifications DQ, IQ, OQ and PQ. Creation, Control and release of Technical Changes (Change-Control) Creation, Control and Training of SOP, GMP and Safety (intercompany) Creation of simple CAD Drawings, e.g. R+I and maintenance shop engineering drawings
Major achievements	Project lead of Pilot Project „Mobile Data capturing with RFID/SAP-PM Planning, Installation and Start-up of a new API-Production and Solvent Tank farm with Project team.
Date	09.1990 till 09.1994
Company	Servo Delden GmbH , Netherlands
Department	Chemical Specialties Production
Function	**Process operator-B/ Chemical Engineer**
Responsibilities	Team leader at the development of chemical specialties in pilot scale plant Batch production of diverse chemical specialties. IPC-Laboratory, AAS, HPLC IPC-Laboratory, Argentometry, HPLC, UV -Vis, KF, IR
Major achievements	Team member for the development of liquid Detergents by means of sulfonation

compulsory military service

Date	10.1988 – 09.1990
Department	Military engineering (NL)
Function	Sergeant

School- and Vocational Training

Date	1991 – 1993
Educational institution	VAPRO (Process operator)
Major subjects	chemical process engineering and process technology Chemistry, Physics and Mathematics
Graduation	With Certificate
Date	1982 – 1988
Educational institution	technical college (Laboratory School for chemical engineer)
Study course	Analytic Chemistry
Graduation	With Certificate
Date	1978 – 1982
Educational institution	MAVO 4D (Secondary School)
Major subjects	Math's Physics, Computer technic, Chemistry, Biology German, English
Date	1972 – 1978
Educational institution	Primary School