CURRICULUM VITAE

PERSONALIA

Name:	Wenmekers
Christian names:	Theodorus Wilhelmus René
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	The Netherlands
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STUDY:

- MSc Industrial Statistics and Quality Engineering, TU/e Eindhoven, NL. 2002-2004
- MBA Business Administration HBO, Heerlen, NL. 1997-1999
- BC/Ing. Chemical Technology, specialization: Polymer technology, HTS Heerlen, NL. 1988-1993
- Molecular Science, Agricultural University, Wageningen, NL. 1987-1988
- Atheneum, Bisschoppelijk College Sittard, NL. 1985-1987
- HAVO, Bisschoppelijk College Sittard, NL. 1982-1985
- MAVO, Land van Gulick Sittard, NL. 1978-1982

WQRE.B.V.:

2012 Foundation of my Own Consultancy firm: WQRE.bv (Wenmekers, Quality and Regulatory Expertise). Chamber of commerce #: NL-56933568

Scope of the organization:

Consultancy for Medical devices (Class I-III) on:

- Regulatory Compliance, (worldwide)
- Quality Compliance
- Technical dossier management
- Statistical data verification
- Training

PHLECS B.V:

Co-founder of PHLECS B.V. (April 2019) a result of a Philips Light & Health management buy-out, to continue a promising business in dermatology treatments. PHLECS B.V. own the assets, clinical and technical data to promote a Psoriasis photo dermatology UV-free treatment.
Chamber of commerce #: NL-74570951

Scope of the organization:

To develop and promote the Photo dermatology treatments for various skin diseases.
Tasks within the PHLECS B.V. Organization: Q&R compliance (CQRO), Operations support, General Management, Shareholder, Technical support.

SPEAKER TO CONGRESSES:

- CSI (Catheter Interventions in Congenital, Structural and Valvular Heart Disease) 2015, 24 June 2015 Frankfurt (Germany) Topic: Case example: Occlutech's global regulatory pathway, the importance of a global regulatory strategy.

PREVIOUS ASSIGNMENTS / PROJECTS WQRE.BV:

- Sonion Nederland B.V.: Regulatory affairs consultant, to define the Regulatory strategy for a US submission (DeNovo). Define, setup, prepare and complete the DeNovo US route for an additional feature (blood pressure measurement) in a hearing aid.

- Philips NV Business Unit (BU): Light and Health Q&R Manager, Manage the Q&R aspects of the business. Leading a group of 5 engineers supporting operational activities. Bring the BU to FDA registration, and support various other local registrations (Iran, Israel, Hong Kong).
  FDA 510 (k) registration (k171055)
  Completed the ISO 13485:2016 transition,
  Implementation of the MDR for this BU
  Member of MT.

- Replacement Illness: Sr. Quality Operations Manager European Center of Operations (ECO) Boston Scientific Kerkrade (NL).
  Manage the quality aspects of the operations side of the ECO. Leading a group of 20 engineers / inspectors supporting operational activities. Guide the ECO organization projects and bring the entire ECO organization to Quality excellence.

- Philips NV. BU: SVAL, Support the End to End quality initiatives. To transform Philips from a procedural driven organization to a process driven organization.

- Occlutech GmbH, Inc., Cologne Germany, Istanbul Turkey, Associate Director RA/QA/CA since Feb 2014 and Global Head RA/QA/QC since Sept 2014. Occlutech is a manufacturer of Occluder like devices (MDD Class III)

- CircuLite GmbH, Aachen Germany, Regulatory Affairs Director EU, since November 2012. CircuLite manufactures am implantable blood pump (AIMD) (details see below)

- DEKRA BV, Arnhem the Netherlands, File reviewer for CE Marking, FDA 510K, Health Canada, TGA, JPAL and KFDA submissions. (details see below)
  DEKRA is one of Netherlands leading Notified bodies.

- DEKRA BV, Arnhem the Netherlands, lead auditor, for ISO 13485, QS Reg's, CMDCAS. (details see below)

- Innogenetics NV, Gent Belgium, internal ISO 13485 auditor, trainer for FDA readiness program.

(FORMER) EMPLOYERS (Fixed Contract):

• Microsure B.V. Q&R Manager, Manage the Q&R aspects of the business, define various regulatory strategies for none EU markets, like China , US, and Japan. Prepare the required submissions, and Maintain ISO 13485 and MDR Compliance. Implementation of the MDR for this organization. MT member
• Plasmacure B.V Q&R Manager, Manage the Q&R aspects of the business. Bring the organization to ISO 13485 certification and CE marking, define various other regulatory strategies for none EU markets (US, CHINA, MEA) Implementation of the MDR for this organization. Member of MT.
• DEKRA/KEMA, Notified Body (0344), - Function: Senior Certification specialist medical devices, Arnhem (NL). - Accredited 510(k) File reviewer - JPAL specialist.
• Kimberly-Clark, - Function: Regulatory Affairs and Quality Assurance Manager EMEA Healthcare (RA/QA Manager EMEA) Brussels (BE).
• Medtronic - Bakken Research Center Maastricht (NL), Function: Reliability Manager Medical Devices. - EOC (European Operation Center) Medtronic Heerlen (NL), Function: interim Complaint Handling Manager.
• Philips N.V. - Philips N.V Sittard (NL), dept. shadow masks, Function: Quality engineer - Berg Electronics s' Hertogenbosch (NL), Function: consultant for Philips in the function of interim Quality Manager/Consultant
• LUC B.V.(Limburgse Urethaan Chemie) Brunssum (NL), Maasmechelen (B) and Neuss (D), - Function: Chief MAVE (Milieu, Arbeidsomstandigheden, Veiligheid en Energie)
• KIWA Rijswijk NL., - Function: certification specialist and Product - Process Auditor

APPLIED LINGUISTICS:

Language	*Speech*	*Writing*	
Dutch	Excellent	Excellent	Native speech
English	Very good	Very good	
German	Very good	Good	

SOFTWARE PACKAGE KNOWLEDGE:

Excellent knowledge of the most common Microsoft software like: Word, Excel, MS Projects, Access, Outlook, Visio and PowerPoint.

Excellent knowledge of the following statistical analysis packages: Statgraphics, SPSS,
Minitab
Design Expert (DOE-analysis)
Custom QC (SPC-software)

MOOC (Massive Open Online Courses):

Name of the course	*Year followed*	*Institute*	*Certificate*
The Law of the European Union: An Introduction	Jan 2014	University Leiden	Not available for this course
Design and Interpretation of Clinical Trials	Feb 2014	John Hopkins University	Successfully completed Average score 9.3

COURSES:

Areas of attention	*Course*
Management Science	Management Science (PBNA)
	Integraal besturen van produktie- eenheden voor lager en midden kader
	Process optimization and integration (internal Phillips)
	Medtronic Leadership
	Medtronic performance management
Production Quality	ESD (Electro Static Discharge) coordinator
Quality/Regulatory	Auditor PQA-90
	Internal auditor ISO 9000
	MDD /AIMD training
	MDR training
	GMP training
	Usability (ISO 62366) training
	QS 9000
	ISO 13485-2003 lead auditor
	ISO 13485-2003 auditor
	Risk management EN 1441 and ISO 14971
	Lead Assessor / Assessor ISO 9000

Areas of attention	*Course*
	Auditor TS-ISO 16949
	FMEA-course
	CMDCAS auditor
	J-Pal auditor
	Six sigma/ Lean sigma
	Risk management
	Vigilance according MPG (Medizinproduktegezetz)
	EUDAMED reporting
	Training MDR
Statistics	Statistics 1A (OU)
	Statistics 1B (OU)
	Design of Experiments
	Statistical Process Control Basics & advanced topics
	Weibull analysis
	Clinical Statistics introduction
Personnel effectiveness	Presentation skills
	OZ-principle training
	Effective leadership
	Project management

DETAILED WQRE.BV CONSULTING ACTIVITIES:

ACTIVITIES AS CONSULTANT FOR SONION NEDERLAN b.v. Hoofddorp:

Consultant (No Management roles).

This (time limited) project, focus is around the fact that Sonion, a sub supplier of hearing aid components, wants to bring a component to the US/EU market, to support the end manufacturer with a “validated” package of information, to ease up their device submission. The complexity of this project lays in the fac that the regulatory pathways do not recognize components.

ACTIVITIES AS CONSULTANT FOR PHILIPS LIGHT & HEALTH Eindhoven:

Manager Q&R.

This job focusses on the daily Quality & Regulatory support and management of the operational aspects of the of this particular Philips Business Unit. The main regulatory goal is to obtain the FDA device clearance for “Prescription” and “Over the Counter” (OTC) devices. Where also other minor submission, to various other Countries, like Israel, Hong Kong and Iran, were obtained.
Obtain the FDA 510k (k171055) clearance.
The two main quality goals are: the implement the ISO 13485;2016 and the MDR into the QMS of the organization.
And directly perform a critical analysis of the “lean” character of the organization.
Due to closure of the Business, setup the regulatory strategy with BU-emerging businesses management, with respect to “devices in the field”.

ACTIVITIES AS CONSULTANT FOR BOSTON SCIENTIFIC. Kerkrade:

Sr. Quality Operations Manager European Center of Operations (ECO) Boston Scientific Kerkrade (NL). Replacement of Illness.

This job focusses on the daily Quality support and management of the operational aspects of the ECO. Larger goals are transform the ECO into a risk based driven organization. Create more lean, compliant process flows, and provide a maximum service level to internal/external customers.

ACTIVITIES AS CONSULTANT FOR PHILIPS N.V. **Eindhoven:**

Quality Business Process Expert.

As Quality Business Process Expert supporting various programs and projects within the Philips 'accelerate' quality program, that has the objective to harmonize and synchronize multiple business processes within the global Philips business frame work. The support exists of contributing to the process modeling and ensuring that the defined processes are in line with various (FDA 820, ISO 13485. TGA, KFDA, PAL) Medical Device standards and regulations.

Processes that are supported are:

- Regulatory
  - Define the compliance aspects for the Regulatory compliance processes
- Risk and Compliance,
  - Mainly Manage Risk management, Manage Audits, MDR, Change & Configuration management, Supplier management.
- Manage Software development,
  - Agile software development, Native software development.
- Manage HR
  - Develop Job catalog, Manage Performance evaluation, Develop training and Learning

ACTIVITIES AS CONSULTANT FOR OCCLUTECH GmbH (Cologne/Jena), Inc. (Turkey), SA (Sweden):

RA/QA Director

RA related aspects:

- Provide focused regulatory direction to research and development, manufacturing and quality functions within the company, especially for the Cologne/Jena and Turkish manufacturing sites.
- Support the local RA team in country registrations.
- Project manager for local RA submissions, registrations.
- People manager for local RA teams, 4 direct reports.
- Advice on submission strategies to Notified Body
- Prepare reimbursement files
- Lead and guide the organization through the Vigilance/EUDAMED reporting
- Advise the organization on labeling requirements (IFU, Brochures as well as Labels)
- Contact point for Notified body, Competent Authorities, and Local Government departments.
- Define the reimbursement strategies and go to Market strategies, with respect to the Regulatory implications.
- Addresses Regulatory compliance issues.

QA/QC related aspects:

- Driver of the global FDA readiness program (impact for 4 sites)
- Addresses Quality compliance issues.
- Support the local QA team in daily Quality related aspects, like CAPA, NCR, Validations, Cleanroom monitoring, Sterilization validations, QC aspects, Compliant management, etc.

- People manager for local QA teams, 6 direct reports.

CA related aspects: (only for Function as Associate Director RA/QA/CA)

- Intermediar to the (external) CRO organization.
- Addresses Clinical affairs compliance issues.
- Project manager for local CA projects/studies.
- People manager for global CA team, 2 direct reports.

General aspects:

- Member of the Management team for Occlutech Global.

ACTIVITIES AS CONSULTANT FOR CIRCULITE GmbH Aachen:

RA Director EMEA

- Provide focused regulatory direction to research and development, manufacturing and quality functions within the company.
- Maintain the CE mark (obtained Sept 2012)
- Prepare submissions to Notified body (addenda to the existing technical file, or new technical file submissions)
- Advice on country release strategies, US, EU, Japan, Australia, and China.
- Advice on submission strategies to Notified Body
- Prepare reimbursement files
- Lead and guide the organization through the Vigilance/EUDAMED reporting
- Advise the organization on labeling requirements (IFU, Brochures as well as Labels)
- Contact point for Notified body, Competent Authorities, and Local Government departments.
- Define the reimbursement strategies and go to Market strategies, with respect to the Regulatory implications.
- Addresses Regulatory compliance issues.
- Advise US colleague on the IDE/PMA study
- Driver of the Risk management process
- Safety officer (Sicherheitsbeauftragter) according MPG (German Medizinproduktegezetz)
- Explore the Regulatory release strategies/opportunities for various countries.
- Oversight and management of post-market registry in Europe including trial conduct and data integrity, Day to day management of the Clinical study manager (CSM) and Clinical Research Associate (CRA)
- Interact with the complaint and corrective action programs to evaluate and report on adverse events

General aspects:

- Member of the Management team for CircuLite GmbH

CONSULTING ACTIVITIES OTHER CUSTOMERS:

- Internal auditing program according ISO13485
- Internal auditing program according MDD, and AIMD, and MDR
- Internal auditing program according QS-reg's (21CFR)
- Preparation for FDA audits
- Build up of 510(k) file for US FDA submission
- Preparation of the JPAL submission file, AIMD device.
- Guidance on STED setup (technical dossie

EXPERIENCE GAINED DURING MY WORKING CAREER (FIXED CONTRACT):

MICROSURE B.V. SON:

Manager Q&R.

- This job focusses on the daily Quality & Regulatory support and management of the operational aspects of the of Microsure B.V. The main regulatory goal is to maintain the CE marking for the current device under MDD, and obtain the CE marking for the next generation device under MDR. Drive and define various regulatory strategies for several none EU countries like, US, China and Japan. Support de the organization on the go to market strategy for their first products.
- Define various regulatory routes for the organizations ambition. And eventually create the submission files accordingly
- MT member
- Participate in the Venture Capitalist discussions and exit strategies.

PLASMACURE B.V. Eindhoven:

Manager Q&R.

- This job focusses on the daily Quality & Regulatory support and management of the operational aspects of the of Plasmacure B.V. The main regulatory goal is to obtain the CE marking and define various regulatory strategies for several none EU countries like, US and China. Support de the organization on the go to market strategy for their first products.
- Define various regulatory routes for the organizations ambition.
- The main quality objective is MDR compliance into the QMS of the organization.
- Implementation of a e-QMS.

KEMA/DEKRA Arnhem:

Senior Certification specialist medical devices

- Project leader for 15 Notified body customers. (large accounts)
- Global Account manager for Boston Scientific.
- ISO 13485 and ISO 9001 notified body lead auditor.
- MDD notified body lead auditor.
- AIMD notified body lead auditor.
- Registered CMDCAS notified body lead auditor.
- Registered J-PAL notified body lead auditor.
- Responsible for J-PAL developments (Japanese Market).
- Technical Dossier reviewer MDD for Cardiovascular devices.
- Technical Dossier reviewer AIMD for Active Cardiovascular devices.
- Consultant for Meddev, guidance documents and interpretations.
- Consultant for MDD, AIMD and ISO 13485 document interpretations

KIMBERLY-CLARK HEALTHCARE Brussels:

RA/QA Manager EMEA

- Set up and manage the RA/QA department for EMEA.

RA related aspects:

- Provide regulatory guidance for product releases in the EMEA area. Mainly Class 1 and 2a/b

products.
- Coordinate the vigilance responsibilities.
- Reviewer of technical files prior to product release activities
- Coordinate Reimbursement files for EMEA
- Legal manufacturer representative, EU
- Member of various standard committees.
- Manage 1 employee: (level: WO)

QA Related aspects:

- Develop and improve (manufacturing and administrative) processes in general. Using the lean- and or six-sigma approach.
- Lead improvement activities for the manufacturing plants under my responsibility, with the ultimate goal of a 6σ manufacturing site in Germany and the UK.
- Complaint analysis trending/reporting
- EU Management representative for Kimberly-Clark
- Full production responsibility for the European manufacturing sites in Germany, Slovakia, UK and Ireland
- Introduce SPC, FMEA, CAPA principles for a production site in Germany.
- Coordinate EU initiated product Recalls
- Consultant for ISO 13485 certification for high volume manufacturing plant in Czech-Republic
- Creating a center of excellence on various products line.
- Strengthen the existing QMS.
- Implementing continuous improvement techniques throughout various parts of the EMEA organization
- Manage 3 employees: (level: 3 MBO/MBO+)

MEDTRONIC EOC (European Operation Center) Kerkrade:

Complaint handling Manager on a one (1) year Interim base.

- Set up a Customer communication process around Customer complaints.
- Process streamlining around complaint handling.
- Create a BU awareness of an EMEA complaint handling center at the EOC.
- Fulfill the regulatory requirements around complaint handling and integrate the regulatory/vigilance decisions taking processes into the complaint handling process. (class 3 products)
- Integration of new BU's/devices into the complaint handling system.
- Manage 15 employees (level: HBO/HBO+).
- Provide feedback to the business for design improvement.
- Provide feedback to country organizations and country BU-management.
- Push the continues improvement cycle and act as Champion in the Six sigma improvement program.

MEDTRONIC BRC (Bakken Research Center) Maastricht:

Reliability Manager:

- Implementation and embed TQM and Lean - Six Sigma elements into the BRC organization.
- Make available for the organization Process- and Product characterization-, Qualification- and Validation Statistics.
- Establish a quality strategy and facilitate implementation in an effective way.
- Regulatory compliance checks for custom made devices (MDD/AIMD). And low volume CE

market products.
- Responsible for cost reduction plans in the reliability/product testing area.
- Responsible for the quality of the BRC products manufactured at the Medtronic high volume manufacturing plants in Puerto Rico (US). In this setting, regular plant assessments.
- Streamlining the design and manufacturing processes, to assure flawless product launches
- Manage 9 employees (level: HBO/HBO+).
- Implementation of risk management principles (FMEA and QFD) as fundament for the whole development process.
- Risk management EN 1441 and ISO 14971.
- Fulfill the regulatory production requirements.
- Introduction and implementation of Statistical process control principles in the manufacturing area
- Conduct internal Medtronic-audits (ISO 13485-2003/ ISO 9001-2001).
- Responsible for PCAR (Preventive and Corrective Action Report) management.
- Conduct supplier Audits (as lead- or senior auditor).
- "Voice of the customer" representative in the organization.
- Training and awareness creation of quality aspects/programs for various levels in the organization.
- Implementation of process- and product improvement initiatives.
- Implementation of an electronically documentation system.
- Process and system streamlining though out the entire organization.
- As Sr. Reliability Manager I'm the pivot in several (inter)national multidisciplinary product/process and or system development processes/projects.
- Introduction of the visual quality approach, (quality performance indicators or balanced scorecards) and there under laying databases, for (upper) management support.
- As "greenbelt" participate in several Lean - Six Sigma quality improvement projects.
- Act as statistical trainer for Black-belt's and Green-belt's in various parts of the Medtronic internal Lean Sigma course.

PHILIPS N.V ELECTRONICS FSM (Flat shadow mask dept) Sittard:

QA Engineer;

- Project leader: Introduction of SPC (Statistical Process Control) for 3 high volume production lines.
- FMEA and introduction of Risk management for design- and manufacturing processes.
- Customer and incoming inspection complaint handling (for internal and external customers). According an 8-D problem solving-technique.
- Manage 14 Technicians/Engineers (level: MBO).
- Introduction of new inspection methodology.
- Project leader: Streamlining and optimization of the complaint handling process.
- Statistical trainer: SPC techniques.

BERG ELECTRONICS: (Philips-consultant) s'Hertogenbosch:

QA engineer:

- As Philips-consultant my main task was to optimize and streamline the Berg Electronics Quality System, to assure that both quality systems (Philips-Berg Electronics) perfectly match. Practically this meant: Implementation of an OEE (Overall Equipment Effectiveness)-system, implementation of several TQM/QS9000/ ISO-TS 16949 aspects, and implementation of a TPM

(Total Preventive Maintenance)-system and implementation of the 5S housekeeping strategy. The implemented systems are up till now still active and a success factor in the organization.

- As Philips-consultant my other main task was to optimize and streamline the Berg Electronics manufacturing process (Compound molding processes, pin assembly and logistics), by introduction of a Kanban system and process capability determination.
- Liaison for Berg Electronics and automotive suppliers to represent the “customer” in the organization.
- During this period strategic communication throughout all levels of the organization, on national as well as international level, was of vital importance for succeeding in my task.
- Training and awareness creation of quality and or lean aspects/programs for various levels in the organization.
- As interim Quality Manager I managed 6 employees (level: MBO/HBO).
- Introduction of the visual quality approach (quality performance indicators) and there under laying databases.
- Start of Takt time analysis, unfortunately not able to close this project due to career change.

LUC (Brunsum):

Chief of MAVE (Environment, health, safety and energy) department for a polyurethane manufacturing plant.

- Deploy the governmental aspects in the area of Environment, Working conditions, Safety and Energy in the organization via procedures, work instructions and training in a euregional organization (The Netherlands, Belgium and Germany).
- Prepare and create safe working conditions on shop floor level.
- Act as sounding board for the Quality Manager on the certification of the ISO 9001. (Due to my working experience for the certification body KIWA).

KIWA Rijswijk):

Certification Specialist

- As certification specialist I lead multidisciplinary project teams for creation of national guidelines in the specific area, of underground oil storage containers. The multidisciplinary project teams were represented by (inter)national specialists, representatives of the industry and government.
- As certification specialist I was also responsible for the process and product certification on ISO and KOMO aspects in Europe, Middle East and Far East.

CONTENTS OF THE MASTER DEGREE:

Industrial statistics and quality engineering

Mandatory Modules: Statistical techniques
Regression analysis
Generalized linear models
Design of experiments
Robust designs
Multivariate methods
Neural networks
Statistical Process Control
Communication

Management Science modules: Project management
Analysis and control of project risks
Human factors in safety and reliability

Free Statistical modules: Time series
Reliability engineering

Master thesis: Reliability Calculations for lead models

CONTENTS OF BACHELORS (MBA) COURSE:

BUSINESS ADMINISTRATION

Mandatory Modules: Effective Management
Production control
Quality management
Planning and Control
Business planning
Industrial Marketing
Change processes
System Management