PROCESS VISION

DOWN TO EARTH QUALITY SERVICES

Curriculum Vitae

Willem van den Biggelaar

Quality & Regulatory consultant

More than 30 years of experience in multi-disciplinary (medical) product development & production environments.
Pragmatic and result driven.

▪ Medical Quality Assurance consultant	21 years
▪ Medical Regulatory Affairs consultant	16 years
▪ Certified ISO9001/13485 lead auditor	10 years
▪ Certified CE lead auditor	2 year
▪ Process Improvement consultant	7 years
▪ Project leader	2 years
▪ System tester	1 year
▪ Software engineer	7 years

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1. Management Summary

Willem offers lean QA/RA consultancy on medical device development / production / market access. Customers are start-ups, medium and large companies. Being an ISO13485 and CE auditor, Willem can easily form a bridge between customer and notified body.
Role of QA manager

- Setup and maintain MDR, ISO13485 & 21CFR820 compliant quality system
- Guide development and production sites on QA matters
- Guide external audits executed by notified bodies and FDA

Role of RA manager

- Setup technical files to access and keep markets (e.g. Europe, US)
- Guide development and production sites on RA matters
- Communicate with notified bodies and FDA

Apart from above Willem offers training courses in the area of medical QA/RA.
Willem is also part of a consultancy network.

Willem starts his career in 1985 after receiving his bachelor's degree in Electronics. For 12 years, he worked as a (embedded) software engineer, next as system tester and as project leader. Customers were companies like Océ vd Grinten, Organon Technica, Philips Medical Systems and Dräger Medical Electronics.
Next, he started working in the QA/RA field for medical device customers like Philips (Consumer Lifestyle, Healthcare, AdapTx, Digital Pathology, Handheld Diagnostics), MediSpirit, Ventinova Medical, Preceyes, Vitestro, UTC Imaging and D.O.R.C. International. Other customers are medical device development / production suppliers like Frencken Mechatronics, Sioux CCM, TOPIC, Unitron Group. Also, non-medical companies like ASML, Philips Applied Technologies, Centric TSolve and EventIS have been customer.
For Preceyes, Ventinova Medical, Philips Digital Pathology, Sioux CCM and Frencken Mechatronics this led to an ISO13485 certification. For Philips Consumer Lifestyle and Ventinova Medical the certificate was extended with CMDCAS. For Preceyes, Philips Consumer Lifestyle, MediSpirit, UTC and D.O.R.C. this has led to European and US market access.

Per 2011, Willem is a certified lead auditor for ISO9001, ISO13485 and CMDCAS for DEKRA notified body. Per 2018, he is certified lead auditor for CE/ISO13485 for Dare!! notified body.

As a trainer, he has developed and given courses on ISO13485, Auditor, CE MDD, CMDR, 21CFR820, 21CFR11, IEC62304, QMS setup, CMMI, QA, peer reviews, requirements management and software testing. He is currently trainer for Mikrocentrum training institute.

From 2007 till 2010 he has been member of the program committee for the annual QA &Test conference in Bilbao, Spain.

2. General

A. Personal details

Name	WFM van den Biggelaar
Address	Rogier v Leefdaelstraat 29, 5081 JK Hilvarenbeek, the Netherlands
Place and date of birth	Biest-Houtakker, 24 September 1963
Nationality	Dutch
Languages	fluent English, moderate German

B. Education

Period	*Institute*	*Education*
1995 -1997	Institute for Career & Development	Bedrijfskundig management
1985 - 1986	Militaire dienst	Officier Civiele vakopleiding
1981 - 1985	IHBO, Eindhoven	HTS-Electrotechniek, Technische Computerkunde
1976 - 1981	Odulphus lyceum, Tilburg	Atheneum-B

C. Knowledge of regulations, models & standards

Regulations	European Medical Device Regulation (MDR) 2017/745 European Directive 93/42/EEC Medical Devices European Directive 98/79/EC In Vitro Diagnostics Medical Devices European Directive 2006/42/EC Machinery FDA 21 CFR part 11 Electronic Records; Electronic Signatures FDA 21 CFR part 803 Medical Device Reporting FDA 21 CFR part 806 Medical Devices; Reports of Corrections and Removals FDA 21 CFR part 820 Quality System Regulations Canadian Medical Device Regulations SOR98-282
Standards (most used)	ISO13485 Medical Devices – Quality Management Systems - Requirements ISO9001 Quality Management Systems - Requirements ISO14971 Medical devices — Application of risk management to medical devices IEC62304 Medical Device Software – Software lifecycle processes IEC62366-1 Medical Devices – Application of usability engineering IEC60601-1 Medical Electrical Equipment – Basic Safety and essential performance
Guidelines	Europe: MEDDEV, GHTF, NB-MED, NBOG US: numerous guidelines
Assessment methods	ISO17021, CMM(I): Philips Assessment Method (PAM)
Process models	CMM(I), TMM, SCRUM

D. Courses

Process, Quality & Regulatory		
2019	MDProject	EU MDR (2017/745)
2019	DEKRA	Conformity assessment procedures according ISO17021 & MDR
2019	GreyRA	IEC60601 family standards
2019	Dare!!	Auditing under MDD
2017	DEKRA	Transition ISO13485:2016 and ISO9001:2015
2016	Philips Medical	Good Documentation Practices
2015	DEKRA	Council Directive 93/42/EEC
2011	Mikrocentrum	Medical Devices Release routes and QSR for U.S.A. (FDA)
2010	KEMA Quality	ISO 13485:2003 and auditing
2010	Accademia Qualitas	Canadian Medical Devices Conformity Assessment System (CMDCAS)
2009	Qserve	Medical Device Regulations European Union (CE)
2008	CTT	Philips Appraisal Workshop for CMMI (PAW)
2005	Philips Medical	Capability Maturity Model Integrated (CMMI)
2005	Philips CTI	Software Configuration Management
2003	Philips Medical	Size estimations
2001	CTT	Accelerated SPI
2000	AAS	Personal Software Process
1999	PAO	Usability testing
1998	ASML	Total Quality Management
1998	AAS	CMM training
1996	PAO	Software Metrics
1996	CTT	Philips Assessment Method for CMM (PAM)
1995	ISES	Testing of realtime systems
1994	ISES	Project management for projectmanagers
1993	CTT	Capability Maturity Model (CMM)
1990	ISES	Project management for designers
Personal training		
2000	AAS	Discussion skills for consultants
1998	Schouten & Nelissen	Discussion skills for consultants
1998	Schouten & Nelissen	Negotiating and conflict handling
1994	Metavisie	Presentation skills
1988	Mansal	Customer service training
1988	Comdes	Communication skills
ICT methods and tools		
1997	IT opleidingen	MS Project
1993	Post HBO	System Design
1992	PAO	Object oriënted methods
1991	Novi	Ambi HP6
1990	AT computing	Unix systems
1990	ISES	Relational databases
1990	ISES	Data communication and networks
1989	Jackson	Jackson Structured Design for real time systems

E. Supporting tools

Project Planning & Tracking	Microsoft Project, Niku open workbench
Configuration Management / Document Management Systems	Sharepoint, CodeManager, SCCS, RCS, Continuus, ClearCase, TestTrack Pro, Perforce, (Tortoise)CVS, FIT tracker, Agile
Change Control	ClearQuest, Fast Issue tracker, DDTS, Track, Jira
Code Quality	QA-C (++), Lint, Purify, C-Cover, Code Wizard

3. Recommendations

Peter Wijnhoven
Quality Assurance Manager & Group Leader at Sioux
December 3, 2019, Peter was a client of Willem's

Willem supported us several years in defining our Quality Management System and in applying regulatory requirements. has outstanding knowledge of these requirements and is able turn them into pragmatic approaches.

Dirk Van Asseldonk
Founder & CEO at Ventinova Medical
December 28, 2018, Dirk managed Willem directly

Willem has been our QA manager for over 4 years and has fulfilled this function with great expertise. He completely redesigned our Quality Management System into a much leaner and more user-friendly version and expanded it in a practical way. Whereas before our QMS was sometimes regarded as something you need to have but don't really want to have, we now really embrace the system, see the benefits of working with it and use the system also for processes that are regulatory-wise not demanded to be put in. Our business is growing so we came in the phase of having a payroll QA manager, instead of a consultant. However, we will definitely remain asking Willem for help in the future; it has always been a pleasure working with him!

Arend-Jan Beltman
Manager Mechatronics / Program Manager Technology at Sioux CCM
June 24, 2011, Arend-Jan was a client of Willem's

Willem supported CCM to get our ISO13485 certification. Besides his in depth knowledge concerning Q&R for medical device development (and production), he demonstrated his excellent skills in project management.

Thea van Lopik
Audit Manager at Philips Health Systems
July 7, 2016, Thea managed Willem directly

Working with Willem is a joy because of his energetic personality. In the Philips business unit IGT systems Willem has shown his worth by developing a training program for internal auditors and by improving the internal audit program with me. The one-day audit approach is a big success!

Kris Kollmer
Head of Quality & Regulatory, Mother & Child Care and Pain Relief Products
May 28, 2015, Kris managed Willem directly

Willem is a highly skilled professional consultant and I would recommend him as an asset to any product development team for medical devices.

I have worked closely with Willem during the development of connected consumer medical devices for pain management at Philips HealthTech. These products were new to the market and new to the development site and the role of Willem was to use his experience to ensure that the development team managed all relevant risks and documented their development in a way that supported the certification of these medical devices for EU and US markets.

Through the leadership of Willem, we were able to meet our launch dates due to the fast certification times with minimal review periods by regulatory authorities. More importantly, he was able to improve the competence of the entire development team with respect to medical devices.

Willem was very approachable by everyone in his team and spent much of his time in a consultant role. Because of his good nature and depth of knowledge, he has had a lasting influence on the way of working within the team, which continues to pay dividends with new product developments.

At the beginning of his role, the Pain Management development team was a small, start-up team that did not fully understand the regulatory needs of creating a medical device. By the time the initial products were launched, the team that Willem had developed was perceived as a best-in-class medical device development team that has influenced all other businesses operating at the same site and has made a considerable impact to the management of these businesses as to the effort and activities associated with medical device development.

I would highly recommend Willem to strengthen any product development team to establish a best-in-class process in a way that is beneficial to the team and to the business.

Peter Bentvelsen
Senior Architect at Royal Philips Electronics
March 4, 2015, Willem worked with Peter in the same group

As quality manager Willem was responsible for risk management file and CE-certification (including STED file). Willem is very effective and fast. He has a vast knowledge on CE submission and ISO14971 processes and the IEC60601 medical device standards family. It was always fun working together!

Hans Freriks
Director Quality & Regulatory at Philips
May 26, 2014, Hans was a client of Willem's

As Q&R Consultant, Willem has revised part of our ISO-13485 Quality Management System. His structured approach and in-depth knowledge has resulted in improvements to our system that are pragmatic, reducing overhead and easy to implement.

Antonie van Noort
Senior Project Manager at Philips Research
September 30, 2013, Antonie was a client of Willem's

As Project Manager of the Philips AdapTx project, I have experienced Willem as a very dedicated, flexible and pragmatic guy. He is very experienced in implementing an ISO13485 and FDA based Quality Management Systems for development and production of medical devices. Willem was a good sparring-partner for the project team members for Quality related issues, which was very useful during the project. It is a pleasure to work with him.

Paul van Cruchten
Manager NPI at Frencken Mechatronics
May 20, 2013, Paul was a client of Willem's

Willem did a great job during the implementation of the ISO 13485 for Frencken Mechatronics. He has a great experience in implementing Quality Management Systems (QMS) for Medical products, which was very useful during the project.
Willem has a practical way of working and can be a great sparring-partner for other people. He translates the ISO standards into a natural way of working for your organization. He is an expert on document control and visualizing the processes in your organization.
Willem, it was a pleasure working with you. Thank you for the educational cooperation.

Piet de Vries
Manager Business Improvement at Frencken Group Limited (Precico Group Sdn Bhd)
April 28, 2013, Piet was a client of Willem's

We have hired Willem,for ISO13485 and FDA certfication, for this he assisted us with a total new set-up of the system of Q procedures. Besides this he trained people on FDA and ISO 13485 and helped us with the set-up of new procedures.
He did a great job !! He is not only a good expert and very practical guy but also very amiable and a motivator to keep things on track.
Willem, thanks again, Piet

Dirk Vossen
Head of Strategy & New Business Development at Philips Digital Pathology Solutions
October 8, 2009, Dirk was a client of Willem's

I had (and have) the pleasure to work with Willem during the implementation of a Quality Management System (ISO13485 based) for our Digital Pathology venture; we are starting the certification process soon.... Willem has a deep knowledge and experience in the quality management for medical device development and an extended network.

Pierre Heuvelmans
Director Quality & Regulatory BPO for Idea2Market at Philips Healthcare
October 11, 2011, Pierre was a client of Willem's

Als je Willem inhuurt voor een klus op het gebied van quality binnen software development, heb je een expert op dit gebied die kennis van zaken combineert met een pragmatische insteek, waardoor compliancy aan de benodigde standaarden en regelgeving efficient afgedekt worden.
Daarnaast communiceert hij makkelijk met alle lagen in de organisatie en is hij een bruggebouwer in probleemoplossing situaties.

Ray Arell
Founder and Principal Coach at nuCognitive
May 2, 2007, Ray worked with Willem but at different companies

I had the pleasure in meeting Willem at the 2006 International Conference on QA&Testing for Embedded. Prior to seeing Willem give his presentation on requirements management, I don't think I have seen an industry expert with his level of energy and ability to keep the participants engaged. This combined with teaching a balanced view of real world requirement management, I know he inspired others to adopt his message. I look forward to seeing him at future conferences.

Tonny Baalmans
Senior Test Engineer at Philips Health Systems
April 2, 2006, Willem worked with Tonny in the same group

Willem is an enthousiastic motivating collegue who knows a lot about software processes. Willem keeps the whole team alert in his role as QA officer and is very good in deploying software processes.

Con Vissenberg
Software Configuration Manager at Thermo Fisher Scientific
October 11, 2005, Con worked with Willem in different groups

Software Quality Assurance Officer who can translate his excellent process insights into practical advice for his teams.

Piet Welles
NoMust Manager
April 3, 2006, Piet was senior to Willem but didn't manage directly

- Willem positioned his independent authority role within the team by example.
- In a pro-active manner he increased the process quality.
- I liked his style of acting in the team.

4. Work Experience

Quality Assurance & Regulatory Affairs consultant		
2020 - now	Mikrocentrum	Trainer for medical devices
2020 - now	EMRobotics	RA manager
2019 – now	TOPIC	QA manager
2019 – now	Dare!! medical certifications	CE & ISO 13485 lead auditor
2019 – now	Ventinova Medical	QA consultant, Management Representative
2017 – now	Preceyes	QA manager, setup/review CE files
2011 – now	DEKRA certification	ISO 9001/13485/CMDCAS lead auditor
2012 – 2019	Sioux CCM	Assist QA manager, consult on medical projects
2014 – 2018	Ventinova Medical	QA manager, review CE files
2018	Vitestro Medical Robots	QA manager
2017 – 2018	Philips Health IGT Systems	Software Tool Validation manager
2016 – 2017	Frencken Mechatronics	Setup FDA 21CFR part 11 QMS, resolve FDA scope audit issues
2012 – 2017	MediSpirit	Setup ISO 13485 QMS, CE file, Setup CFDA file
2015 - 2016	Philips Health IGT Systems	Internal Lead auditor, train auditors, improve audit process
2013 - 2014	Philips Consumer Lifestyle	Setup 2 CE files, made QMS CMDR compliant, QA officer
2013	Philips Healthcare Incubator Handheld	Maintenance ISO 13485 QMS for IVD product
2011 – 2013	Philips Healthcare Incubator AdapTx	Setup FDA / ISO 13485 certified QMS
2011– 2013	UTC Imaging	Setup CE file
2010 – 2011	Sioux CCM	Setup and maintain ISO 9001/13485 certified QMS
2010 – 2013	Frencken Mechatronics	Setup ISO 13485 QMS and FDA compliant production line
2009	Philips Digital Pathology	Setup FDA / ISO 13485 certified QMS for IVD product
2008	Sintecs	Setup QMS
2008	Philips Healthcare PII	Medical QA officer
2007	D.O.R.C.	Get FDA clearance on software device
2007	EventIS	QA & CM manager
2006	Centric Tsolve	Setup CMM-I compliant QMS
2003 – 2005	Philips Medical Cardio Vascular	Medical System QA officer
2002 – 2003	Philips Medical Components	Medical Software QA officer
2001	Philips Medical, Components	Group lead SQA team /SPI coordinator
2000	Philips ASA lab	System QA officer
1996 – 1999	ASML	Software QA officer
Embedded Software / Test Engineer		
1995	Dräger (ATOS Origin)	System Test Engineer / Embedded Software Engineer
1993 – 1995	Philips Medical, CV & MR (ATOS Origin)	Embedded Software Engineer
1993	Philips Nederland (ATOS Origin)	Embedded Software Engineer
1990 - 1991	Van Aaken	Embedded Software Engineer
1989 – 1990	Organon Technica (ATOS Origin)	Embedded Software Engineer
1988	Océ vd Grinten (ATOS Origin)	Embedded Software Engineer
1987 – 1988	Comdes	Embedded Software Engineer
1987	Volmac toptraining	Trainee

Track record on medical device market clearance			
Task	*Application*	*Classification* *EU*	*US*
Setup CE file	Robot eye surgical device	IIa	--
Review CE file	Ultrathin sterile ventilation tube for adult patients	IIa	--
Review CE file	Active device for ventilation through a small-bore tube	IIa	--
Review CE & 510k file	single-use ventilation device for obstructed airways.	IIa	2
Setup CE file	TENS / Blue touch pain management devices	IIa	--
Setup CE file	Handheld lung function measuring device for infants	IIa	--
Setup CE file	Ultrasound Tissue Characterization Scanner	I	--
Setup CE / 510k file	Active Medical device for cancer treatment	IIb	2
Setup part of 510k file	Anterior & posterior ophthalmic surgery device	--	2

Project leader		
Period	*Customer*	*Role*
2010	Centre Concepts Mechatronics	Project lead ISO 13485 certification
1995 – 1996	Dräger	Project lead redesign software package
1992	Van Aaken	Project lead conversion software
Consultant / Trainer		
Period	*Customer*	*Consultancy / Course*
1997 – 2009	Stan Ackermans , TU Eindhoven	Quality Control & Quality Assurance
2006	QA&Test, Spain	Requirements Management
2004	Fontys Eindhoven	Quality Assurance
2002	Philips RTG	Requirements Management/Engineering
2001	Getronics	Fagan Inspection
2001	SERC	Requirements Management
1997 – 1998	ATOS Origin	Safer-C + inspection
1996 – 1999	ASML	Course coordinator
1996	VDO Car Systems	Test process software department
1986	Ministry of Defense	Course coordinator

5. Relevant details work experience

Trainer

Mikrocentrum · Part-time
Aug 2020 – Present · 5 mos
Eindhoven, North Brabant, Netherlands

Willem provides the following medical device training courses both for Mikrocentrum as well as via his own company:
- Medical Device Regulatory introduction
- How to bring your device to the EU market (CE)
- How to bring your device to the US market (FDA)
- How to design a lean but compliant Quality Management System
- ISO13485 Quality Management System for medical devices
- ISO13485 Auditor
- ISO14971 Risk Management for medical devices
- IEC62366 Usability Engineering for medical devices
- IEC62304 Software development for medical devices
- IEC60601 Basic Safety & Essential Performance for medical electrical equipment
- Medical Device Regulation (MDR)
- FDA 21CFR part 820 Quality System Regulations
- FDA 21CFR part 11 Electronic records and Electronic Signatures

RA manager

Eindhoven Medical Robotics · Part-time
Apr 2020 – Present · 9 mos
Eindhoven, Noord-Brabant, Nederland

Eindhoven Medical Robotics develops high precision surgical robotics.
They work in close collaboration with TU/e, engineering partners, suppliers and hospitals worldwide. They are a multi-disciplinary project team comprising of system architects, mechanical, electrical and software engineers. Willem takes up the role of Regulatory Affairs Manager.

QA Manager
TOPIC Embedded Systems
Jan 2019 – Present · 1 yr
Best

TOPIC Projects (about 30 FTE) has established an impressive track-record in in-house execution of their client's projects. The content of these projects may vary from a 'software-only' project or a 'hardware-only' project to an entire development project for which they develop the entire system in-house.
Included are projects for medical device development.

Willem is the QA manager and responsible for
- Keep ISO13485 certificate
- Make the QMS more effective and efficient
- CAPA control, management reviews, internal audits
- Quality assurance on design and development projects
- Internal Audits on development on ISO13485 and IEC62304

QA Manager
PRECEYES B.V. · Contract
Aug 2017 – Present · 2 yrs 5 mos
Eindhoven Area, Netherlands

Preceyes develops innovative robotic solutions to assist eye surgeons in performing the most demanding surgical tasks. Preceyes enables the development of new, high-precision treatments and facilitates existing vitreoretinal surgery.

Setup an ISO 13485 and FDA compliant QMS. QA manager for the current projects.
He also with the team setup the CE files for the robot and its accessories (class I & class IIa) and gained CE within 1 month (!) after the submission.

ISO13485 / CE lead auditor
Dare!! Medical Certifications
Mar 2019 – Present · 10 mos
Woerden

DARE!! Medical Certifications is an EN45011/ISO/IEC 17065 accredited (by the Dutch Council for Accreditation (RvA) under number C447) company that carries out product certifications under EMC, Low Voltage and Medical Devices.

Willem performs CE / ISO13485 audit for the clients of Dare!! in the field of active medical devices with software as specialism

Certified ISO 9001/13485/CMDCAS Lead Assessor

DEKRA Product Testing & Certification
Jan 2011 – Present · 9 yrs
Arnhem

DEKRA certification is a worldwide accredited notified body also for medical devices.
Willem performs audits for ISO 9001 / 13485 and CMDCAS for DEKRA clients in the field of active medical devices

Q&R consultant

Sioux CCM
Jan 2010 – Dec 2019 · 10 yrs
Nuenen

Sioux CCM develops both medical and non medical products in a business to business model.

Willem has led a project that had the goal of having a more accessible, readable, ISO 9001/ 13485 certified Quality Management System (QMS). This goal has been reached in May 2011.
He assists all (medical) projects on QA\RA matters, performs internal audits, prepares management reviews and helps the process owner keeping the QMS effective, efficient and ISO 9001\13485 compliant.

QA Manager

Ventinova Medical
Sep 2014 – Dec 2018 · 4 yrs 4 mos
Eindhoven Area, Netherlands

Ventinova Medical BV is a medical device manufacturer of respiratory devices and catheters.
With their products:
- patients are ventilated through a thin tube instead of a thick tube;
- ventilation at positive and at negative lung pressures is possible (EVA technique)

They have a distribution network in over 20 countries in 4 different continents.

WIllem is the QA manager, part of the MT and responsible for
- Get ISO13485\CMDCAS certificate - received in Nov 2015.
- Get and keep the QMS compliant with CE, FDA and CMDR regulations
- Review of all CE technical files and FDA 510k files
- Contact with Notified Body
- CAPA control, management reviews, internal audits, vigilance and recalls.
- Quality assurance on design and development projects
- Audits on development and manufacture suppliers on ISO13485; FDA QSR820 and IEC62304

Q&R consultant

MediSpirit BV
May 2012 – Jun 2017 · 5 yrs 2 mos
Nuenen, the Netherlands

MediSpirit was a startup medical company that released one product: a lung function measurement device for babies, infants and adults who are unable to produce sufficient forced expiration for spirometry.
Willem has setup an ISO 13485 / CE Quality Management System for design, development and manufacturing. The ISO certificate was received in April 2013.
He also helped the CE certification trajectory of the lung function measurement device. The EU admission has been achieved in November 2012. He helped with a CFDA submission.

Software Tool Validation Manager

Philips
May 2017 – Dec 2018 · 1 yr 8 mos
Eindhoven Area, Netherlands

Improve software tool validation process
Review and approve software tool validation deliverables

Q&R consultant
Frencken Mechatronics (M) Sdn Bhd
Jan 2016 – May 2017 · 1 yr 5 mos
Eindhoven Area, Netherlands

Frencken Mechatronics is expert in high-mix, low-volume, high-complexity and high-flexibility production of assemblies and systems for the medical, analytical and semiconductor markets.

Setup and implemented a corrective action plan for a FDA 21 CFR820 based audit from the customer. The plans included actions mostly for production, design & development, and quality departments.
Implemented FDA 21 CFR part 11 Electronic Records & Electronic Signatures regulations in the Quality Management System including training for stakeholders

Philips
5 yrs

Lead Auditor Cardio Vascular devices
Dec 2014 – 2016 · 2 yrs
Best

Philips Health IGT Systems delivers minimally invasive cardiovascular treatment systems worldwide. Willem has trained a new pool of internal auditors and is one of the lead auditors for the internal audit program of IGT Systems. He has accelerated the internal audit speed by setting up an approach of one internal audit per week with clear focus.

Quality & Regulatory officer
Feb 2014 – Mar 2015 · 1 yr 2 mos
Eindhoven

Pain Management is a category within Philips Consumer Lifestyle. Two existing class IIa medical devices (TENS and Bluetouch) have undergone a cost down with extended functionality (e.g. control by mobile software app).

For both products, Willem has
- Setup and maintained the product risk management file
- Assissted the project in regulatory affairs and quality assurance
- Organized and created part of the CE technical file (STED)
- Assessed new suppliers on ISO 13485 / IEC62304 capabilities
- Made the QMS CMDCAS compliant leading to an extension of the ISO13485 certificate
- Performed an IEC62304 supplier audit in 2016.

Quality consultant for IVD medical devices
Oct 2013 – May 2014 · 8 mos
Eindhoven Area, Netherlands

Handheld Diagnostics is a venture within the Philips Healthcare incubator. It is developing a handheld IVD blood testing device with results available at the point-of-care within minutes. Willem has done maintenance on part of the ISO 13485 / FDA compliant Quality Management System with the aim to up date it to the current way of working (and downsize if possible).

Q&R consultant for cancer threatment devices
Sep 2011 – Sep 2013 · 2 yrs 1 mo
Eindhoven Area, Netherlands

Philips AdapTx is a venture within the Philips Healthcare Incubator. The goal is to develop innovative new approaches that allow clinicians to treat cancer (ultrasound guided brachytherapy) in a better way. Willem has setup an ISO 13485 and FDA compliant Quality Management System for design, development and manufacturing and guided the project on regulatory and quality issues

Q&R consultant

Frencken Mechatronics
Jan 2010 – Apr 2013 · 3 yrs 4 mos
Eindhoven Area, Netherlands

Frencken Mechatronics develops and produces medical and non medical assemblies and products for legal manufacturers. Willem has helped the organisation to become ISO 13485 certified (Dec 2011) and FDA compliant and has setup their QMS accordingly.
He also setup the requirements for a production trace tool coupled to the ERP system and guided the implementation and testing of it.
He led the quality team for a project that has to make the production of a medical subsystem (patient postion table for X-ray systems for Philips IGT Systems) FDA compliant. Worked on tool validation, process validation, component traceability, setup of DHR, incoming inspection.

Philips Healtcare Digital Pathology
1 yr 11 mos

Quality & Regulatory Officer
Dec 2008 – Mar 2010 · 1 yr 4 mos
Eindhoven

A first of a kind medical Digital Pathology System which digitizes images that pathologists normally view through a microscope is brought to the market. Willem advises the emerging Philips organisation on all processes and regulatory affairs (FDA/ISO 13485). He developed and deployed a new Quality System which has been ISO 13485 certified in March 2010.

Performed a CMDR gap assessment in 2017.

see less

Quality Officer
May 2008 – Jan 2009 · 9 mos
Best

Philips Informatics Infrastructure (PII) is a business unit within Philips Healthcare Informatics (HI). They (120 people) develop a software platform for other medical business units within Healthcare.

Willem supported the main development projects in PII as quality officer.(milestone audits, baseline audits, project management advice). He prepared the department for an FDA visit.

Project Leader
D.O.R.C. Limited
Jan 2007 – Apr 2008 · 1 yr 4 mos
Zuidland

D.O.R.C. International provides ophthalmic surgeons throughout the world with instruments and equipment especially designed for anterior & posterior ophthalmic surgery. A new version of a medical device has to be introduced to the American market for which for the first time the software application is recognized as a medical device. Clearance was achieved in January 2008
Tasks
- Assess the new version and the current R&D process on compliance to FDA regulations.
- Make existing documentation (requirements & design) compliant to FDA regulations.
- Let software validation be executed.
- Make and deploy R&D processes & tooling compliant to FDA regulations.

Quality Assurance Officer / Configuration Manager

Eventis
Jun 2007 – Jan 2008 · 8 mos
Eindhoven

EventIS develops systems for managing and distributing metadata for the digital television market (e.g. electronic programming guide and video on demand). Customers are large cable companies. EventIS has emerged from 3 persons in 2003 to 40 people in 2007.

Introducing stricter change management and configuration management in a fast growing product development company. Being the configuration manager, release chair and buildmanager.
Tasks
- Create and deploy configuration management process
- Create and deploy change control process
- Create and deploy peer review process
- Chair weekly release board
- Baseline and release software releases

Software Quality Officer

ASML
Jan 2007 – Jun 2007 · 6 mos
Veldhoven

Providing management insight in status of documentation and review process of a large software product development project.
Helping the system integration team getting grip on the project

Process Improvement Consultant

Centric TSolve
Apr 2006 – Dec 2006 · 9 mos

Centric TSolve is specialised in embedded solutions (software and hardware development) for international customers in the automotive industry. TSolve has 3 locations spread over the Netherlands and Germany.
Tasks: Training hardware and software engineers on the most important development processes via a 6 days training. Improving the quality system to CMMi level 2.

Philips Medical Systems

6 yrs

Quality Assurance Officer \ Group Leader Software SQA \ SPI manager

Dec 2000 – Mar 2006 · 5 yrs 4 mos

Best

Cardio Vascular (C/V) is a business unit within Philips Healthcare. They develop and produce medical X-ray systems. The systems are put on the international market.
The system development group consists of 70 people. The software development group consists of 200 people. Within development, a quality assurance group exists of 6 people. A large project (150 people) divided in several subprojects develops the new generation of X-ray systems. Willem has een Quality Officer for the system project and a software sub project
Tasks

- Perform monthly audits on the projects on quality targets
- Perform baseline audits and process audits (against CMM)
- Perform supplie audits at supplier site
- Deploy QMS (CMM level 2)
- Assist in metric program as metrics officer
- On system sub project: compliance checks to regulatory
- Perform CMM assessment on KPA QA at other business units

As Group Leader Software SQA \ SPI manager (1 year)

- Train, guide and evaluate the QA group
- Put QA group onto the projects in stead of line function (visibility)
- Create and implement improvement plan to reach CMM level 2

see less

Quality Assurance Officer

2000 – 2001 · 1 yr

Eindhoven

Philips ASA lab developed products for the consumer market. The Super Audio CD project (SACD) delivers a first of a kind SACD player (development and production). It is a multi-side project (40 members) with a hardware and software team in the Netherlands, a hardware team in Japan and production in Belgium. Willem was the Quality Officer of this project:

- Setup and deploy project specific procedures
- Monthly audit project on CMM level compliance
- Streamline project on communication between members

Quality Assurance Officer
ASML
1996 – 1999 · 3 yrs
Veldhoven

ASML is a multi disciplinary development and production company for lithographic systems. It has 2 software departments with a mutual quality system. Willem was Quality Officer for both departments (overall function)

- Create and deploy software development life cycle (V-model)
- Improve and deploy peer review process
- Improve and deploy document control process
- Guide and instruct project leaders on quality matters
- Setup and coordinate monthly introduction training for new employees

Medical Device Software tester
Draeger
1995 – 1996 · 1 yr

Software developer/Team leader
Atos Origin
1988 – 1995 · 7 yrs
Eindhoven Area, Netherlands

Software Developer on several embedded software projects. Customers were Oce vd Grinten, Brinkman, Organon Technica and Philips Medical Systems