



Curriculum Vitae



Willem van den Biggelaar

Quality & Regulatory / Process Improvement consultant

25 years of experience in multi disciplinary product development environments. Pragmatic and result driven.

- Regulatory Consultant 6 years
- Quality Assurance / Process improvement 11 years
- Project lead / Group lead 32 years
- Trainer from '92
- Metrics officer / Configuration Manager 1 year
- Software engineer /system tester 7 years

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1. Management Summary

Willem starts his career in 1985 after receiving his bachelor's degree in Electronics. For 12 years he works for companies like Océ vd Grinten, Organon Technica, Philips Medical Systems and Dräger Medical Electronics. First as software engineer, next as system tester and finally as project leader.

From 1997 onwards, he switches to the Quality Assurance (QA), Process Improvement (PI) and Regulatory business. As QA/PI consultant he works for multi disciplinary development organizations like ASML, Philips Applied Technologies and Philips Healthcare. But also smaller companies like Centric TSolve, Dorc International and EventIS. His main tasks are assessing adherence to the Quality Management Systems (QMS), creating, deploying and maintaining these systems and advising projects and departments on quality assurance matters.

For the medical device manufacturers (Philips Healthcare, Dorc International and Philips Digital Pathology) the regulatory aspects are taken into account. For Philips Digital Pathology, CCM and Frencken Mechatronics the setup and deployment of an ISO 13485 compliant QMS has been accomplished by Willem.

As a trainer he has developed and given courses on CMMI process areas, inspections, requirements management, software testing and quality assurance. From 2007 till 2010 he has been member of the program committee for the annual QA&Test conference in Bilbao, Spain.

Per 2011 Willem is a certified lead auditor for ISO 9001, ISO 13485 and CMDCAS ISO 13485.

**2. General****A. Personal details**

Name	W.F.M. van den Biggelaar
Adress	Koningskruis 1, 5081 XM Hilvarenbeek, the Netherlands
Place and date of birth	Biest-Houtakker, 24 september 1963
Nationality	Dutch
Languages	fluent English, moderate German

B. Education

<i>Period</i>	<i>Institute</i>	<i>Education</i>
1995 -1997	Institute for Career & Development	Bedrijfskundig management
1981 -1985	IHBO, Eindhoven	HTS-Electrotechniek, Technische Computerkunde
1976 -1981	Odulphus lyceum, Tilburg	Atheneum-B

C. Courses

<i>Process and Quality</i>		
2010	KEMA Quality	ISO 13485:2003 and auditing
2010	Accademia Qualitas	Canadian Medical Devices Conformity Assessment System
2009	Qserve	Medical Device Regulations European Union
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
<i>Personal training</i>		
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
<i>Methods and tools</i>		
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	Ise	Data communication and networks
1989	Jackson	Jackson Structured Design for real time systems

D. Regulations, models & standards

Regulations	FDA 21 CFR part 820 & part 11, IVD-MD, MDD
Standards	ISO 13485, ISO 9001, ISO 14971, EN 62304
Process models	CMM(I), TMM, SCRUM
Assessment methods	CMM(I): Philips Assessment Method (PAM)

E. Supporting tools

Project Planning & Tracking	Microsoft Project, Niku open workbench
Configuration Management	CodeManager, SCCS, RCS, Continuous, ClearCase, TestTrack Pro, Perforce, (Tortoise)CVS, Sharepoint
Change Control	ClearQuest, Issue tracker, DDTS
Code Quality	QA-C (++), Lint, Purify, C-Cover, Code Wizard



F. Recommendations, www.linkedin.com

Arend-Jan Beltman, CTO CCM, June 22, 2011.	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. Top qualities: Personable, Expert, On Time
Bob van Gemen, General Manager, Digital Pathology, October 9, 2009	Willem has established successfully an ISO 13485 quality system for our business. He worked very well with our team and managed to translate our business goals into a meaningful quality management system (QMS). Deliverables were always on time and working with Willem was experienced as pleasant by the whole team.” Top qualities: Expert, Good Value, On Time
Dirk Vossen, Q&R manager, Digital Pathology, October 8, 2009	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 devices. Top qualities: Personable, Expert, Good Value
Pierre Heuvelmans, Quality Manager, Philips, Healthcare Informatics, PII January 30, 2009	“By hiring Willem, you get a person in house who adapts to your organization quick and efficient. He's well accepted among all colleagues and through his combination of social skills and knowledge on Quality and SPI within the software development area; he gives significant added value to the organization.” Top qualities: Personable, Good Value, High Integrity
Ray Arell, Sr. Engineering Manager, Intel presenter at the QA& Testing conference May 2, 2007	“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, System Test Engineer, Philips Medical Systems April 2, 2006	“Willem is an enthusiastic motivating colleague 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, Group leader, Philips Medical Systems, October 11, 2005	“Software Quality Assurance Officer who can translate his excellent process insights into practical advice for his teams.”
Piet Welles, Project Leader, Philips ASA lab, April 3, 2006	“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.”



3. Working Experience

Regulatory / Quality Assurance / Process Improver			
<i>Period</i>	<i>Customer</i>	<i>Role</i>	<i>Details</i>
2010 – 2011	Frencken Mechatronics	Regulatory consultant	§ 4.1
2010 – 2011	CCM (Centre Concepts Mechatronics)	Regulatory consultant	§ 4.2
2009	Philips Digital Pathology	QA & Regulatory officer	§ 4.3
2008	Philips Healthcare. PII	QA & Regulatory officer	§ 4.4
2008	Sintecs	Process Improvement consultant	§ 4.5
2007	DORC International	QA & Regulatory consultant	§ 4.6
2007	eventIS	QA & CM manager	§ 4.7
2006	Centric Tsolve	Process Improvement consultant	§ 4.8
2003 – 2005	Philips Medical, Cardio Vasculair	Software / System Quality & Regulatory officer	§ 4.9
2002 – 2003	Philips Medical, Components	Software Quality officer	§ 4.9
2001	Philips Medical, Components	Group leader SQA team SPI coordinator	§ 4.10
2000	Philips ASA lab	Quality officer	§ 4.11
1996 – 1999	ASML	Software Quality officer	§ 4.12

Project leader		
<i>Period</i>	<i>Customer</i>	<i>Role</i>
2010	CCM (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		
<i>Period</i>	<i>Customer</i>	<i>Consultancy / Course</i>
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	Origin	Safer-C + inspection
1996 – 1999	ASML	Course coordinator
1996	VDO Car Systems	Test process software department
1986	Ministry of Defense	Course coordinator

Software & Test Engineer	
<i>Period</i>	<i>Customer</i>
1995	Dräger
1993 – 1995	Philips Medical, Cardio Vascular & Magnetic Resonance
1993	Philips Nederland
1990 - 1991	Van Aaken / Brinkman
1989 – 1990	Organon Technica



Curriculum Vitae – Willem van den Biggelaar

1998	Océ vd Grinten
1987 – 1988	Autolease Holland



4. Relevant details work experience

4.1. Regulatory Consultant, Frencken Mechatronics, April 2010 – current

Organisation	Frencken Mechatronics develops and manufactures medical and non medical device products in a business to business model.
Tasks	<ul style="list-style-type: none"> • Create and deploy an ISO 13485 and FDA compliant quality management system • Lead the quality team for a project that has to make the production of a medical subsystem FDA compliant. Worked on tool validation, process validation, component traceability, setup of DHR, incoming inspection

4.2. Regulatory Consultant, CCM (Centre Concepts Mechatronics), April 2010 – July 2011

Organisation	CCM develops innovative mechatronics products and systems in a business to business model; from concept till prototyping and small series production. The organization consists of 120 people.
Tasks	<ul style="list-style-type: none"> • Create and deploy an ISO 13485 and FDA compliant quality management system (13485 certification reached in March 2011). • Be project leader for the ISO 13485 project • Assist a medical project on quality matters

4.3. Quality & Regulatory Officer, Philips Digital Pathology, January 2009 – March 2010

Organisation	Philips Digital Pathology is an incubator from Philips Corporate Technologies. In 2010 they will release a first of a kind digital pathology IVD medical system. For the development of the system, a partnership with 5 other companies has been established.
Tasks	<ul style="list-style-type: none"> • Create and deploy an ISO 13485, FDA and IVD MD compliant quality management system (13485 certification reached in March 2010). • Assess the partners on ISO 13485, FDA and IVD MD compliancy • Regulatory preparation for the USA and European market

4.4. Quality & Regulatory Officer, Philips Healthcare HI/ PII, 2008 (11 months)

Organisation	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.
Tasks	<ul style="list-style-type: none"> • Create and execute quality plan • Perform project milestone audits • Perform baseline audits • Advice management on project releases • Prepare department for FDA visit • Deploy quality management system

4.5. Process Improvement consultant, Sintecs, 2008 (1 month)

Organization	Sintecs is a manufacturer of high-speed electronics for the international market. Due to growth of the company, the need for a Quality Management System arose.
Tasks	<ul style="list-style-type: none"> • Initial setup of the Quality Management System • Initial deployment of the QMS



4.6. Quality & Regulatory Consultant, DORC International, 2007 (3 months)

Organisation	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 part of the medical device.
Tasks	<ul style="list-style-type: none"> • 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 (Configuration management, Requirements Management, Change Management) compliant to FDA regulations.

4.7. QA Manager & Configuration Manager, EventIS, 2007 (9 months)

Organisation	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.
Tasks	<ul style="list-style-type: none"> • 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

4.8. Process Improvement Consultant, Centric TSolve, 2006

Organisation	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	<ul style="list-style-type: none"> • Make the QMS CMMI level 2 compliant • Assess projects with respect to the QMS and report to Quality Manager • Train all locations on process awareness

4.9. Quality Officer, Philips Healthcare (C/V & Components), 2002 - 2005

Organisation	<p>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.</p> <p>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 been Quality Officer for</p> <ul style="list-style-type: none"> • the system sub project for 1 ½ year • software sub project including 5 suppliers for 1 ½ year • software sub project for 1 year
Tasks	<ul style="list-style-type: none"> • Perform monthly audits on the projects on quality targets • Perform baseline audits and process audits (against CMM) • Perform supplier 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



4.10. Group leader Software SQA, SPI manager, Philips Healthcare (Components), 2001

Organisation	X-Ray Components was a business unit within Philips Healthcare. They developed the platform for medical X-ray systems. Customer was C/V. The software development group consisted of 100 people. Within development, a software QA group exists of 5 people. Willem has been Group leader for this QA group and was also the Software Process Improvement manager for the whole software department.
Tasks	<ul style="list-style-type: none">• 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

4.11. Quality Officer, Philips ASA lab, 2000

Organisation	Philips ASA lab (now Applied Technologies) develops 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.
Tasks	<ul style="list-style-type: none">• Setup and deploy project specific procedures• Monthly audit project on CMM level compliance• Streamline project on communication between members

4.12. Software Quality Officer, ASML, 1996 - 1999

Organisation	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)
Tasks	<ul style="list-style-type: none">• 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