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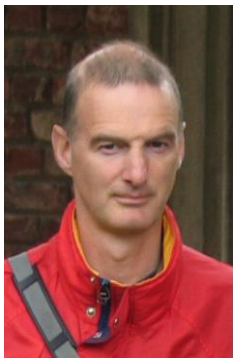

GENERAL

Name	Ir. J.J. Jonker (Hans)
Function	Senior Process Consultant
Date of Birth	29 May 1958
Nationality	Netherlands
Language	English, German
Education	Master at the Technical University of Twente: - Electronics - Biomedical Engineering - Computer Science Business Management
Specialty	Setting up / Auditing QMS (ISO-13485 / FDA)

EMPLOYERS

2008 – now	Argo Consultancy B.V.	(ZZP / Owner)
2009 – now	DEKRA Quality	(lead auditor)
2009 – now	Mikrocentrum	(trainer)
1997 – 2008	Sioux Embedded Systems	(software house)
1990 – 1997	High Tech Automation	(software house)
1985 – 1990	Océ van der Grinten	

LINKS

Website: www.ArgoConsultancy.eu (incl. references of customers)
LinkedIn: http://nl.linkedin.com/in/HansJonkerArgoConsultancy

SUMMARY

- ISO-13485, ISO-9001, ISO-14971, IEC-62304, MDD
- FDA Regulations (21 CFR part 820)
- Lead Auditing Notified Body
- Management Reviews, CAPA's, Complaints, NCR's, Internal Audits, Changes
- SPI, Assessments, Audits, CMM, CMMi
- PRINCE2, Change Management, Project Management, Peer Reviews, QA-Auditing, Metrics, PM-BOK, TQM, HRM
- Waterfall, V-model, Evolution, Agile, Lean, Scrum, DfSS, Medic
- Real-time systems, Graphical User-Interfaces, testsystems, measurement systems, controlsystems, datacommunication, Object Oriented, Hatley & Pirbhai, Yourdon
- C++, C, Assembler, AWK, PASCAL, FORTRAN,
- Microsoft Office, MS-Project, Lotus Notes, Outlook, Visio, Paint Shop Pro, FrontPage, IPS, SharePoint, Mindmanager
- ClearCase, SubVersion, VSS, NSE, Code Manager, Xfig, OSF/Motif, emulator, logic analyzer, TEAMWORK, ClearQuest, Trac, DataDrill, QAC, McCabe, C-Cover

ISO-13485 AUDITS

Period	Nr of audits	Remarks
2016	11	Added: Monitoring Audits
2015	13	Added: Unannounced Audits
2014	11	
2013	12	Added: Guiding Trainees
2012	14	
2011	8	
2010	7	As Lead Auditor
Oct 2009 – Jan 2010	6	As Trainee

FDA INSPECTIONS

Period	Type	Remarks
2015	FDA Mock Inspection	Supported (incl. FrontRoom and BackRoom)
2014	FDA Mock Inspection	Organized (incl. FrontRoom and BackRoom)
2014	FDA Assessment	Organized / Preparing / Guiding Interviews
2013	FDA Inspection	Supporting solving Warning-letter on CAPA
2013	FDA Inspection	Preparing / Followed in BackRoom
2010	FDA Inspection	Preparing / Get interviewed
2007	FDA Mock Inspection	Preparing / Get interviewed

ABBREVIATIONS

Abbreviation	Description
CAPA	Corrective Action Preventive Action
CMM(I)	Capability Maturity Model (Integration)
DPI	Development Process Improvement (more disciplines)
QA	Quality Assurance
SPI	Software Process Improvement
IME	Internal Maturity Evaluation
PIT	Process Improvement Team

MAIN COURSES

May 2016 ->	Medical Device Single Audit Program (MDSAP)
Apr 2016	ISO-13485: 2016
Mar 2015	FDA Quality System Requirements (AAMI)
Feb 2015	Medical Device Directive 93/2/EEC (DEKRA)
Aug 2014	Unannounced Audits
Jun 2014	FDA Design Control (AAMI)
Jul 2013	CAPA-process, CAPA-content, CAPA-tool
Jul 2013	Complaint-process, Complaint-content
Jul 2013	NCR-process, NCR-content
Jul 2013	Risk Management
Nov 2011	CE-marking of Medical Devices
Nov 2011	QSR and Medical Devices routes for USA
Nov 2011	ISO-14971 - Risk Assessment for Medical Devices
May 2011	Internal corporate CAPA Training
Oct 2011	Vigilance
Jul 2010	USA Main Medical Devices Regulations and related Standards (FDA)
Apr 2010	Lead-Auditor ISO-9001 and ISO-13485 (Certification)
Mar 2010	PRINCE2 Foundation (Certification)
Feb 2010	ISO-9001 and ISO-13485 Theory Training
Jan 2010	ISO-9001 and ISO-13485 Auditor Training (Certification)
Nov 2007	Essential Unified Processes
Sep 2007	Workshop Configuration Management
Aug 2007	Philips SPI-Coordinator Workshop (Cleveland)
Nov 2005	Scrum Master
2004 – 2005	Advanced English
Nov 2004	Introduction to the CMMI
End 2004	Communication Skills
2003 – 2004	Consultancy Skills
Jun 2002	Process Measurement & Analysis
Feb 2002	Effective Leadership
Dec 2001	Influencing by Persuading
Nov 2001	Emotional Intelligence
Jul 2001	Walkthrough and Fagan Inspections (moderator)
May 2000	Philips Assessment Method (PAM)
May 2000	Walkthrough and Fagan Inspections (general)
May 2000	SPI / CMM
Apr 2000	Personal Mission Statement / Kernel Qualities / Performance Agreement
Sep 1999	Recruitment and retaining of experienced ICT-personnel
Jul 1998	Time Management
Apr 1998	Spider Congress: Software Development
Nov 1995	Project Management: PRESS
Oct 1995	Software Process Improvement
Jun 1994	Total Quality Management
Mar 1994	Customer focused Software-development
Dec 1993	Customer focused Personal Skills
Jan 1993	Project Management for Project- and Team-leaders
Nov 1992	Testing for Designers and Analysts
Nov 1991	C++
Jun 1991	Advanced Programming with UNIX and C
Jan 1989	General course Personal Communication
May 1988	Practical Reliability Engineering

JOB DESCRIPTIONS

Jun 2009 – Now **DEKRA - Notified Body / Certifying Body (Arnhem)**

Role Freelance ISO Lead Auditor

Task
- Following the training traject to ISO Lead Auditor
- Performing ISO-13485 audits
- Started with the MDSAP-training

Results
- Performing ISO-13485 Audits (on average 1 per month)

Apr 2009 – Now **Mikrocentrum - Training Institute (Eindhoven)**

Role Freelance trainer

Task
- Setting up courses on the area of Technical Product Development processes:
  - Overview Product Development Process
  - Quality Assurance in Projects
  - Document Reviews
  - Defining and using Metrics
- Giving these trainings (on average 1 per year)

Apr 2008 – Now **Philips Medical Systems (Best)**

Role Senior Process Consultant

Situation Within the CTO the group System & Software Performance Improvement (SSPI) exist, that coordinates the CMMI program for all Business Units.

Task Stimulating the different BU's to share their Best Practices.

Activities
- Setting up of a Website for the static information about the CMMI program
- Setting up of a SharePoint for sharing CMMI Best Practices

Tools
- Intranet Publishing Service (IPS)
- MS-SharePoint
- Visio

Result
- SSPI Website
- SSPI SharePoint
- Deployment of the involved CMMI project leaders

Jan 2014 – Now **Philips Consumer Lifestyle – ISE Medical Products (Eindhoven)**

Role QMS-Manager

Situation A lean Quality Management System that was developed for a small organization with experts in Medical Devices. The organization however has grown to a size of 275 people of which the majority has little or no experience with developing of Medical Devices.
An FDA Mock Inspection has underlined this.

Task
- Own and build the Quality Management System
- Ensure compliancy of the QMS to the ISO13485:2003 standard, and FDA Regulations (21 CFR parts 808, 812 and 820)
- Ensure consistency within the QMS
- Maintain consistency of the QMS with the overall BMS
- Coach the Process Owners (POs) to develop consistent and effective procedures, processes and work instructions.
- Finalize QMS documents, written by POs and enter these in the Document Management System for review and approval.
- Own the internal audit program and execution of internal audits
- Take up the role of management representative, reporting QMS performance to management with executive responsibility for organizing the Management Review
- Coordinating CAPA's

Activities
- Setting up the process improvement infra-structure, including Process Owners for each Process Area
- Support the Process Owners
- Training and coaching of the Quality Assurance Managers (QAM) for deploying the QMS and guiding projects
- Setting-up an intranet portal to the QMS for easy access
- Setting-up a CAPA-system, incl. CAPA-Overview, CAPA-Form, CAPA-metrics and CAPA-Scrum-Board and guiding employees in performing the CAPA-process.
- Setting-up and organizing Management Reviews
- Setting-up and organizing Internal Audits
- Organizing and guiding external DEKRA Audits
- Organizing and guiding a full blown FDA-Mock-Inspection (incl. FrontRoom, Runners, BackRoom)

Tools
- SharePoint
- CemaFore – IPM
- Doors

Result
- ISO-13485 and FDA-compliant Quality Management System
- ISE-Q: Intranet portal to the QMS
- Positive FDA-Mock-Inspection
- ISO-13485 Renewal Audit, without NonConformities

Jul 2013 – Dec 2013 **J&J / Synthes - Producer of e.g. instruments and implants for surgical fixation (Basel)**

Role Senior CAPA-consultant

Situation The company has had an FDA-Inspection, which has resulted in an FDA-Warning-letter

Task The hired external CAPA-consultants were split into 2 groups:

1. CAPA Legacy Reviewer (I took part of this group)
   Review all CAPA's till 2 years back on process and content
2. Subject Matter Expert (SME)
   Started with the Open CAPA's to handle them on the correct way

Activities

- Get trained in the CAPA-process and the nearest Complaint-, NCR- and Risk Management-processes
- Review for a specific site all Legacy CAPA's
- Fill-in a specific CAPA Legacy Review checklist
- Classify each CAPA on Remediation Level
- Handle the review results to the SME's
- Carry out the root cause message of this situation:
  - Medical Device awareness
  - Working in a strong regulated environment (follow the procedures)
- Review the on corporate level developed new CAPA-, Complaint-, NCR- and Risk Management-processes

Tools

- CATSWeb
- EtQ

Result

- All Legacy CAPA's were reviewed and classified for the Remediation

May 2013 – Jun 2013 **Terumo - Producer of medical syringes /needles (Leuven)**

Role Senior NCR-consultant

Situation The company was preparing for an FDA-Inspection.
The QA/QC-group was reviewing all the NCR's till 2 years back

Task Support the QA/QC-group with the NCR-review

Activities

- Get trained in the NCR-process and the nearest CAPA- and Complaint-processes
- Make an overview of all NCR's per department to be reviewed
- Train the QA/QC-group in the FDA way-of-auditing
- Support the QA/QC-group for specific NCR questions and how to correct them
- Monitor and control the progress of NCR-review

Tools

- Own NCR-tool
- EtQ

Result

- All Legacy NCR's were checked and corrected if needed
- The FDA-Inspection was passed very well

Jan 2011 – Nov 2012 **Philips Light&Health Venture - Pain Relief Patch (Eindhoven)**

Role QMS-Manager
SQM-Manager (a.i.)

Situation The Venture (a separate group within the big organization to develop a completely new product) was developing a new product for relieving back pain.
A couple of procedures of the Quality Management System were written.

Task The tasks related to the ISO-13485 compliant Quality Management System has changed over time:

1. Reviewing of the already finished procedures
2. Supporting in writing procedures
3. Setting up the whole QMS

Activities

- Setting up the process improvement infra-structure, including Process Owners for each Process Area
- Support the Process Owners by:
    - Training them in their Process Area
    - Setting up and writing procedures / templates
    - Tailoring of some adopted processes from other existing BU's
    - Setting up Training material
- Training and coaching of the QA-Officers
- Setting-up a CAPA-system, incl. CAPA-Overview, CAPA-Form and CAPA-metrics and guiding employees in performing the CAPA-process.
- Organizing of a training day for the whole team trained by the Process Owners
- Coaching and monitoring the project
- Organizing 2 preparation-audits
- Organizing the Certification Audit
- Supporting the CE-Certification (e.g. Essential Requirements, Technical File)
- Organizing a Supplier Audit by the CE-Certification institute
- Guiding the supplier with the production of the new product e.g.:
    - Production Process FMEA
    - Production Process Validation
    - Work Instructions
    - Training plan
    - Traceability

Tools

- SubVersion / Trac
- FrontPage

Result

- ISO-13485 certified Complete Quality Management System incl. templates and trainings material (in fact realized in 4 months)
- Intranet portal to the QMS

Jul 2009 – Dec 2012 **Philips LABOSYS - Producer Laboratory Information Systems (Eindhoven)**

Role Process Improvement Coordinator

Situation The department has developed and maintained a very successful Laboratory Information Systems for many decades. The used Quality Management System however was not fully suited anymore for the actual situation.
It was decided to make use of an existing Quality Management System of a colleague development group in Best and:

- to define tailoring rules to make the procedures suitable
- to setup an own subset of process / templates to give more room for their own specific situation

Task To define a Quality Management System which is compliant with the ISO-13485

Activities

- Setting up the process improvement project (Brake!!)
- Coaching and monitoring the PIT-teams
- Training/Awareness of the team in the QMS
- Coaching and monitoring Maintenance and the projects
- Training and coaching of the new QA-Officer
- Guiding employees in using the corporate CAPA-system

Tools

- SubVersion
- ClearQuest
- Quality Center
- Caliber

Result

- Complete Quality System incl. tailoring rules, templates and trainings material
- Quality Management System which is compliant with the ISO-13485
- Intranet portal to the QMS
- ISO-13485 certified (1 Minor NonConformity and 1 Observation)

Jan 2011 – Oct 2011 **MRC-Holland - Producer of DNA Tests (Amsterdam)**

Role Senior Software Process Consultant

Situation The company was developing a software tool that could be used for analyzing the DNA test results, but was missing a documented Software Development Process.

Task To define a simple Software Development Process which is compliant with the ISO-13485

Activities

- Training in Software Basics (e.g. Software Life Cycle, V-model)
- Setting up simple procedures and templates
- Guiding in using the new set of procedures and templates

Tools

- MS-Office

Result

- Software Development Process descriptions (incl. templates) according to the ISO-13485 and the IEC-62304, ready to be audited

Apr 2010 – Dec 2011 **Philips - Medical Imaging Platforms (Best)**

Role Quality & Regulatory Officer / Process Improvement

Situation
- The department, that delivers Imaging Platforms to the other departments, has just had the 5th reorganization in 4 years.
- New multi site organization with teams in Best, Bangalore, Haifa and Cleveland
- The quality organization was not defined.
- There was too less quality capacity for doing the QA-audits / Process Improvements.
- It was not clear which Quality Management System the new organization should use.

Task

Quality Assurance:
- Guiding projects (development and transfer/maintenance)

Regulatory:
- Preparing FDA-Inspection

Process Improvements
- Guidance with setting up new Process Improvement Plan

Activities

Quality Assurance:
- Guidance in archiving, reviewing, preparing for passing Management Milestones for the development- and transfer-projects
- Participating in project meetings

Regulatory:
- QA-Audit on the archiving process
- Preparing CAPA-meetings
- Training

Process Improvements
- Defining a quality organization structure (roles, tasks, meetings)
- Setting up new Process Improvement Plan
- Participating in short-time high-priority improvements (Customer Notifications, CAPA)

Tools
- EDIT / LiveLink
- ClearQuest
- Communicator

Result
- Structured quality team
- Up-to-date archive
- Revitalized Audit program
- Process Improvement Plan

Jan 2008 – Nov 2008 **Philips - Producer Medical X-ray Systems (Best / Hamburg)**

Role DPI-coordinator

Situation The department in Best had a CMMI-2 certified Quality System.
The department in Hamburg was just started with improving their Quality System for CMMI-2. After reaching that level, the goal was to go together for CMMI-3.

After a short study, it is decided for efficiency reasons tot directly go for the common Quality System, to certify Hamburg on CMMI-2 and than go for CMMI-3.

Task To realize a common Quality System for Best and Hamburg.

Activities
- Setup a DPI-infrastructure (see previous job) for Best and Hamburg and to take care for a balanced workload and a synchronized way-of-improving between the 2 departments.
- General progress monitoring:
  - PIT-teams (common for both departments)
  - Active support for the Project Leaders
  - Guided IME's / CMMI-mapping
- Organizing of CMMI-assessment in Hamburg
- Preparation for an FDA-Inspection in Best

Tools
- ClearCase / ClearQuest
- Niku / Clearity
- DataDrill
- Intranet Publishing Service (IPS)

Result
- Complete Quality System incl. templates and trainings material
- Extension of the Intranet (Q-Web) with also the not-development departments (e.g. Purchasing, Marketing, Application)

Jul 2005 – May 2009 **FIMI- Producer Medical LCD-monitors (Milan)**

Role SPI-coordinator

Situation A Quality System that just met the minimal expectations for the ISO-9001.
The growing and increasing complexity, special for the Firmware, asked for more guidelines to better control the projects on quality and on delivery times.

Task Obtain the CMMI-2 certificate, with a Quality System that fits with the 'lean & mean' organization.

Activities
- Setup a SPI-infra-structure (see previous job description)
- General progress monitoring:
  - Process Owners
  - Active support for the Project Leaders
  - Guided IME's / CMMI-mapping
- Organizing of CMMI-2-assessment in Milan.

Tools
- Lotus Notes (as a Document Management System)
- SubVersion
- MS-project
- FrontPage

Result
- Complete Quality System incl. templates, trainings material (focus on Requirements-, Configuration- and Project-Management)
- Simple, but very good accessible, and easy maintainable Intranet
- Projects are compliant with Quality system
- Status Mei 2009: Documentation/Training on CMMI-2 level; including Peer Review Pre-Assessment done.

Aug 2005 – Dec 2007 **Philips - Producer Medical X-ray systems (Best)**

Role DPI-coordinator

Situation An old Quality System (based on CMM-2) from a couple of years ago, when the organization consists of 2 separate independent groups (in Best). The 2 groups are now integrated, but because the Quality System wasn't integrated, minimal deployed, very difficult to access, so it was hardly used

Task Improve the multidisciplinary Quality System and take care that the organization works again according to CMMI-2 level.

Activities

- Setup an SPI-infra-structure:
  - DPI-steering group
  - Process Improvement Teams (PIT-teams) per process area
  - Process Owners per process area
  - General templates for documentation, procedures, presentations, ...
  - Quality System on Intranet for simple and quick access
  - Trainings Program
- Support per PIT-team:
  - Investigation why the processes were followed that bad
  - Write a PIT-plan
  - First draft for the procedures, templates and metrics
  - Support by finalizing the procedures and templates (Training CMMI, background information)
- Being Process Owner of the PIT-teams:
  - Configuration Management
  - Subcontract Management
- General progress monitoring:
  - PIT-teams
  - Active support for the Project Leaders
  - Guided IME's / CMMI-mapping
- Organizing the CMMI-assessment
- Preparation for an FDA-Inspection

Tools

- ClearCase / ClearQuest
- Niku / Clearity
- DataDrill (metrics)
- DfSS
- Intranet Publishing Service (IPS)

Result CMMI-2; Including some Process Area's on level-3
(Being the first group within Philips that have reached CMMI-2; Certification was presented by Kleisterlee, CEO Royal Philips)

Aug 2003 – Jul 2005 **Philips-APM - Producer Automotive CD/DVD players (Wetzlar)**

Role SPI-coordinator

Situation There was an old Software Quality System (CMM-2; ISO-9000; ISO-16949) that did not match with the actual way-of-working of the software projects. Because it gave almost no guidance and support, it was minimal used.
Moreover the Quality System was minimal trained and difficult to access.

Task Improve the Quality System and take care that the organization works again on CMM-2 level.

Activities

- Setup an SPI-infra-structure:
  - SPI-steering group
  - Process Improvement Teams (PIT-teams) per process area
  - Process Owners per process area
  - General templates for documentation, procedures, presentations, ...
  - Quality System on Intranet for simple and quick access
  - Trainings Program
- Support per PIT-team:
  - Investigation why the processes were followed that bad
  - Write a PIT-plan
  - First draft for the procedures, templates and metrics
  - Support by finalizing the procedures and templates (Training CMM, background information, visit to other organizations)
- Being Process Owner of the PIT-teams:
  - Project Management
  - Subcontract Management
- General progress monitoring:
  - PIT-teams
  - Active support for the Software Project Leaders
  - Guided IME's / CMM-mapping
- Organizing the CMM-assessment

Tools

- ClearCase
- MS-Project
- FrontPage

Result Sw CMM-2; including Peer Review

Dec 2002 – Jul 2003 **Philips-APM - Producer Automotive CD/DVD players (Wetzlar)**

Role SwQA-Officer

Situation As a result of the enormous project pressure, the software projects were:

- Hardly using the CMM-2 processes.
- Less predictable in their releasing dates.
- Delivering less quality

The management was also taken shortcuts to arrange that things get done for some special customers with high priority or to get project information.

Task Re-organize the SwQA-audits, so that:

- The projects works according to the processes.
- The management got more insight in how the projects were following the processes.

Activities

- Performing SwQA-audits:
    - Preparation
    - Audits
    - Reporting
    - Tracking
    - Escalating
- Supporting the:
    - Software project leaders and developers with following the processes.
    - Management by being involved by the projects.
      (e.g. Reading and giving feedback on project reporting)

Tools

- ClearCase
- MS-Project
- FrontPage

Result Making aware that the hectic situation has lead to a more or less chaotic way-of-working (certainly not according to the Quality System, or CMM-2).
The plans for getting CMM-3 were put on hold to first improve the Quality System so it better fits tot the current organization and to train and deploy it to the developers.

Sep 2002 – Nov 2004 **Pie Medical Imaging - Producer of Medical Imaging Systems (Maastricht)**

Role SPI-coordinator

Situation Organization was rapidly expanded from 5 to 20 persons and there was a need to extend the Quality System (ISO-9001: 2000), so that it better supports the software development.
In the past own attempts to process improvement have failed.
Customers had also problems with the project delivery dates and the delivered quality.

Task Setting up a pragmatic Quality System that fits with the way-of-working of the organization and that is also compliant with CMM-2.

Activities

- Setup an SPI-infra-structure:
  - SPI-steering group
  - SPI-Projects per process area
  - Process Owners per process area
  - General templates for documentation, procedures, presentations, ...
  - Quality System on Intranet for simple and quick access
  - Trainings Program
- Support per SPI-Project:
  - Investigation why the processes were followed that bad
  - Writing a SPI-project-plan
  - Writing procedures, templates and metrics (Training CMM, background information)
- General progress monitoring:
  - SPI-Projects
  - Deployment of the Process Owners
  - Guided IME's / CMM-mapping
- Organizing the CMM-assessment

Tools

- VSS
- MS-Project
- FrontPage

Result CMM-2; including Peer Review

Sep 2001 – Jun 2002 **Philips - Producer Medical X-ray systems (Best)**

Role SPI

Activities Inspired by a presentation of Tom Gilb about Evolutionary Development, the project that I supported as an SQA-Officer, has decided to combine their Best Practices with the idea's of Tom Gilb and to describe this in a process.

Because of my process knowledge and the enormous project stress, I have worked out this "Acquisition goes EVO"- with as most important actions:

- Describing the parallel-incremental development process
- Setup the necessary documentation structure
- Setup weekly project status information
- Checklist for the tasks of the most important roles around this EVO-process
- Deployment in the project, the overall project and the development department
- Auditing and improvement of the EVO-process
- Secure the process as a part of the Quality System of the development department (V-model)

Result Enthusiastic team that works according to the Evolutionary Development process

Sep 2000 – Jun 2002 **Philips - Producer Medical X-ray Systems (Best)**

Role SPI, SQA-Officer, Teamleader SQA-Officers

Activities Setting up, supporting and performing of QA-Audits activities:

- Preparation
- Audits
- Reporting
- Tracking
- Escalation

Because the projects, but also the SQA-Officers had little experience on SQA and processes, I have setup the concept of 'The Process of the Month'. Every month a different process area was handled with all aspects like:

- Studying department-processes,
- Studying CMM-2-requirements
- Setup Audit Question List
- Performing audits in the projects
- Writing QA-Audits Reports with the findings
- Reporting to the project and the department
- Presenting findings and improvement actions to the project members
- Guiding of the improvement actions
- Escalation if needed
- Evaluation

Supporting the projects on processes e.g.:

- Project Plan (guiding the writing)
- Software Quality Assurance Plan (written myself)
- Deployment of processes

Tools

- ClearCase / DDTS
- PMW
- PM-BOK
- Medic

Result Good close working team of SQA-Officers

Sep 2000 – Aug 2001 **Sioux Project Office (Eindhoven)**

Role SPI

Activities Setting up and deployment of the Peer Review process within the Sioux Project Office:

- Investigation current review process
- Investigation wishes of the Project Office with respect to the review process
- Setup Sioux Peer Review process
  (incl. Review Form, Review Scheduler, Review Metrics Form, Checklists, Default Review Table).
- Deployment of Sioux Peer Review process by actively following the reviews and coaching of the moderators and project leaders
- Evaluation

Result New Peer Review process that better fits to Sioux

Sep 1999 – Sep 2000 **Philips - Producer Medical X-ray Systems (Best)**

Role SPI: Quality Assurance

Activities Organizing the pre-conditions to be able to perform QA-Audits on projects in the software department:

- Investigation current software processes
- Selection of the still relevant software processes
- Making these processes accessible via the Intranet
  - Re-structuring of current intranet
  - Creating a Graphical User Interface layer around the Quality System on the intranet, with as metaphor the well known 'V-model'
- Setting up the QA-Audit process (incl. templates, etc.), according to CMM-2
- Active deployment with presentations and guidance on the work floor.

Result Complete Quality System that is easy accessible via the intranet.

Sep 1998 – Sep 1999 **Sioux (Eindhoven)**

Role People Manager

Activities For Sioux:

- Acquiring & Selection (strategy and implementation),
- People Manager,
- HRM support,
- Setting up for Sioux on business level: Mission, Vision, Identity, Strategy,
- Setting up Sioux Quality System compliant with CMM-2,

Sep 1997 – Sep 1998 **Philips-ASA-Lab - Producer van DVD Players (Eindhoven)**

Role Verification Manager / Supporting Project Manager

Activities Development 2nd generation DVD video player. The most important project goal was to realize a cost reduction by integration of the 4 hardware IC's, after which the DVD player could be launched as a mass-product on the electronic market. The project was divided in 5 international teams:

- Netherlands: Project control, setup and monitoring architecture, defining software development traject + integration and testing software-deliverables
- Belgium: Acceptance of DVD player and setup manufacturing
- France: Development of hardware and the related software-drivers
- England: Porting of the Operating System to the new chip
- India: Adapting of the Graphical User Interface

My activities:

- Investigation of the problems around testing during the 1st generation DVD player.
- Writing the Verification & Validation Plan
- Deployment new test approach to the project-teams
- Setting up templates for test-specifications and test-reports
- Coordinating of the module-, deliverable-, integration-tests
- Supporting the Quality Officer with the test related subjects (reviews, code-reviews, syntax-checker, test coverage, training)
- Coordinating of extensions of the project Intranet
- Teamleader acceptance-team for the software drivers (5 persons)

Tools Document Configuration Tool (DCM)
Code Configuration Management tool (CCM)
Test: Test Generator + Test Harness,
Code: QAC, McCabe

Result Well organized test- and integration traject, which performed better, more structured and with less slippage than during the 1st generation DVD player.

Mar 1997 – Sep 1997 **Philips-ASA-LAb - Producer TV's (Eindhoven)**

Role Part architecture team

Activities Define the Interfaces between the different sub-systems of a professional TV. Defining and embedding of a 'Global System Design' process. Setting up a performance investigation with help of simulation programs.

Tools Performax, RMA, PERTS
Continuus

1996 – Mar 1997 **Dräger - Producer Patient Monitoring Systems (Best)**

Role System Architect / Projectleader during feasibility study

Activities Organizing of a feasibility study for a successor of the Haemodynamic Parameterbox for patient monitoring as part of the future Workspot Monitoring System.
The most important goals were: lower cost price, smaller volume and more functionality. Because of the major importance for the future, this multidisciplinary project quickly increases from 3 to more than 20 persons and so shifted my activities from technical to coordinating.

Performed tasks:

- Setup product requirements, Intended Use;
- Mechanical housing/design;
- System specifications;
- Hardware architecture (possibilities ASICS, DSP);
- Make or buy decision for different sub-systems;
- Legal requirements (e.g. FDA, UL, TüV, ISO, NeN);
- Risk analysis;
- Coordinating technical workgroups;
- Communicating with other departments;
- Defining development sub-system (software, hardware, mechanical).

Tools MS-Project

Result Well closed feasibility study, which was followed up by a development project

1995 – 1996 **Dräger - Producer Patient Monitoring Systems (Best)**

Role Setup Intranet

Activities Setup of a pilot for an Intranet to have a quick and easy access to the most important business information. As pilot-project the feasibility study project (described above) was chosen, while for this project a good overview of all the information of all involved departments was very important.

Performed tasks:

- Writing a Project Plan;
- Decision on hardware and software;
- Setup, maintenance and evaluation of the Intranet;
- Determine final shape.

Tools MS Internet Information Server,
MS Internet Explorer,
MS FrontPage

Result Intranet for the feasibility study project, but also already parts of the general organization (e.g. who-is-who page)

1995 – 1996 **Dräger - Producer Patient Monitoring Systems (Best)**

Role Sub-Projectleader developing ECG-monitor software

Activities Responsible for making the patient monitoring system (ECG-monitor) less sensitive for electrical interference, which is caused by the use of electrical surgery equipment in the operating theatre.

Performed tasks:

- Define and monitor of the Project Plan;
- Coordinating the communication between the involved departments;
- Developing a prototype to define the system specification;
- Clinical testing of the prototype;
- Design, code and test;
- Clinical evaluation of the final product.
- Supporting improvements on the software development process;

Tools Teamwork,
MS-Project
Resource Control System

Result An ECG-monitor, that was less sensitive for electrical interference

1995 – 1995 **Océ - Producer Copier- and Printing-systems (Venlo)**

Role Developer: NetWare connectivity

Activities Extend the connectivity software for a professional high volume printer for NOVELL/NetWare-users (NetWare connectivity).

Result De NetWare connectivity functionality is realized by embedding "third party software" in the printer-software.

1994 – 1995 **ASML - Producer Wafer Steppers (Veldhoven)**

Role Projectleader: Batch Streaming

Activities Responsible for the Batch Streaming project for a wafer stepper. Batch Streaming (BS) aims to maximize the productivity of the wafer stepper, by eliminating both the operator overhead as well as the time caused by the following sequential tasks/batches:

- Defining of the batch;
- Sequential loading of the material (wafers and reticles);
- Processing of the wafers;
- Unloading of the material.

One part of the BS was the Task Streamer (TS), which controlled the different, possible parallel tasks for the batches that must be processed. It was very important to guide the operator with a user friendly, task-oriented Graphical User Interface.

Performed tasks:

- Defining System Specification;
- Writing and monitoring of the Project Plan;
- Defining and implementing of the prototype;
- User study with the prototype at the customer's location (U.S.A);
- Specification, design, implementation and (integration)tests;
- Support beta test at the customer's location (U.S.A);

Tools TeamWork,
Open Windows,
Code Manager

Result Very, very lucrative software option, to increase the throughput of the wafer stepper.

1994 – 1995 **ASML - Producer Wafer Steppers (Veldhoven)**

Role Test-developer: test-program

Activities Specify, design and implementing of a test for a wafer stepper, which guides the operator by executing a series of mutual dependent tests. It must be possible to interrupt the test and follow up after a while.

Tools C, Open Windows, Code Manager, TeamWork

1993 **ASML - Producer Wafer Steppers (Veldhoven)**

Role Test- developer: Adapting test-software

Activities Adapting of the test software of a wafer stepper, to make it possible to start tests from a pre-defined test-queue.

Tools C, OpenWindows, NSE

1993 **ASML - Producer Wafer Steppers (Veldhoven)**
Role Developing testsoftware
Activities Specify, design and implementing of testsoftware to check the specification of a wafer stepper. Developing in close contact with the customer. Acceptance test at the customer location in Grenoble.
Tools C, OpenWindows, NSE, AWK

1993 **HTA (Utrecht)**
Role Making a quotation
Activities Making a quotation for a mobile radar system together with the hardware supplier.

1992 **ASML - Producer Wafer Steppers (Veldhoven)**
Role Metrology software
Activities Responsible for the software-subsystem Image Quality of a wafer stepper, which performs run-time corrections to monitor and control the quality of the image on the wafer. The goal was to implement “Statistical Process Control” into the corrections.

Performed tasks:
- Functional Specifications;
- Design;
- Software development;
- Subsystem tests;
- System-integration tests.
- Introduction beta test in Tempe (U.S.A.).

Tools AWK

1990 -1992 **ASML - Producer Wafer Steppers (Veldhoven)**
Role Metrology software
Activities Responsible for the software for the subsystem Level Control of the wafer stepper. This subsystem is a layer between the "user-interface" and the "driver-software".

Performed tasks:
- Feasibility study
- Functional Specifications
- Design and implementation
- Software Development;
- Test of the software interfaces and the final system test;

Tools AWK
TeamWork

1989 **Océ - Producer Copier- and Printing-systems (Venlo)**
Role Original handler
Activities Adapting of the Scheduler software of the "Original Handler" of a copier, to make the handler suitable to make more copies per minutes.
Tools C, 8051-Assembler

1987 - 1989 **Océ - Producer Copier- and Printing-systems (Venlo)**
Role Original handler
Activities Responsible for the whole software- and hardware-development of the "Original Handler" of a copier (e.g. using the digital motor controller from the master-thesis; see previous job-description).
Tools C, 8051-Assembler

1985 -1987 **Océ - Producer Copier- and Printing-systems (Venlo)**
Role Master-thesis description: "A digital servo-system for paper transport"
Activities The design, the simulation, and realization of a digital motor controller for a paper transport mechanism in an Océ copier. The software-implementation made it possible to drive the motor with an arbitrary position- / speed-curve.
Tools C, 8051-Assembler

1982- 1983 **T.H. Twente (UT-Twente)**
Role Bachelors-thesis
Activities To control a row-machine and all necessary measurement equipment for a revalidation centre.
Tools BASIC, 6502-Assembler