Argo Consultancy B.V.
Argonautenlaan 2
5631 LL Eindhoven
The Netherlands

GSM: +31 (0) 6 55 85 49 25

info@ArgoConsultancy.eu
www.ArgoConsultancy.eu

IBAN: NL71 RABO 0105.8009.45
VAT: NL8541.67.018.B01
CoC: 61 01 67 80

Curriculum Vitae: Hans Jonker

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

Experience	17 years: Setting up Quality Management Systems (ISO-13485 / FDA / CMMi) 7 years: Lead Auditing ISO-13485 8 years: Running own business 2 years: Quality Assurance Officer 1 year: People Manager (HRM) 15 year: Software Development (Developer, Tester Manager, Project Manager) (31 years total: Product Development)
QMS	Realized with 3 organizations a very successful ISO-13485 certification and for 1 organization a very successful FDA-Mock-Inspection. Brought 3 organizations to the CMM(i) level 2, which now operate according to that Quality System and still continuously improve !!
Auditing	As ISO-13485 lead auditor performed about 82 audits As QA-Officer completed 2 years of auditing in development projects. As Process Improvement Coordinator / QMS-Manager trained and guided a lot of QA-Officers to structure their auditing process. Performed 5 assessments on CMM(i) level 2/3.
CAPA	As part of setting-up QMS, setting-up CAPA-systems, incl. CAPA-Overview, CAPA-Form and CAPA-metrics. As Process Improvement Coordinator guided teams in the CAPA-process. Supported a huge CAPA-Legacy-Review as result of an FDA-Warning-letter, also as a CAPA-Teamlead. Having followed a huge and complex corporate CAPA-system. Being CAPA-Process Owner and CAPA-Manager.
Project Management	As a Project Manager organized 2 very successful projects. As a Process Improvement Coordinator guided a lot of Project Managers to structure their project management process.
International Experience	Worked 4 years in Germany, 3 years in Italy and 0.5 year in Switzerland. Assessments done in Taiwan, Singapore and U.S.A. Audits performed in Germany (in German)
Courses	Medical Device (ISO-13485, Risk, Vigilance, CAPA, CE-marking) FDA-AAMI: Design Control, Quality System Requirements, Compendium) Lead Auditing at Notified Body Technical (Software, User Interfaces, Testing, …) Process Improvement Change Management Soft Skills SCRUM (Master) / Prince 2
Soft Skills	Communication Social / Interested in people Optimist Drive / Energy

LATEST 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

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 – Jun 2014 **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 to 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 (Oct 2013) 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 2 full blown FDA-Mock-Inspections (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 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 questionnaire checklist • Classify the CAPA on Remediation Level • Handle the results to the SME's • Carry out the root cause message of this situation: o Medical Device awareness o Working in a strong regulated environment (following 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 all kind 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 • 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 new QA-Officer
- Setting-up some CAPA-systems, 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, 1 Observation, with compliments of the auditor)

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