Curriculum Vitae – Jörgen Sjöholm

About me

I was first introduced to development of medical devices in 1993. I knew nothing about it and had to find everything out the hard way. The regulations were not that elaborated back then, but I still find it an achievement that a colleague and I in less than two days created a quality management system from scratch, which on day three was rewarded with a certificate from SEMCO. Those were the days!

Since then, an increasing part of my work has been in the field of medical devices, and since 2005 or so I have done nothing else. I am originally an engineer and started off with mainly a technical perspective. However, I also like structure and to do things in the proper way, why it came naturally to take interest also for the regulatory aspect of things. So now I have ended up where I feel the most at home, on the borderline between technical development and regulatory affairs/quality assurance. My background makes me understand the situation of the engineers who are supposed to do much of the work to fulfil the regulatory requirements, but I also understand the regulations well enough to argue strong and adequate when the engineers want to take short-cuts.

I have also had a lot of teaching assignments, where my basic philosophy is that the best way to explain a complex issue is to start with a simplified overall framework model onto which the details can be organized. Starting with the details makes it much harder to see the bigger picture, and then the detailed knowledge is quite worthless.

I was born in 1965 in Ystad, almost as far down in the south of Sweden as you can come. Since then I have moved around a bit, with the longest stay in Halmstad from 1988 to 2007 when I returned to the south-east of Skåne where my present location is in Tommarp, Simrishamn. For more personal information, should you be interested, visit www.dalagard.com (only available in Swedish though).

I have been a consultant almost all my career, coming in contact with a lot of different clients and products. I am still a consultant, but since mid-2011 I act out of my own company, Akademi Arnwulf AB, instead of being employed by a larger consultancy firm.

My formal educational title would be BSc in Innovation Engineering, but given my work experience there should be an amendment like "specialising in QA/RA-issues regarding medical devices" or similar in order for that title to be adequate today.

My main asset is a logical and analytical mind, giving the capability to create a well-structured view of a complex issue. Another asset is my writing skills, where I think I can create quite decent texts in Swedish as well as in English. To me "writing is thinking" and I cannot really separate the two.

One drawback of this analytical asset might be that I prefer things to mature in my mind until I can visualize the overall picture, which sometimes makes it hard for me to present immediate solutions. Fortunately, since I left the military I am hardly ever in situations which require this type of instant decisiveness and it is rarely any problem in my present occupation.

Education

Exams

- **BSc in Innovation Engineering**,
  Halmstad University (1991)
- **Mechanical Engineering** ("gymnasieingenjör" – "upper secondary school"),
  Pauliskolan Malmö (1985)

Additional training/courses

- Auditor for Medical Devices: Key2Compliance (6 days 2013)
- Medical Device Usability "Usability Engineering"; MedicoIndustrien (2 days 2013)
- Risk Management for Medical Devices; SIS (2 days, 2012)
- IEC/EN 60601-1 3rd edition and ISO14971; Intertek (2011)
- Quality System Regulation and industry practice; AAMI (2009)
- CE-marking of medical devices; IBC Euroforum (2007)
- 21 CFR 820, QSR, GMP; Preventia (2006)
- MDD, MDD draft 2005, ISO14971; Preventia (2006)
- Sterilization; Innovation Team (2006)
- Regulatory demands on development of medical devices; Innovation Team (2006)
- Management rhetoric; TEK (2001)
- MS-Project software; TEK (2000)
- Customer Service; Vox Nova (1999)
- Project Management; Wenell (1998)
- Business Negotiation; Vox Nova (1997)
- MHS ROK ("Captains Course"); FJS/SSN (1996)
- Sports Psychology; Halmstad University (1994)
- ROK ("Reserve Officers Course"); FJS/SSN (1986/87)
- Military Service; FJS (Swedish Airborne Special Forces) (1985/86)

General qualifications

Computer qualifications

- Proficient in MS Office, MS Project, MS Visio
- Some knowledge of SolidWorks, FrameMaker and Adobe Creative Suite

Language qualifications

- Swedish
- English
- understanding of Danish

Other qualifications, including earlier employments

- Co-founded the company *Innovation Team AB* in 1991, remained partner until 2008 and employee until 2011. Presently around 50 or so employees but has changed name to *Etteplan Halmstad* after being acquired by the *Etteplan Group*.
- Co-founder of several innovation based start-up companies.
- Several employment periods as an officer/instructor in the Swedish Armed Forces.
- Martial arts instructor since 1983 in jujutsu, later also in aikido and iaido.

Professional experience

This is a selection of assignments carried out by me, many of them performed as an employee of the consultancy firm Innovation Team AB (published with their approval).

Assignment	Client
QA/RA "Special projects" General QA/RA-support in prioritized areas where Medtentia's ordinary resources are not sufficient, such as compiling document files, process validation, updating procedures etc. Project QA/RA for their ongoing development project for catheter based intervention.	**Medtentia AB** Medtentia is a start-up company developing a new heart implant for mitral valve repair. www.medtentia.com
Clinical Evaluation	**Ursus Medical AB**
Performing and reporting a clinical evaluation compliant with MEDDEV 2.7.1, including literature search, for a biopsy needle.	Ursus manufactures and markets highly specialized medical instruments and equipment for diagnosis and treatment of cancer. www.ursusmedical.com
QA/RA Manager Appointed Quality & Regulatory Manager in the client's organization. Maintenance of Quality Management System, current QA/RA support etc.	**Carponovum AB** Carponovum is a start-up company developing new instruments for cancer surgery in colon and rectum. www.carponovum.com
Clinical Evaluation Performing and reporting a clinical evaluation compliant with MEDDEV 2.7.1, including literature search, for dental implant abutments and anchoring components.	**Heraeus Kulzer GmbH** Heraeus is an international group, among others supplying components for dental implants.
Development of Design Control System Development of a Quality Management System for Design Control in a specific DELTA department transferring its focus from research and general D&D to development of medical devices.	**DELTA A/S** DELTA is a diversified company including test house services, ASIC development etc. www.delta.dk
Quality Management System development and support Development and implementation of an ISO13485/QSR compliant quality management system. Advisory in regulatory and structural issues. Appointed QA/RA and D&D Manager in the client's organization.	**IctalCare A/S** Ictal is a start-up company providing intelligent solutions facilitating the life of people with epilepsy. www.ictalcare.com
510(k) application support Compiling the supporting documentation for a 510(k) application regarding a new product version of one of the client's hygiene lift chairs.	**Arjo Huntleigh AB** Arjo is a multinational company providing among others bathing/showering and lift equipment for elderly and disabled persons. www.arjo.com
Investigation/assessment of potential non-conformities The client had indications of improper design/manufacturing in one of their products, and wanted an independent investigation of the issue, analysing causes-effects, assessing the need for corrective actions and recommending such actions as necessary.	**Arjo Huntleigh AB** See above.
Implementation of ISO9001 Advisor/coach in the process of implementing ISO9001 in several departments.	**Getinge Infection Control AB** Getinge is a multinational company providing disinfectant equipment etc. www.getinge.com

Generic final release testing Expansion of previous project (see below) to include the complete product range into a coherent work/document structure.	**Arjo Huntleigh AB** See above.
Regulatory Affairs medical devices Internal advisor at Innovation Team, also performing internal training sessions on regulatory issues.	**Innovation Team AB** Innovation Team was a consultancy firm and my former employer.
Implant tool Concept development and feasibility testing of tool for implanting the Medtentia Annuloplasty Ring.	**Medtentia AB** See above
Customer and service documentation Revision of supportive documentation (parts lists etc) in connection to release of new product.	**Getinge Sterilization AB** Getinge Sterilization is the division of Getinge manufacturing the autoclaves.
Final release testing Project manager regarding final release production testing of a bath tub for elderly/disabled people. Project management, test selection, test method descriptions, spec of test station equipment, test instructions and records, calibration plan/instructions including calculations and rationale.	**Arjo Huntleigh AB** See above
Annuloplasty ring Project coordinator, technical investigations, risk management, design verification, documentation etc in the development of a heart implant, a class III medical device.	**Medtentia AB** See above
Foot Wound healing Technical Project Manager in an EU-funded R&D project of a medical orthopaedic device class I.	**Camp Scandinavia AB** Developer and supplier of orthopaedic equipment.
Lecturer Responsible for a number of courses in project management and innovation engineering at University of Halmstad on the following educational programs: • Innovation engineering • Biomechanics • Mechatronics • Pedagogic software development	**Halmstad University** www.hh.se
Comfort Conference Digital hearing aid for persons with impaired hearing. Documentation, labelling, IFU.	**Comfort Audio AB** Comfort Audio as a start-up company was co-founded by Innovation Team, and launched the first digital hearing aid ever. The company has grown significantly and is still moving forward 20+ years later.
Meniett™ Development of electromechanical medical device, class IIb. Mechanical engineering and regulatory work (QMS, risk analysis, labelling etc).	**Pascal Medical AB** Pascal Medical was a start-up company was co-founded by Innovation Team, which was later sold to Medtronic. Developed a method and device for treatment of the inner ear disease "Meniere's syndrome".