Curriculum Vitae

Per-Gunnar Viklund
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Education:

Chalmers University of Technology, 1980

- **Master of Science, Electrical Engineering**

Work Experiences:

Artimplant AB 2008-ongoing

- **Quality & Regulatory Manager**

At Artimplant I have implemented major changes to assure that the company is prepared for external audits, including FDA audit, and to simplify the processes. The quality management system is restructured into clear processes. This has resulted in, among others, improved suppliers quality, that the product development is clear and well accepted by the product managers, and that the internal audits are performed smoothly as a good tool for improvements. The results are furthermore clearly seen in the audits performed by Lloyds. In the regulatory field we have new class III products that are CE-marked and old ones that are reevaluated by the notified body without any remarks.

Novosense AB 2007-2008

- **Quality & Regulatory Manager**

Novosense was a new medical device company that would develop wireless ECG. Unfortunately the company never got the necessary funding. My tasks during this period was to support the Managing Director in the funding process, in preparation of design input with requirement specification and planning, and structure for the quality management system.

Ultrazonix DNT AB, 2002-2007

- **Quality & Regulatory Manager, Logistics Manager, Development Manager**

At Ultrazonix I was employed as Quality and Regulatory Manager which included the responsibility for clinical investigations. I build up the entire quality management system and developed a regulatory strategy that gave us CE-mark and a 510(k) approval.

To avoid the risk of shortage of products for testing and trials I also got responsibility for the logistics department. I assured that we had reliable suppliers and necessary order flexibility to get products in time. I engaged and contracted suppliers for manufacturing of the Control Unit in Sweden and the Probe in a clean room facility Lithuania.

To minimize delays in the product development I dropped the logistics and accepted to take responsibility for the development. The project included development of high frequency electronics, advanced control and safety software, and mechanics including piezoelectric crystal development.

In total at Ultrazonix I had staff liability for thirteen employees and managed about twenty consultants. To be able to encourage the staff and see them develop was my most valuable experience from Ultrazonix.

Viklund & Co Konsult AB, 1996-2009

- **Quality & Regulatory Consultant**

Consultancy was mainly marketed by **Preventia** with the owner of Preventia and me as the leading consultants.

As a quality consultant I worked with many different lines of business including anything from pillow manufacturer to architects, but mainly it was medical device manufacturers. The work comprised quality management systems, CE-marking, product registration world wide, quality problems in development, manufacturing or at suppliers facilities, support to the managerial, quality manager or managing director. In some companies I was acting quality manager.

I held many courses within, for instance, medical device directive, quality management systems, 510(k), statistics, risk analysis and other quality tools. The course I held most, for totally over 1000 persons, was the US FDA's Quality System Regulation (QSR). Besides I made a translation of the QSR into Swedish which still is sold by Preventia with a total sale of about 5000 copies.

Working as a consultant was very fruitful for me since I could learn a lot from many companies and it has given me a big network with colleagues. Many assignments where short but I also had a number of recurring customers. The last year as a full time consultant I had assignments for all the companies I worked for the first year as a consultant. During this period, apart from knowledge in quality, requirements, customer satisfaction, and development of organizations, I also learned a lot about business enterprising, book keeping, and marketing e.t.c.

In cooperation with a former managing director of DGM, the Danish notified body for medical devices, and a customer of mine, I started **Medical Devices Services Scandinavia AB** which acted an authorized representative for non-European medical device manufacturers, as required by the medical device directive.

Jostra AB, 1994-1996

- **Quality Manager**

At Jostra I had an appointment for two years to implement the medical device directive. The task was to develop a quality management system that fulfilled the requirements from the directive and FDA's good manufacturing practice. As well I worked with the suppliers to improve their quality and the quality in the manufacturing. At Jostra I had staff liability for one person.

Tetra Pak, 1991-1994

- **Quality Specialist**

As quality specialist I supported the companies within Tetra Pak as a company internal consultant, for instance by performing project audits. I performed tasks for the corporate management, like managing an international team that developed global quality management system guidelines for the Tetra Pak Processing System division. This division developed and manufactured the machines for food packaging. I also had the opportunity to follow up the guidelines in different Tetra Pak companies within Europe.

Alfa-Laval Automation AB, 1984-1991

- **Quality Engineer**

At Alfa-Laval I started to work with test preparations and programming of test equipment. I also improved the production by analyzing and reducing our biggest production problems, ESD.

Gradually I worked more with new products and prototype testing. We tested that the products could withstand different environmental stresses. I built up the laboratory for EMC tests. I took initiative and build up our system for software testing as a part of the prototype tests. At this time software test was a new area for us so we had to develop the test methods and I involved a group from different companies in Sweden and Norway for this purpose. I was responsible for testing and approving new products and I was project manager for test project with up to twelve persons. The development projects varied from very small up to hundreds of man years that should be verified and reviewed.

On request from the development managements I participated in implementation of the ISO 9001 quality system standard in the development division.

Gambro AB, 1981-1984

- **Quality Engineer**

My responsibility at Gambro was to develop test equipment for the circuit board testing group and to support the group in the best manner to avoid production problems. It was both very old equipment that should be maintained, and new automated equipment that should be adapted and programmed. I took the initiative and worked to integrate the test systems with the electronic CAD system to reduce time for programming and to improve the productivity.

Livsmedelsinstitutet, 1980-1981

- **Design Engineer**

After finalizing my master's thesis, control of semi-automatic potatoes boiler for large-scale catering establishment, at Livsmedelsinstitutet I had a project employment for some months to develop control system for food preparation equipments.

CURRICULUM VITAE
Summary

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Education / courses (examples)

Master of science
Electrical Engineering
Chalmers, 1980

- UGL, Development Group and Leaders
- Intercultural Management
- Business Economics
- Project Management
- Positive Negotiations

- ISO9000
- Lead Auditor
- Swedish Quality Award
- Medical Device Directive
- EMC Directive
- Low Voltage Directive
- Medical Device Global harmonisation
- Medical Device Labelling

- Reliability
- Risk Analysis
- Test preparations
- SW test
- Configuration Management
- C-programming
- Object programming
- Statistics

Employments

Livsmedelsinstitutet 1980-1981
Design Engineer
- Control system development

Gambro 1981-1984
Quality Engineer
- Electronics test development

Alfa-Laval Automation 1984-1991
Quality Engineer
- Manufacturing & Design Quality Assurance
- ISO 9000 implementation

Tetra Pak 1991-1994
Quality Specialist
- Global Quality System Guidelines
- Support

Jostra 1994-1996
Quality Manager
- Supplier & Internal Quality
- Medical Device Directive and GMP implementation

Viklund & Co Konsult AB
- Quality Consultant 1996 – 2009

Ultrazonix DNT AB 2002 - 2007
Quality & Regulatory Director
- Management of Regulatory, Quality, Design & Logistics
- Quality Management System development & implementation
- CE mark and 510(k)

Novosense AB 2007 – 2008
Quality & Regulatory Manager

Artimplant AB 2008 – ongoing
Quality & Regulatory Manager

Co-operations / Boards (examples)

SIS-STG
- Quality Standards development (for instance ISO 9000-series)

SIS-SEK
- Electrical Medical Device standards development

Swedish Association for Quality (SFK), region south
Member of the board

SFK Utveckling AB
Chairman of the board

Medical Devices Services Scandinavia AB
Chairman of the board

Preventia AB
Consulting

BRF Trådbussen
Chairman of the board

Consulting (Examples)

Business

Medical Device Industry

Pharmaceutical Industry

Electronic/ Electro Mechanical/ Engineering Industry

Software Industry

Textile Industry
Architects

Notified Body

Public Service

Assignments performed in

Denmark
England
Germany
Portugal
Sweden

Tasks

Managerial
- Quality Manager
- "Quality inspirer"

Regulatory
- CE-mark
  - Medical Devices
  - Machinery
  - EMC
  - Low voltage
- Medical Device registration world wide
- PMA, 510(k), IDE (USA)

Quality System
- ISO 9001
- ISO13485
- QSR/GMP (USA)

Quality Assurance
- Development/ Project quality
- SW quality
- Validation
- Manufacturing
- Risk management
- Statistical techniques
- Improvements

Courses in the above mentioned areas

2011-11-27