

From: Göran Frenning [<mailto:frenning@telia.com>]
Sent: Thursday, January 07, 2010 1:54 PM
To: Personal Assistant
Subject: Quality Assurance and Regulatory Affairs in South Africa

Dear SAMED !

My name is Göran Frenning. I am living in Sweden and I am a Swedish citizen. I have more than 12 years experience in quality assurance and regulatory affairs aspects of medical device manufacturing from an European/CE (ISO 13485) and FDA perspective.

The question I have, is if you think my experience would be of any interest to any South African medical device manufacturer and/or regulatory body and if so, if you please could suggest how to get in contact with and approach such companies and/or regulatory bodies. I enclose my CV for your information.

Myself and my family have recently visited South Africa and we have all agreed that it would be a interesting and developing experience for us to live and work in South Africa.

Kind Regards
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Curriculum Vitae

1 Personal Data

Göran Frenning
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2 Family

Married with Hima who runs her own business as well as working as Vice President, Movex User Association. Movex is an integrated enterprise management system for business operations in manufacturing and distribution industries (used by e.g. IKEA).

Two kids, Kima born 91 and Sara born 94.

We all live in a house in the countryside, just outside Malmö.

3 Hobbies

Horseback riding (the whole family is doing that) and generally trying to stay fit through running and boxing training.

4 Education

4.1 Basic Education

08.1981 - 08.1985	Lund Institute of Technology, M. Sc. in Mech. Engineering	Sweden
08.1975 - 06.1979	Österportskolan, High School, Ystad	Sweden

4.2 Quality and environmental education (main ones)

01.2008 – 01.2008	2 d CAPA and Recall, training course	MD&M/USA
10.2006 – 10.2006	3 d Statistical Process Analysis Sandholm/Sweden	
09.2005 – 09.2005	1 d Statistics for Validation & Capability calc.	Preventia/Sweden
02.2001 – 02.2001	1 d SW validation & Part 11	

	Lundén&Elow/Sweden	
10.2000 – 10.2000	5 d GMP/QS Requirements and Industry practice AAMI&FDA/USA	
03.2000 – 03.2000	2 d Process development	CANEA/Sweden
10.1998 - 10.1998	2 d Medical Device Regulations in EEC and US	Preventia/Sweden
03.1998 – 03.1998	5 d Environmental Lead Auditor accord. to EARA	CANEA/Sweden
03.1987 – 04.1988	8 d Quality Lead Auditor according to ISO 9001 Education/Sweden	ABB

4.3 *Degrees*

1998 Environmental Lead Auditor according to EARA (ISO 14001, CANEA/Sweden)
 1988 Quality Lead Auditor according to ISO 9001 (ABB Education/Sweden)
 1985 Master of Science in Mechanical Engineering, Lund Institute of Technology, Design
 and Production Development

5 Awards

1980 “Best Soldier during Military Service”, Swedish Army

6 Languages

Swedish, English and Danish fluently (Danish, not in writing)
 Other Scandinavian languages, good
 German, fair
 Spanish, basic
 Farsi (Persian), basic

7 Military Service

Deputy Company Commander as Second Lieutenant in Anti Aircraft Regiment
 Swedish Army, Malmö & Göteborg/Sweden
 June 1979 to August 1980

8 Work experience (in summary)

- *Arjo Hospital Equipment AB/Sweden, Director of QA & RA* 01.2007 -
presently
- *GN ReSound A/S/Denmark, Quality System Development Manager* 06.2003 –
12.2006
- *Gambro Renal Products Monitor Division/Sweden, QS Manager* 10.98 –
06.2003
- *Polykemi AB, Quality and Environmental Manager, Ystad, Sweden* 08 97 - 10. 98
- *Management Consultant, Promentor Management AB, Malmö, Sweden* 07. 96 – 08.97
- *Manager Fuel Technology at Barsebäck Nuclear Power Plant, Sweden* 12.86 – 06.96
- *Software Engineer, Satt Control AB, Malmö Sweden* 08.85 – 12.86

9 Business, Work experience

9.1 Arjo Hospital Equipment AB/Sweden 01.2007 – presently

Arjo Hospital Equipment AB (AHE) in Eslöv, Sweden is part of the Getinge Group, which has about 7500 employees, and an annual revenue of approximately 1,5 billion EUR. The Getinge Group is divided into three different business areas, Medical Systems, Infection Control and Extended Care. AHE is part of the Extended Care business area.

AHE develop and manufacture Hygiene and Patient Handling Systems at the site in Eslöv which employs around 200 people. The annual sale from the site is approximately 60 million EUR.

9.1.1 Director of Quality Assurance and Regulatory Affairs, AHE 01.2007 – presently

The Quality Assurance and Regulatory Affairs (QA/RA) department consists of 13 employees, where I am the Manager. The department is responsible for developing and maintaining the Quality and Environmental Management System as well as handling incident reporting, incoming inspection and supplier evaluation. The management systems are certified according to ISO 9001:2000, ISO 14001 and ISO 13485:2003 as well as designed to fulfill applicable US/FDA quality regulations, (e.g. cGMP, QSR CFR Part 820, etc).

The department is directly supporting the R&D department in quality related matters, e.g. in development projects and process development matters. The manufacturing quality engineer is reporting to me via a dotted line.

The Supplier Quality Engineer is directly reporting to me. He is responsible for supporting the Purchasing department in supplier evaluation matters as well as managing the receiving inspection department and sorting out supplier related quality issues at site and at the supplier.

It is the responsibility of the department to capture, monitor and compile quality data from many different sources internally as well as externally. Based on this data, the QA/RA department initiates different corrective and preventive actions within the organization as well as improvements on the products. This role includes reporting to and communicating with different competent authorities in EU as well as in the USA (FDA) and Canada. The department also handles product registration in EU, Canada and in the USA.

All Internal Audits are managed, monitored and controlled by the QA/RA department through a number of internal auditors within the organization.

9.1.2 Results

Under my supervision a new, more product quality focused quality initiative has been started. This involves creating closer and better communication paths within the organization, especially between Purchasing, R&D and the Manufacturing department. Better and stronger feedback loops has been created.

Also, the view that the individual employee and operator actually is the expert on what he or she is doing has been communicated in order to empower individuals to more often take the initiative to implement quality enhancing actions AND communicate this to the rest of the organization.

This new initiative has so far resulted in a three times lower complaint rate on a problem stricken product, which performance on the market we focused on improving in the short term. We however expect much more results and pay-off in the future, based on this initiative.

Process and SW-validation activities has also been revitalized and initiated by the QA/RA department but will further on be integrated in the normal day-to-day activity in the respective organization.

AHE sells products on the US market and FDA has since 2008 performed a number of audits within the Extended Care business area. An audit at our US sales subsidiary 2008, highly involved the QA/RA department where we during the audit supported the US organization with detailed information regarding product data, incident investigation reports and corrective and preventive actions initiated in manufacturing as well as recall activities in the field, etc.

9.2 GN ReSound A/S/Denmark 12.2006

06.2003 –

GN ReSound Group, a subsidiary of GN Great Nordic A/S, is the one of the leading international manufacturer of advanced hearing instrument technology. The company offers a full range of hearing instruments under the GN ReSound and Beltone brands, including software-based digital instruments and digitally programmable and traditional products in all sizes and models.

GN ReSound Group ranks among the absolute leaders in its industry, with subsidiaries in 22 countries and distributors in 60 countries. GN ReSound is headquartered in Copenhagen, Denmark, and presently employs approx. 4,000 people and has a turnover of approximately 4,5 Billion SEK.

9.2.1 Manager Quality System Development, Corporate Quality 12.2006

06.2003 –

Corporate Quality is located at the Corporate Headquarter in Copenhagen. The group is responsible for the overall Global Quality activities within the GN ReSound Group. Manager Corporate Quality Development reports to the Corporate Quality Manager who in turn reports directly to the CEO of GN ReSound A/S. As Manager of Quality System Development it was my responsibility to develop and maintain the Corporate Quality System as well as coordinate quality activities at the other sites within the group. All operations are subjected to European requirements as well as FDA requirements The other sites consists of 4 major component and device manufacturing sites (in Denmark, Ireland, USA and China) as well as custom manufacturing sites in 22 countries.

The main objectives were;

- 1.) to make sure that all these sites had an appropriate certified Quality System and that the different quality activities and initiatives were coordinated and aligned and

- 2.) to improve Product Quality by focusing on the development and manufacturing processes and improve awareness and performance within these areas.

Internal Audits was also performed by the department at Corporate level as well local site level. The audits are performed according to applicable quality standards as well as established procedures.

9.2.2 Results

The first task for the Quality System Development department was to create, implement and certify a Corporate Quality System as a top level system. We started virtually from scratch and during 4 month, August –November 2003, we developed the system, implemented and trained necessary personnel. In mid November we achieved certification by DQS (Deutsche Gesellschaft zur Zertifizierung von Managementsystemen) according to ISO 13485:2003 (ISO 9001:2000 for Medical Device). The certificate gives us the right to CE-mark our products as Medical Devices.

Next task was to coordinate, guide and assist the other sites within the group in developing and updating their Quality Systems. We also initiated a transfer of all sites to DQS Certification Services, which gave the group economical as well as efficiency benefits.

The third and major focus area was to improve the Quality of our Products. Within Corporate Quality we identified two major improvement areas in order to achieve this; the Design and Development departments as well as the different manufacturing facilities. Not least are the coordination, communication and interaction between these two areas crucial. Given the fact that the company had development departments in Denmark, in the US and in China and manufacturing facilities in Denmark, Ireland, the US and China, efficient and clear communication is crucial.

Our goal was to create structured processes within these areas, without creating too much bureaucratize. Together with the design and development departments we created more structured development processes, which e.g. made the development department's communication with the Marketing department more efficient. We have also implemented structured processes for Manufacturing Verification & Validation by which the interaction and coordination with the different design departments were made more efficient.

The result was a substantial increase of cross-functional and cross-site communication. The communication was facilitated by the fact that all departments was given one common process description/picture to relate to. A more concrete result is that the latest product launches actually met and somewhat exceeded the planned launch date for the first time in recent years.

9.3 Gambro Renal Products Monitor Division/Sweden & Italy
06.2003

10.98 –

Gambro Group AB is a global healthcare company with leading positions in Renal Care for patients with renal diseases. Gambro Group has a turnover of 22.2 Billion SEK, noted at the Swedish stock market and has 19000 employees. Gambro consists of three business Areas, Gambro Renal Products, (GRP), Gambro Healthcare (GHC) and Blood component Technology (BCT). GRP provides the market mainly with monitors, bloodlines, filters and solutions for Hemodialysis, Peritoneal dialysis and Water treatment. Gambro Healthcare owns and runs over 600 dialysis clinics worldwide providing treatments to patients and Gambro Blood Component Technology provides the market with blood component technology and products.

GRP is divided besides of the market organization in operations containing four divisions: Monitors, Bloodlines, Filters and Solutions with all in all 22 plants spread around the world. Monitor division consists of 3 plants, one in Lund, one in Malmö and one outside Bologna/Italy. Manufacturing was transferred to Europe in 2000, from a previously fourth plant in Denver/USA. Turnover of Monitor division is 1.2 Billion SEK with 450 employees manufacturing about 13000 monitors/year in all three plants in total in Lund Malmö and Mirandola/Italy. 98% of the monitors are shipped outside Sweden all over the world with main markets in Europe, US, Japan, Korea and Taiwan

9.3.1 Manager Quality System Monitor Division in Lund
06.2003

10.98 –

Monitor Division in Lund is the biggest of the three plants representing 650 MSEK turnover and 310 employees containing Manufacturing/Engineering, Development, Quality, Purchasing and International Technical Services of all monitors.

Manager Quality System reports to the Quality and Regulatory Manager, MD Lund (Manager of Quality Department) who in turn reports to Manager of Monitor Division. The Quality System Department, today consisting of 2 persons, has the responsibility to develop and maintain the Quality Management System (QMS). The QMS is built up according to ISO 13485 and CGMP 21 CFR Part 820 Quality System Regulations and are audited regularly by notified body (BSI), FDA and several other authorities from PR of China to Brasilia. The QMS is an electronic system with a fully developed and implemented electronic document handling system.

The unit also is responsible for all internal audits as well as organizing and hosting all external audits of the Monitor Division in Lund. The annual internal audit program consists of a full audit schedule for all departments of the Lund site including management, development, manufacturing and servicing. The unit is also responsible for the regular training in Quality System requirements, which is performed semi-monthly for all newly employed personnel and annually/semiannually for the whole organization.

The Quality System department also runs different process development projects within the organization. The unit also has the responsibility of Software-validation activities as well as different Part 11 activities/projects.

One such process development project which we have started, is the implementation of ISO 9000:2000 (ISO 13485:2003). Here the unit has started a benchmark cooperation with Tetra Pak in Lund which have recently been certified according to ISO 9000:2000.

9.3.2 Results

The Quality System department participated in a re-design and re-organization project of the QMS where I acted as project leader. During the project we updated the QMS procedures to comply with CGMP 21 CFR Part 820, US Quality System Regulations. In the same project I was leading the work of develop and implement the fully electronic document handling system, used by the whole organization.

During the re-design project, the development process was totally redesigned complying now with FDA requirements and ISO 13485 as well as ISO 12207.

I also participated in a project on corporate level, developing and implementing Corporate Procedures regarding Purchasing control and Supplier Qualification. The project ran over approx. 1 year and involved people from different Divisions and countries. The result was a Package of Corporate Procedures implemented on the highest level of Corporate QMS and then implemented in Lund and all other manufacturing sites globally.

The unit also has the responsibility to develop and implement internal contracts/agreements between internal units, which interactions need to be regulated. One such agreement was signed between Monitor Division Lund and Global Supply in 2001 regulation medical tracking etc and another is under development between MD Lund and MTC (Microbiology, Toxicology and Clinical Affairs).

A software validation procedure package has also been developed and implemented by the unit according to FDA guidelines and is now used as Gambro standard procedure on a global level. This was done as part of our update of the QMS to comply with CAMDCAS and ISO-13485:1996 requirements.

Successfully we have also run a project to develop and implement the Design Transfer Process, the transfer of design between Development department and Manufacturing department. In this project I had the responsibility to develop and implementing the written procedures, which meant interaction and discussions with key personnel from development and manufacturing as well as training of the whole organization.

The QMS is now brought to a much higher standard, giving much faster and better control of procedures as well as the day-to-day operations, which starts showing significant positive trends in improvement of the product quality and compliance to the standards.

9.4 *Polykemi AB in Ystad Sweden, Quality and Environmental Manager 08 97 - 10. 98*

Polykemi has approx. 150 employees and about 500 MSEK turnover, located in Ystad in southern Sweden and is the leading manufacturer in northern Europe of custom made plastic raw material. Main products are plastic raw material, which are developed and manufactured according to customer specification.

9.5 The products are sold mainly to the automotive industry in Sweden as well as exported to Germany, France, Czech Republic, Brazil and Iran.

9.4.1 *Results*

My primary tasks at Polykemi was to maintain and develop the existing Quality System, certified according to ISO 9001, and to develop and implement a new Environmental Management System (EMS) according to ISO 14001.

During my employment at Polykemi, I successfully led the work of implementing the Environmental Management System, which resulted in an ISO 14001 certificate 1998. I also organized and hosted three semi-annual external quality audits conducted by SIS. We also implemented a simpler and better-running system for corrective and preventive action, which led to shorter implementation time for corrective actions resulting in lower rejection rate in manufacturing.

9.6 *Management Consultant, Promentor Management AB, Malmö Sweden 07. 96 – 08.97*

Promentor Management A/S is a Danish consultant company providing management consultant services in the field of Quality and Environmental Management. In 1995/1996 Promentor started up a Swedish affiliate in Malmö and started to build the business around their previous Swedish customer. I was employed to provide management-training services in the fields of Quality and Environmental Management.

9.5.1 *Results*

Promentor was providing services to customers as SAS, Länsförsäkringar, Sydkraft and Swedish Postal Services. We developed an Environmental Management training concept, which we marketed and provided in Sweden as well as Denmark. In 1997 I was offered the position at Polykemi, which I accepted and therefore left the company.

9.7 *Manager Fuel Technology at Barsebäck Nuclear Power Plant, Sweden 12.86 – 06.96*

Barsebäck Nuclear Power Plant is a 1200 MW Boiling Water Reactor plant, at the time owned by Sydkraft, the second largest power Utility in Sweden. As Manager of Fuel Technology I had the responsibility of the procurement, manufacturing monitoring, operation and performance of the nuclear fuel. The Fuel Technology department consisted of 8-10 highly educated persons, mostly with a M. Sc. Degree.

The department managed different projects e. g. procurement of fuel manufacturing services (worth 100 MSEK/annually), fuel manufacturing follow-up activities of the fuel suppliers (ABB Atom and Siemens), on-line fuel operation surveillance, procurement and project leading of fuel performance investigations and close contacts with national (SKi) as well as international (IAEA) authorities.

9.6.1 *Project Leader, Environmental Radiation Monitoring system 02.93 – 01.94*

During 1993, I was appointed project leader of an Environmental Radiation Monitoring System project. The objective of the project was to design, procure and implement a Radiation Monitoring system covering the outside perimeter (including the sea) of the power plant. The purpose of the system was to provide information of any radiation release to the environmental in the event of an accident. The budget of the project was approximately 20 MSEK.

I managed the project during the design and procurement phase and handed over it to another project leader for the implementation and returned myself to the then re-organized Fuel Technology department. The system is today successfully in operation.

9.6.2 *Results*

During my employment at the Barsebäck plant, the Fuel Technology department was developed from a small unit, to a unit which was much more integrated in the daily operation with highly skilled personnel performing different qualified tasks. By implementing an advanced fuel operation and planning system, the annual fuel cost could be reduced by approx. 15 %. The systematic work of the whole department in all the different areas, highly contributed to a operation with a record low fuel failure rate which in turn leads to lower maintenance costs for the plant.

9.8 *Software Engineer, Satt Control AB (acquired by ABB Automation) 08.85 – 12.86*

Satt Control developed and manufactured systems (hardware as well as software) for Automated Material and Product Handling Systems. Worked with software development on a system for simulation of layouts of systems for automated guided vehicles as part of the Automated MPS-system.

During my employment, I worked 2 months in England at Satt Control's affiliate in Aldershot outside London. I did customization development of the software in order to help a major customer.

9.9 *Part time work during University Studies 08.85 – 08.85*

During my studies at the Institute of Technology in Lund, I worked part time as teacher at the High School in Ystad.

During summer breaks, I also worked as Prison Warder at the local prison in Ystad. I grew up in Ystad and lived there during study breaks.