ANDERS SKOGLUND

SENIOR VICE PRESIDENT
REGULATORY AFFAIRS & QUAITY

"assure predictable and sustainable market access"

Core Compentencies

- Medical Device Regulations
- Quality System Regulations
- Adverse Event Reporting
- Export Control Regulations
- Radiation Safety & Security
- Medical Device Standards

Languages

Swedish ●●●●●
English ●●●●●
German ●●○○○
Japanese ●○○○○

Executive Summary

Senior regulatory affairs & quality assurance professional in the medical device industry. Significant experience with international regulatory, compliance, and quality systems requirements. Experienced leader for both FDA and Notified Body inspections. Demonstrated skills in obtaining regulatory marketing clearance, attaining regulatory compliance, developing quality systems, and working with cross-functional teams. A highly credible and respected leader and collaborator with strengths in problem solving, influencing, evaluating, planning and communicating.

Highlights

Success collaborating with multifunctional teams comprised of Engineering, Marketing, Quality Assurance, Regulatory Affairs and Manufacturing to register new products globally.

Understanding of the intent and objectives behind regulations and knowledge of how to operate within that framework.

Progressive responsibilities in Regulatory Affairs, Quality Assurance, departmental management, worldwide corporate leadership, and financial planning spanning several companies.

Recognized for ideas and team leadership, innovation, consensus building and meeting regulatory requirements.

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Experiences

2019 - Now — **Senior Vice President Regulatory Affairs & Quality**
Elekta Solutions AB, Stockholm

- Leading the Regulatory Affairs & Quality function within the Elekta Group. The function consists of 100 persons with 14 direct reports.
- Leading the Regulatory Affairs & Quality Management Team.
- Budget responsibility for all Regulatory Affairs & Quality budgets, including direct submission costs, quality system certifications, outsourcing costs and standards compliance testing.
- Responsible for the implementation of the new European MDR regulation and Notified Body consolidation.
- Responsible for transformation of the Quality and Regulatory function.

2016 - 2019 — **Vice President Regulatory Affairs**
Elekta Instrument AB, Stockholm

- Leading the Regulatory Affairs & Quality function within the Elekta Group. The function consists of 100 persons with 14 direct reports.
- Leading the Regulatory Affairs & Quality Management Team.
- Budget responsibility for all Regulatory Affairs & Quality budgets, including direct submission costs, quality system certifications, outsourcing costs and standards compliance testing.
- Responsible for the implementation of the new European MDR regulation and Notified Body consolidation.
- Responsible for transformation of the Quality and Regulatory function.

2010 - 2016 — **Vice President Blobal Regulatory Affairs**
Elekta Instrument AB, Stockholm

- Leading the Global Regulatory Affairs support function within the Elekta Group.
- Participate in the Global Quality and Regulatory management team.
- Responsible for the Global Export Control function.
- Responsible for the Global Radiation Safety function.
- Responsible for the development of the Global Regulatory Affairs processes, including Regulatory Submission process, Regulatory Communication process, Regulatory Intelligence process, Regulatory Advertisement and Promotion Labeling Review process, Export Control Process and Radiation Safety Process.
- Responsible for implementation of STED (Standard Technical Documentation) as internal format for Regulatory Submission Files.

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Experiences

2008 - 2010 — **Director Regulatory Affairs**
Elekta Instrument AB, Neurosience, Stockholm

- Leading the Regulatory Affairs department at Elekta Instrument AB (Business Area Neuroscience)
- Responsible for the compliance of the product and services and the overall planning of regulatory submissions for Elekta Instrument AB.
- Responsible for review of labeling, i.e. press releases, instruction for use, web pages etc. to assure compliance to external requirements.
- Participate in the Global Regulatory Affairs Management Group.
- Continued participate in standardization for electrical medical equipment.
- Responsible for the Export Control function.
- Responsible for the development of the Regulatory Intelligence process.

2003 - 2008 — **Regulatory Affairs Engineer**
Elekta Instrument AB, Stockholm

- Responsible for development and maintenance of authority approvals i.e. technical files for CE-marking, 510(k) applications for USA, technical documentation for Canada, China, Japan, Taiwan, Thailand, and rest of world including application for transportation, service, and handling of radioactive materials.
- Participate in development projects to ensure compliance to authority requirements, quality system, and standards.
- Participate in standardization for electrical medical equipment, both nationally and internationally.
- Implement authority requirements, i.e. QSR and ISO 13485, as procedures and instructions both locally within Elekta Instrument AB and globally within the Elekta Group.
- Participate in authority inspections and audits of Elekta Instrument AB.
- Responsible for the authority reporting of complaints.
- Act as regulatory support to the different regional regulatory departments within the Elekta Group with primary focus on Japan.
- Act as regulatory support for the marketing group and product management and development of regulatory submission plans and strategies.
- Responsible for the implementation and maintenance of the Regulatory Affairs Intranet Portal.
- Participate in the development of procedures and templates for the Global Regulatory Affairs function and responsible for the development of the procedures for submissions in Japan and CE-marking and templates for 510(k) submissions and application in Canada.

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Experiences

2002 - 2003 — **Manager Complaint Handling, Test & Production Tech.**
Siemens-Elema AB, Sustaining Engineering, Solna

- Leading the Complaint Handling, Test & Production Technique team with 13 direct reports, 7 complaint handlers, 3 test engineers and 3 production engineers.
- Responsible for the complaint process and authority vigilance reporting.
- The complaint group handles customer complaints, initiates investigations, reports to authorities and starts engineering changes.
- The test group performs verification of changes and investigates devices from complaints.
- The production group transfers finished products from design to production, takes part in process validation and writes instructions for manufacturing.
- Continued participation in standardization for anaesthesia and ventilation i.e. ISO TC 121 and CEN TC 215.

1998 - 2002 — **Regulatory / Senior Regulatory Affairs Engineer**
Siemens-Elema AB, Solna

- Responsible for development and maintenance of authority approvals i.e. technical files for CE-marking, 510(k) applications for USA, technical documentation for Canada and Japan.
- Participate in development projects to ensure compliance to authority requirements, quality system and standards.
- Participate in standardization for anaesthesia and ventilation i.e. ISO TC 121 and CEN TC 215.
- Implement authority requirements, i.e. QSR and ISO 9000, as procedures and instructions.
- Participate in authority inspections and audits of Siemens. Two FDA audits, four SEMKO audits and a number of other audits from different countries authorities and test houses.
- Project manager for quality improvement project, Quality Installed Base, during 2001.

2010 - 2016 — **Project Engineer**
SEMKO AB, Medical and laboratory equipment, Kista

- Testing of medical devices for S-marking, compliance to standards and/or compliance to the medical devices directive (MDD). Testing for countries outside Europe i.e. Canada, Japan and USA. Testing and investigations of laboratory equipment for compliance to standards and/or directives i.e. the low-voltage directive.
- Writing articles and documentation for SEMKOs information service. A part of this service is the newspaper "MedTech-aktuellt" which is published four times per year and contains news about standardization and EU legislation.
- Develop work instructions for testing of medical devices i.e. ECG-monitors, infusion pumps, anaesthesia devices, pulse oximeters and gas monitors.
- Responsible for SEMKOs training courses within medical device technology, IEC and ISO standards and directives.

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Experiences

2002 - 2003

Biomedical engineer, 1988-1993
Region Stockholm Healthcare, S:t Görans Hospital, Stockholm

- Service and maintenance of medical devices from most of the departments in the hospital with a focus on intensive care, heart intensive care, anaesthesia, OR and wards serving OR.§

Education

1997
Supplementary Course
Physiological flow and pressure measurements, 2p
Linköpings University, Linköping

1990
Supplementary Course
Mathematics 3
Komvux, Botkyrka

1989
Supplementary Course
Technology 3, Mathematics 2
Komvux, Södertälje

1987-1988
Upper Secondary School
Medical Engineering
Skytteholmsskolan, Solna

1985-1987
Upper Secondary School
Electronics & telecommunication-Measurement & Control
Västergårdsgymnasiet, Södertälje

1977-1985
Compulsory Basic School School
Rosenborgsskolan, Södertälje

Skills

- Broad experience of regulatory affairs, quality assurance, authority communication and standardization.
- Excellence ability to work in a multi-cultural environment.
- Well organized.
- Result oriented: Ability to achieve the target within given time.
- Excellence communication skills.
- Negotiating skills.
- Conflict resolution.
- Analytical thinking. Data driven management.