Stig Larsson
Principal Advisor Medical Device Compliance

Quality Management and Regulatory Affairs

ID1005

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Competences

- Management / Project Management.
- In-depth knowledge of Quality Management Systems World Wide (ISO 9001 / 13485, CMDCAS, MDSAP, Taiwan, TGA, & 21CFR820).
- Design Control and DHF
- In-depth knowledge of establishing, maintaining and certification of Quality Management Systems.
- More than 25 years of international audit experience within Quality Management Systems according to MDD 93/42/EEC, IVDD 98/79/EEC & MDR
- Quality Management, Risk Management, Usability, Validation, Clinical Evaluation, Biocompatibility Evaluations, Shelf life/ Stability study, Electrical Safety, EMC, Vigilance, FSCA, CAPA, Process Validation, Sterilization & Clean Room.
- QP (Qualified Person).
- Management Representative / CTO & Certified Lead Auditor – ISO13485 & CE marking according to MDD 93/42/EEC.
- Training.

Key results

- QA/RA Manager in an international company manufacturing heart / lung machines and disposables for open heart surgery.
- QA Department manager / project manager in an international company manufacturing electrical- and mechanical equipment for the defence industry.
- QA/Logistic Manager in a company manufacturing mechanical equipment.
- Medical Device Manager for an international accredited certification body.
- As Former CTO & part owner of a Dental Laser equipment company, obtained ISO 13485 certification, CE and CFDA approval.
- Establisher & owner of SEL-Innovation ApS.
- As independent consultant prepared a number of medical device companies for ISO 13485 & CE certification.
- Conducted + 1500 international ISO 13485/ CE audit for several NB & Accredited bodies.

Regulations/Standards/Guidance

Extensive knowledge in:

- Medical Device Directive MDD 93/42/EEC, In Vitro Diagnostic Directive 98/79/EC & MDR
- ISO 13485 / 9001 CMDCAS, Taiwan, TGA etc.
- EU Harmonized/Internationally recognized standards i.e. ISO13485, ISO14971, EN62366, MEDDEV 2.7 / 1, ISO10993 EN60601-X-XX, EN62304, MEDDEV2.12/1.etc.
- Project Management. International System & CE auditing including Technical File review.

Personal Characteristics

Stig has a pragmatic and constructive approach and believes that results are best achieved in a straightforward open minded dialogue between the parties.

Stig spends his spare time with the family in the summer house and on sports (golf, mountain biking and skiing). Stig is also interested in literature and music.

References

MEDICOLOGIC A/S

Principal Advisor – Quality Management & Regulatory Affairs – Management Consulting for Medical Devices and In Vitro Diagnostic.

Consultant
International consultant, supporting companies in building up documentation and preparing them for certification.
Different types of Medical equipment under MDD Class I, Is, Im, IIa, IIb & III.
Subcontractor for LNE / G-MED since 2005. ISO 13485 and CE audits worldwide within MDD all Classes and IVDD
Subcontractor for UNFPA since 2007 –Inspection of manufactures of Latex Condoms for men & women.

Genius Periodental AS
Owner and CTO – Manufacturing of Dental Laser equipment for treatment of periodontal Disease. Class IIb device. ISO & CE marked by GMED.

BVC DK – Accredited Certification body
Medical Device Manager - Responsible for coordinating and auditing Medical Device manufacturers. Training of auditors worldwide. Conducting ISO 13485 audits of manufacturers of active and non-active devices.

EBI-Nancke AS
QA / Logistic manager – Responsible for the QA and logistic function in DK and in Skt. Petersburg Russia. Maintaining of the Management System in general and the evaluation of suppliers etc.

DS/DGM
Lead Auditor – conducting audits and facilitating the process of establishing DGM (Dansk Godkendelse af Medicinsk udstyr).

Nea-Lindberg A/S
QA Department Manager – Manager for a group of engineers supporting the production in quality matters. Project responsible for a test program for electronic / mechanical equipment for the defense industry.

Polystan A/S
QA/RA Manager – Building up and maintaining the Management System according to EN 46001. FDA inspection. Involved in the quality of manufacturing of heart lung machines and disposables for open heart surgery. Responsible for release of ETO sterilized products and maintaining the clean room environment according to class 100.000.

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