QualityVision

Owner and principal Consultant Tom Andersen

Experienced QA person with more than 25 years of experience in life science.
I have experience with medical equipment, pharma and biotech.
For the past 18 years, I have mainly worked with medical devices.
I have extensive knowledge of cGMP and in-depth process understanding in quality management systems in life science [ISO9001, cGMP, ISO 13485, 21 CFR 210, 21 CFR 211, 21 CFR 820].
I have management experience from QA and production.
Keywords: pragmatic, systematic and structured, an empathic organizer.

KEY COMPETENCIES

- Quality Manager and Management Representative
- Certified Lead Auditor (conducted + 80 audits according to ISO 13485 and ISO 9001)
- Project Manager I Validation Manager I Risk Manager

- Design, update and improvement of QMS systems, ensuring compliance with legal requirements.
- Implementing Risk Management in accordance with ISO 14971
- Interaction with competent authorities, notified bodies and customers
- Validation I Qualification I Commissioning
- Supplier Management
- Held of numerous courses and training (more than 1000 hours)
- Leadership and communication in international environments
- Preparation of Gap analyzes (ISO 13485, FDAcfr820, ISO 9001)
- Identification and implementation of corrective and preventive actions as well as continuous improvement
- Implementation of documented change control

SELECTED TECHNOLOGIES & PROCESSES:

- Plastic Processing (IVDR Class I & II Products)
- Metalworking (MDR products Class II)
- Stoma products, Hearing aids, Dental implants, Lab Plasticware, Cell culture products
- Production in clean rooms, sterilization

EDUCATION & EXPERIENCE

Dairy Technician, Examinee Lead Auditor

- QA Manager, QM Representative and Risk Manager

- Completion of numerous company certifications and re-certifications from NB
- Gap analysis for ISO 13485:2016, FDA part 820, ISO 9001
- Author of numerous of Policies & Procedures
- CAPA & Continuous Improvement
- Project and Change Management
- Supplier Quality Management
- Auditing

INTERNATIONAL WORK EXPERIENCE

China and as Lead Auditor most of Europa, US, Canada, Brazil, China and Malaysia.

LANGUAGE SKILLS	Speaking	Reading	Writing
Danish	Native language	Native language	Native language
Scandinavian	Possible	Possible	Danish
English	High level	High level	High level
German	Good	Good	Possible

WORK EXPERIENCE

Feb. 2019 - QualityVision Consulting

- Principal Consultant
- Owner

2018 - 2019 Medical device IVD Injection Molding
Quality Compliance Officer

- Responsible for Risk Management
- Responsible Lead auditor for internal/supplier audits
- Responsible for quality training and education

2017 - 2018 Consulting (Medical industry)
Senior consultant

- Conducting client meetings (medical industry)
- Assistance and consulting in medical device industry
- Quality training Medical Device

2016 – 2017 Medical device MDD Hearing Aid
ISO13485 and CMDCAS 13485
Corporate Quality System Development Manager

- Responsible for developing of global quality management system
- Responsible Lead auditor for internal audits, implementation and follow-up
- Development of global quality systems and tools

2015 - 2016 Tianjin China Medical device MDD high precision metal machining
ISO13485 and ISO 14001
QA/RA manager

- QM of QA/RA and responsible for QC in total 28 people.
- Developing QA Strategy and personnel
- Responsible for regulatory and customer audit
- Responsible for quality and environmental KPIs
- Responsible for quality and environmental management system

2014 - 2015 Medical device MDD Dental Implantable high precision metal machining
ISO13485, CMDCAS 13485, ISO 14001
QA/RA manager

- QM of QA/RA and responsible for QC in total 18 people.
- Developing QA Strategy and personnel
- Responsible for regulatory and customer audit
- Responsible for quality and environmental KPIs
- Responsible and implementation of electronical quality management system
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2008 - 2010 Consulting engineering
Senior consultant

- Conducting client meetings (pharmaceutical, medical industry and hospitals)
- Key Account pharma and medical device industry
- Advice and consulting in pharmaceuticals- and medical device industry

2006-2008 API/GMP production
Quality Management system Responsible

- Validation responsible
- Education (cGMP)
- Lead Auditor internal and external suppliers

2001-2006 Medical device MDD Injection molding and Adhesive
Project Manager

- Validation manager of new products and processes
- Validation and change control coordinator
- Risk Management process facilitator
- Lead auditor

Selected Achievements

- Completion of numerous company certifications and re-certifications from NB
- Project Management
- Build, operate, improve QM systems, and secure their certifications for ISO 13485:2016, FDA CFR820 and ISO 9001:2015.
- Build and operate Risk Management systems for ISO 14971 (e.g dfmea/pfmea/fta/hazop)
- Interact with Competent Authorities, Notified Bodies and customers
- Completion of numerous of validation/qualification/commissioning task.
- Audits Examinee Lead Auditor performed 80-100 audit in ISO 13485 and ISO 9001
- Performed courses and training more than 1000 hours

Selected Projects

Risk Management

Task: Preparation of documentation for clean room facility, Risk Management by creating risk assessments (pFMEA) and URS.

Clean room, HVAC, Compressed Air and Water treatment.

Project Details

- Client: Medical Device Company
- Workplace location: Denmark and Poland
- Duration: 3½ month
- Finish date: May 2019

Basis cGMP Training

Task: In House Basis cGMP training for production and QC.

- EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines
- Part IV - GMP requirements for Advanced Therapy Medicinal Products
- Q9 Quality Risk Management
- Annex15 Qualification and validation

Project Details

- Client: Pharmaceutical Company
- Workplace location: Denmark
- Duration: 8 Hours
- Finish date: April 2019

MDR QA project

Task: Preparation of documentation according to MDR, Risk Management, general safety and performance requirements.

Project Details

- Client: Medical Device Company
- Workplace location: Denmark
- Duration: 4 months
- Finish date: May 2020

QA Project Lead

Task: QA project Lead in transfer project, injection molding machine, test method and three products. Creating risk assessments (pFMEA for process and software GXP assessments), Validation plans and IQ, OQ and PQ documents.

Project Details

- Client: Medical Device Company
- Workplace location: Denmark
- Duration: 6 months
- Finish date: November 2019

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COURSES (selected)

Quality:
2018/2019 Webinars focusing on EU MDR/IVDR
2017 IVDR Regulation (NB LRQA)
2016 ISO 13485:2016
2015 Risk Management ISO 14971:2012
2013 LEAN
2007 Cleanroom, design & Validation
2007 Statistical methods
2007 cGMP
2006 Validation and clean room production
2005 Risk Analysis in production and development
2005 Examinee LEAD Auditor
2004 Risk Management
2002 PFMEA production Equipment
2002 Process Validation

Webinars

Greenlight Guru https://www.greenlight.guru/medical-device-resources/webinars

- How and when to register EU Medical Devices and report UDI info to EUDAMED
- Understanding PMS under EU MDR: Being proactive, no reactive
- Prepping your QMS for EU MDR
- EU MDR: How to interpret the new regulations and what do I need to do to be complaint?

Emergo https://www.emergobyul.com/resources/all/webinars/all

- Practical implications of the new EU MDR and ISO 14971 on post-market surveillance
- Clinical data and post-market compliance under the MDR
- Ensure Your CER Complies with MEDDEV 2.7/1 v4
- PMS & PMCF under the European MDR
- Europe's New IVDR 2017/746
- Conducting a Medical Device PMCF Study
- Eudamed Requirements under the EU MDR and IVDR
- The new European Medical Devices Regulation (MDR 2017/745)
- Human factors considerations for Software as Medical Device (SaMD)

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BSI https://www.bsigroup.com/en-GB/medical-devices/resources/webinars/webinar-form/MDR-webinars/

- QMS aspects of the MDR (& IVDR)
- EU Harmonization – MDR Requirements & progress on Key Standards & Labelling
- General Safety and Performance Requirements in the New MDR
- Technical Documentation requirements under MDR, including requirements for your legacy files
- Roles and responsibilities in the Medical Device and IVD Regulations
- MDR Conformity Assessment Routes webinar - 16 July 2019
- Article 120 (3) – What is due in 2020? - 04 December 2019
- How ready are you for the IVD Regulation?
- General Safety and Performance requirements of the IVDR

Others:

- Top 20 EU MDR Questions Answered: Featuring MDR Experts 9. Dec. Castor.com
- Medical Device Manufacturer Distribution Reporting to Health Authorities Reedtech.com
- Understanding EU EUDAMED, Global Requirements and GDSN Reedtech.com

Articles

"The Risk analysis ensures that you hit the spot"
How to utilize risk management to create optimal balance between investment, quality and documentation.
Published in trade journals:
Hospital Operations & Technology and Health Technology and Informatics

For more information please visit www.qualityvision.dk

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