Dahlfelt Consulting ApS

Tom Andersen

principal RISK AND QA Consultant

Experienced QA person with more than 30 years of experience in life science.
Since 2001 I have mainly worked with medical devices.
Extensive knowledge of cGMP and in-depth process understanding in quality management systems in life science
[ISO 13485, MDR, IVDR, 21 CFR 210, 21 CFR 211, 21 CFR 820, cGMP, ISO9001].
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, cGMP 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 analyses (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 Moulding (Sterile 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, MDR/IVDR, FDA part 820, ISO 9001
- Author of numerous of Policies & Procedures
- CAPA & Continuous Improvement
- Project and Change Management
- Supplier Quality Management
- Auditing

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WORK EXPERIENCE	
2021 –	Dahlfelt Consulting Aps Specialist and Senior Consultant • Various projects in QA, Risk management, MDR Compliance
2019 –	QualityVision Consulting Founder and Senior Consultant • Selected projects as QualityVision see below
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
2010 - 2014	Medical device MDD Dental Implantable high precision metal machining QA professional • Global Validation Manager • Responsible Lead Auditor internal and supplier audits • Education (ISO13485, cGMP, FDA cfr820) in Sweden, China and Denmark. • Project Management

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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 ensure their certifications for ISO 13485, ISO 9001 and FDA CFR820 compliance
- 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 as Examinee Lead Auditor performed 80-100 audit in ISO 13485 and ISO 9001
- Performed courses and training more than 1000 hours

Selected projects as QualityVision	• Design Control QA Responsible Task: Preparation of documentation during design control Class IIa/Class I
	  ○ Client: Medical Device Company, location: Denmark
	• 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.
	  ○ Client: Medical Device Company, location: Denmark and Poland
	• Basis cGMP Training Task: In House Basis cGMP training for production and QC.
	  ○ Project Details Client: Pharmaceutical Company, location: Denmark
	• MDR QA project Task: Preparation of documentation according to MDR, Risk Management, general safety and performance requirements.
	  ○ Project Details: Client: Medical Device Company, location: Denmark
	• 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, location: Denmark

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COURSES (selected)	Quality: 2017 IVDR Regulation 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
Webinars	QualityVision attends webinars as much as possible • Greenlight Guru https://www.greenlight.guru/medical-device-resources/webinars • Emergo https://www.emergobyul.com/resources/all/webinars/all • BSI https://www.bsigroup.com/en-GB/medical-devices/resources/webinars/webinar-form/MDR-webinars/
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
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