Adequat
EXPERTISE

Sophie **René**

Indépendent medical devices expert
Consultant for quality and regulatry affairs, auditor
21 years experience in Medical Device

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Sommaire

Key words

Main products

implants, medical devices incorporating animal tissue, reusable surgical instruments, orthopaedics devices, sterile devices, hearing aids, general equipment

Risk-class devices

from Class I to Class III

Main specialities

orthopaedic surgery, digestive surgery, robotic orthopaedic surgery, dental surgery, breast surgery

Audit services

Europe, UK, USA, Asia, EMEA
Internal Audit, Audit for process qualification, audit for due diligence

Skills

Quality affairs

- Standards ISO13485 - cGMP (FDA 21CFR PART 820 / 801 / 803 / 806)
- MDSAP Medical Device Single Audit Program
- Process validation: design, inspection, manufacturing, logistic, purchasing.
- Implementation and management of quality systems
- Support for certification
- Subcontracting qualification
- Medical device industrialization
- Audits for QMS, production and suppliers
- Audits MDSAP

Regulatory affairs

- MDR 745/2017 medical device regulation
- USA – CANADA – JAPAN - BRAZIL - UK
- Animal tissue (ISO22442 series)
- Medical device registration (UK process, US Process)
- 510[k] files
- Labelling / Implant card / UDI / EUDAMED / vigilance
- Medical device classification
- PRRC Person Responsible for the regulatory Conformity

Process validation

- Qualifications IQ/OQ/PQ
- Support for industrialization
- Implementation of the process validation management system

Training services

- Specific custom-made training built upon request
- Vigilance process
- PRRC responsibilities
- New requirements introduced with European regulation 2017/745
- To conduct quality audits for internal and external program
- ISO 13485: 2016
- Risk management process according to ISO 14971

Background & qualification

2023
- Medical devices single audit program MDSAP [BSI – France]
- ISO 22442s series: Medical devices utilizing animal tissues and their derivatives [MS Conseil – France]
- IMedical devices: post market surveillance and vigilance [LNE/GMED – France]

2022
- Regulation related to advertising for medical devices [MD101 – France]

2021
- Risks related to the use of chemical components in the industry [AFPIC – France]

2020
- Environmental controlled areas: Management of contamination for medical devices production [ASPEC – France]
- Risk management and usability (ISO14971v2019 – ISO/TR 24971v2020 – EN62366-1v2015) [IFEP – France]

2019
- Sterilization of healthcare products – Ethylene oxide (ISO 11135 series) [MS Conseil – France]

2018
- Sterilization of healthcare products – Ethylene oxide (ISO 11135 series) [MS Conseil – France]
- ISO9001 v 2015 [AFNOR – e-learning]

2017
- Sterilization of healthcare products – Radiation (ISO 11137 series) [MS Conseil – France]

2016
- Packaging for terminally sterilised medical devices (ISO607 series) [TUV RHEINLAND]

2011
- Medical device regulation: Canada, Australia [LNE – Paris]
- Medical device regulation in Japan – Requirements for a quality system [LNE – Paris]
- Training to become a trainer [ADHARA – Bordeaux - France]

2010
- Risk management ISO 14971v2009 [LNE – Paris - France]

2009
- Certification auditor IRCA [MOODY CERTIFICATION - Paris- France]

2008
- Subcontracting and process audit [Idée Consulting – inter entreprise- France]
- FDA Medical devices regulation [Idée Consulting – inter entreprise- France]

Background & qualification

2005

To conduct internal audits [Idée Consulting – inter entreprise- France]

Regulatory requirements related to design of medical devices & US 21 CFR PART 820 [Idée Consulting – inter entreprise- France]

Risk management ISO 14971 [Idée Consulting – inter entreprise- France]

Software validation [Idée Consulting – inter entreprise- France]

American regulation of medical devices [Idée Consulting – inter entreprise- France]

2004

Training ISO13485v2003 [LNE/GMED - Paris- France]

2003

International regulatory affairs [QUINTILES – inter entreprise- France]

2002

MASTER for SYSTEM MANAGEMENT (environnement) [ESC LA ROCHELLE - France]

1992

DUT Industrial process engineering [University Paul Sabatier Toulouse- France]

Professional experience

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Founder / chief executive

2009 to now (16 years)

Creation of the company and management of a team
Investments and finances, development of activities
Recruitment and training

MEDICREA

Quality and regulatory affairs director

2002 to 2008 (during 7 years)

Management of the quality and regulatory affairs department; Manufacturer of spinal implants and associated instrumentation:

- Set up and management of the quality management system according to ISO 13485, ISO 9001 and 21 CFR Part 820, on 3 locations: headquarter, manufacturing site and distribution site in US.
- Management of regulatory affairs for European and American markets.
- Registrations of medical devices into the other countries (China, Japan, South Korea, Australia, Canada, Brazil, ….etc)
- Management of the quality control department and validation process department.
- Process, subcontractors and internal audits

VIVENDI Environnement

iREPOLIA

Technical project manager for wastewater, drinking water and industrial water treatment

1993 to 2002 (during 10 years)

Development of new processes and industrialization of processes for water treatment (drinking water, waste water and industrial water)

References Adequat Expertise

OUTSOURCED SERVICES FOR MEDICAL DEVICES COMPANIES

2013 to Now

Quality and regulatory affairs manager and PRRC (outsourced resource) for a company which designs and manufactures biological prosthesis. Set up of a quality system according to the requirements ISO 13485, 21 CFR Part 820, and European regulations. Certification ISO 13485 / CE marking procedures / 510[k] registration of devices / ISO 22442 SERIES.

2010 to 2012

Quality and regulatory affairs manager (outsourced resource) for a company which designs and manufactures spinal implants and instrumentation. Implementation of a quality system, management of the certification ISO 13485, CE mark procedure follow-up and 510[k] registration.

2009 to 2018

Quality and regulatory affairs manager (outsourced resource) for a company which designs and manufactures electro-medical devices. Quality system follow-up according to the requirements of the US, Canadian and European regulations. Maintain of the certification ISO 13485 and ISO 9001. CE mark procedures follow-up and international registration procedures (Brazil, Japan, USA, Europe, Canada...).

2009 to 2012

Quality and regulatory affairs manager (outsourced resource) for a subcontracting company of packaging. Implementation of a quality system according to the requirements of the US and European regulations. Management of the certification ISO 13485 and ISO 9001.

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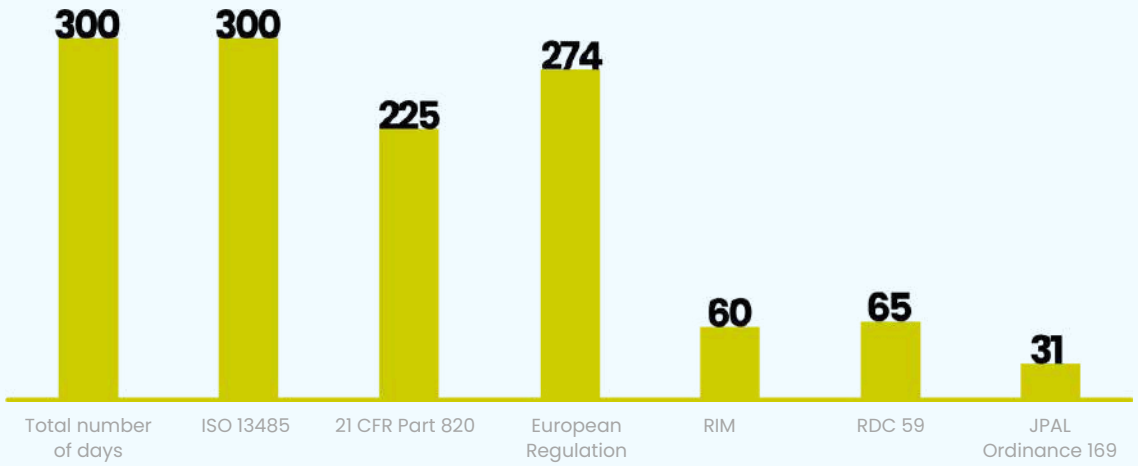
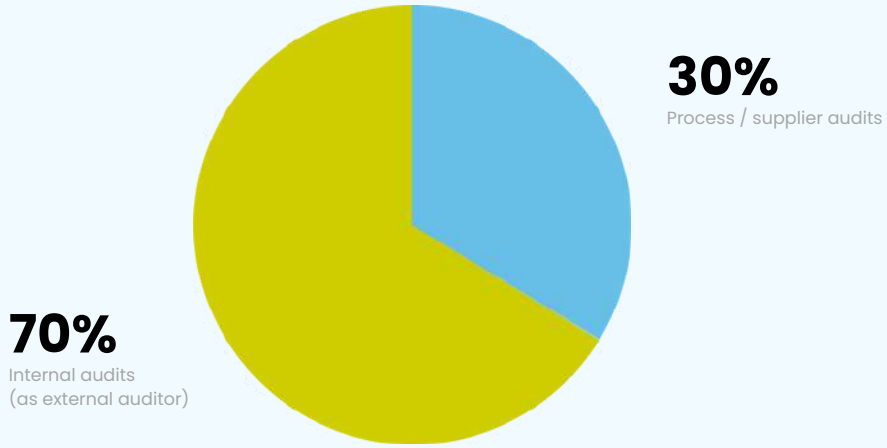
- Gap analysis of the conformity related to MDR 2017/745 for QMS (2021 – Class IIa medical devices)
- Preparation of technical documentation to be compliant with the MDR 2017/745 requirements (2021 – Class I general equipment)
- Support for QMS efficiency and improvement (2021 – QMS & Class IIb medical devices)
- Change management (2021 – Class IIb medical devices and QMS)
- Evaluation of the new EU regulation for medical device and quality system application (2020 –
- QMS and Class III Medical devices)
- Evaluation of ISO 13485: 2016 and determination of an associated action plan (2020 –
- Subcontractor for the manufacturing of orthopedic implants)
- Assistance for the registration of a new product following CE mark procedure (2015 – dental instrument – Class I)
- Support to update technical file for CE Mark (2015 Class IIb – Solution for ocular lenses)
- Feasibility Study for determining the clinical and biocompatibility strategy – combined medical devices Class IIb
- Feasibility study for determining the regulatory strategy to put on the market a new product to measure the intracranial pressure – Class III
- Support for preparation of risk management file according to ISO 14971 standard for the registration of medical devices (ocular implants) in Australia.
- Support for preparation of ANVISA inspection – Class III active medical device
- Support for registration medical devices in Mexico – Class II medical device
- Support for updating technical documentation for CE Mark – Class III Abdominal wall reinforcement prosthesis
- Support for registration medical devices in Japan – Class II active medical device
- Support for CE registration and reimbursement – Class I devices for treatment of bedsores.
- Support for registration medical devices in Canada – Class II medical device
- Support for ISO 13485 Certification – Class II robotic equipment
- Support for ISO 13485 Certification and CE Mark – Class III biological implants
- Support for preparation of ISO 13485 certification – Robotic solution for the manipulation and organization of catheters or supple instrument – France
- Support for writing technical documentation for CE MARK – software medical device - France
- Support for preparation of ISO 13485 certification – Biological prostheses – France
- Support for updating technical documentation for CE Mark – Abdominal wall reinforcement prosthesis - France
- Support for FDA Inspection – Packaging of medical devices - France
- Support for writing technical documentation for CE MARK – Ophthalmology - France
- Support for writing technical documentation for CE MARK – Spine - France
- Support for writing 510[k] file and associated documentation – Spine – France
- Support for preparation to ISO 13485 certification – Subcontractor for spinal implants manufacturing - France
- Protocol of validation – Packaging process for sterile spinal implants – France
- Risk management process related to the implementation of an activity of packaging in a controlled area – Subcontractor for implants treatment - France
- Support for analysis and treatment of materiovigilance events / exchange with competent authorities –Implantable medical devices - France

References Adequat Expertise

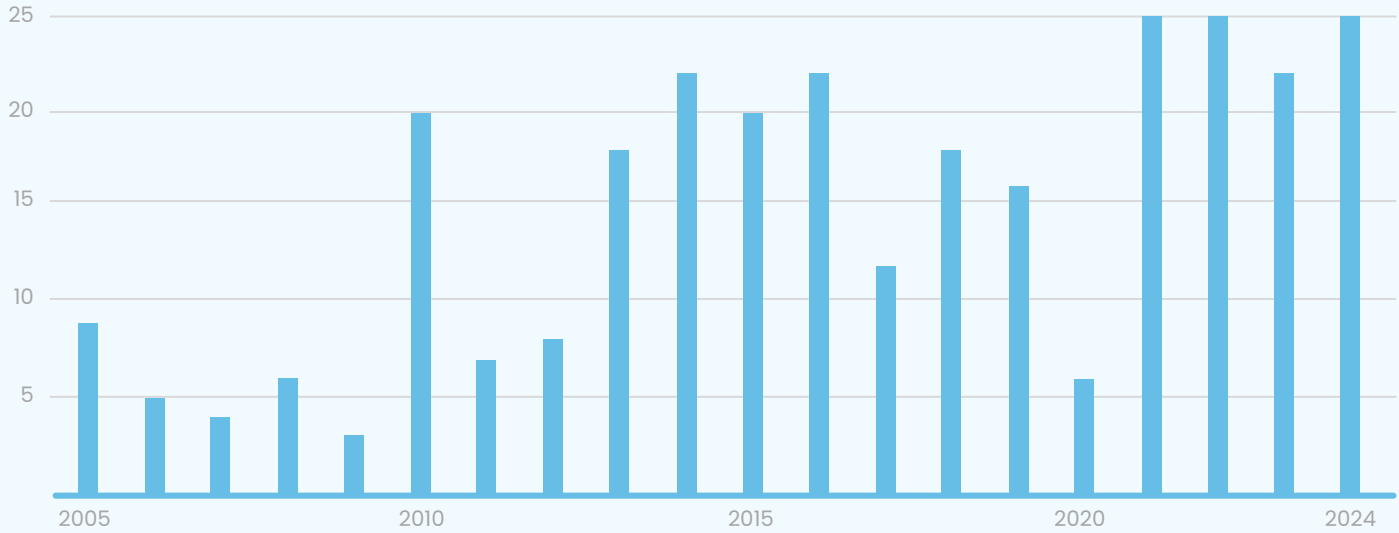
Number of audit days, according to audit criteria (2005-2024)



Type of audits (2005-2024)



Time of audit per year (nber of days)



Auditor qualification of Sophie René is based on

An initial training of internal auditor in 2005

A certification of auditor IRCA in 2009, based on ISO 19011 standard

Several trainings related to all standards, such as ISO 13485 and 21CFR regulations

Several trainings related to international regulations, such as European regulations, FDA regulations

Specific training related to MDSAP program

A large experience of audits, with more than 15 years of audit practice, with a total of 300 days of audits (2005-2024) and an average of 17 days per year of audits since the creation of ADEQUAT EXPERTISE

A good knowledge of companies from medical device field from 20 years

10 years of specific audits of slaughterhouses for animal tissue handling and collection

10 years of specific audits of manufacturers of medical devices utilizing animal tissue origin based on ISO 22442 series

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