77 rue des jars
17000 LA ROCHELLE – France
Tel : +33 (0)6 17 98 16 94
www.adequatexpertise.com

INDEPENDANT CONSULTING FOR QUALITY AND REGULATORY AFFAIRS

EXPERTS FOR MEDICAL DEVICES

REFERENCES

❒ OUTSOURCED SERVICES

DATE	POSITION	ACTIVITIES	MEDICAL DEVICES
2009 to NOW	QUALITY AND REGULATORY AFFAIRS MANAGER	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...).	Electromedical instrument Class IIa (EU) / II (USA) Orthopedics
2013 to Now	QUALITY AND REGULATORY AFFAIRS MANAGER	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. Preparation of the certification ISO 13485	Biological prothesis for soft tissue repairs Class III (EU) / II (USA)
2010-2012	QUALITY AND REGULATORY AFFAIRS MANAGER	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	Spinal implants and instruments Class IIb (EU) / II (USA)
2009 - 2012	QUALITY AND REGULATORY AFFAIRS MANAGER	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.	Subcontracting activities of cleaning, labeling and packaging for sterile devices

77 rue des jars
17000 LA ROCHELLE – France
Tel : +33 (0)6 17 98 16 94
www.adequatexpertise.com

❒ INTERNAL AUDITS / SUPPLIERS-PROCESS AUDITS

ADEQUAT EXPERTISE auditor is qualified and registered as IRCA (International Register of Certificated Auditor), Registration number 30827. Main audited standards are: ISO 13485 / US cGMP

DATE	ACTIVITY	COUNTRY	STATE	NB of days
2003	Orthopedics	France	94	1,5
2004	Orthopedics	FRANCE	86	1,5
2005	sterile packaging	FRANCE	13	2
2005	Orthopedics	FRANCE	17	2
2005	Orthopedics	FRANCE	17	1,5
2005	Orthopedics	FRANCE	17	2
2005	Orthopedics	FRANCE	69	1
2006	Orthopedics	FRANCE	17	1
2006	Orthopedics	FRANCE	17	2
2006	sterile packaging	FRANCE	13	2
2007	Orthopedics	USA	USA	4
2008	Orthopedics	FRANCE	59	1
2008	Orthopedics	FRANCE	69	1,5
2008	Orthopedics	FRANCE	13	3,5
2009	Orthopedics	FRANCE	17	1,5
2009	sterile packaging	FRANCE	17	1,5
janv-10	IVD MD	FRANCE	33	1,5
févr-10	Electronic parts	SINGAPORE	SING	3,5
févr-10	sterilisation	FRANCE	60	1,5
févr-10	sterile packaging	FRANCE	17	1
avr-10	Orthopedics	FRANCE	94	2
juin-10	IVD MD	FRANCE	33	1,5
sept-10	Orthopedics	FRANCE	85	1
oct-10	Cardiac surgery	SUISSE	SUISSE	2
oct-10	Cardiac surgery	SUISSE	SUISSE	2,5
nov-10	Orthopedics	France	92	1
déc-10	Orthopedics	France	94	2
juil-11	IVD MD	FRANCE	33	3
oct-11	IVD MD	INDE	Mumbay	3
sept-11	Orthopedics	FRANCE	59	1
mars-12	Orthopedics	FRANCE	76	1
avr-12	Vascular surgery	FRANCE	59	1
oct-12	Orthopedics	FRANCE	69	2
nov-12	Electronic parts	SINGAPORE	SING	4
mai-13	Orthopedics	DK	DK	3
juin-13	ophtalmic surgery	FRANCE	22	2
sept-13	sterile Packaging	FRANCE	42	2
oct-13	Orthopedics	FRANCE	89	4
oct-13	Orthopedics	TUNISIE	TUNISIE	2
oct-13	Orthopedics	USA	USA	2
déc-13	Orthopedics	FRANCE		3
janv-14	Electronic parts	FRANCE	35	1
mars-14	Orthopedics	SINGAPORE	SING	3,5
avr-14	Cardiac surgery	FRANCE	76	2
mai-14	Orthopedics	DK	DK	2
mai-14	telemedecine	FRANCE	75	1,5
juin-14	Vascular surgery	FRANCE	59	1
juin-14	Orthopedics	FRANCE	69	2
juil-14	Digestive surgery	FRANCE	59	1
oct-14	Orthopedics	USA	USA	2
déc-14	Orthopedics	FRANCE	59	2
déc-14	general equipment	FRANCE	14	2
déc-14	Orthopedics	TUNISIE	TUNISIE	2
janv-15	Electronic parts	FRANCE	35	1
janv-15	Orthopedics	USA	USA	2

77 rue des jars
17000 LA ROCHELLE – France
Tel : +33 (0)6 17 98 16 94
www.adequatexpertise.com

févr-15	IVD MD	FRANCE	91	3
mars-15	Orthopedics	SINGAPORE	SING	3,5
avr-15	Cardiac surgery	FRANCE	76	2
mai-15	general equipment	Belgique	Belgique	2
mai-15	Cardiac surgery	SUISSE	SUISSE	2
juin-15	Orthopedics	DK	DK	2
déc-15	general equipment	FRANCE	14	2
janv-16	Electronic parts	FRANCE	35	1
févr-16	IVD MD	FRANCE	91	3
févr-16	radiology	FRANCE	67	2
mars-16	Electronic parts	SINGAPORE	SING	3,5
mars-16	Electronic parts	Malaysia	MAL	1
mai-16	Orthopedics	DK	DK	2
juin-16	Cardiac surgery	FRANCE	76	2
juin-16	Vascular surgery	FRANCE	59	1
juin-16	Orthopedics	FRANCE	69	2
nov-16	ophtalmic surgery	FRANCE	67	1
déc-16	Digestive surgery	FRANCE	69	3
janv-17	Electronic parts	FRANCE	35	1
mars-17	DMDIV	FRANCE	91	3
mars-17	sterilisation	FRANCE	89	1
avr-17	Orthopedics	DK	DK	2
mai-17	Digestive surgery	Allemagne	ALL	2
sept-17	Orthopedics	FRANCE	63	1
nov-17	Vascular surgery	FRANCE	59	1

Adequat EXPERTISE

77 rue des jars
17000 LA ROCHELLE – France
Tel : +33 (0)6 17 98 16 94
www.adequatexpertise.com

❒ CONSULTING SERVICES

YEAR	Description of services
2017	o Support to maintain the certification ISO 13485 / General equipment o Support to analyze and evaluate the impact of new version 2016 of the ISO 13485 – electronic parts supplier
2016	o Support to implement UDI regulation / FDA – Electronic medical device Class II o Evaluation of the new EU regulation for medical device and quality system application o Evaluation of new ISO 13485 : 2016 and determination of an associated action plan o Support for the registration of a new product following CE mark procedure – dental instrument – Class I
2015	o Support to improve the risk management process (ISO 14971 standard) - Abdominal wall reinforcement prosthesis – class IIb o Support to update technical file for CE Mark – Class IIb – Solution for ocular lenses o Support for the registration of a new product following CE mark procedure – dental instrument – Class I o Feasibility Study for determining the clinical and biocompatibility strategy – combined medical devices Class IIb o Feasibility study for determining the regulatory strategy to put on the market a new product to measure the intracranial pressure – Class III
2014	o Support for preparation of risk management file according to ISO 14971 standard for the registration of medical devices (ocular implants) in Australia. o Support for preparation of ANVISA inspection – Class III active medical device o Support for registration medical devices in Mexico – Class II medical device o Support for updating technical documentation for CE Mark – Abdominal wall reinforcement prosthesis o Support for registration medical devices in Japan – Class II active medical device o Support for CE registration and reimbursement – Class I devices for treatment of bedsores. o Support for registration medical devices in Canada – Class II medical device o Support for ISO 13485 Certification – Class II robotic equipment o Support for ISO 13485 Certification and CE Mark – Class III biological implants
2013	o Support for preparation of ISO 13485 certification – Robotic solution for the manipulation and organization of catheters or supple instrument – **France** o Support for writing technical documentation for CE MARK – software medical device - **France** – France o Support for preparation of ISO 13485 certification – Biological prostheses – **France** o Support for updating technical documentation for CE Mark – Abdominal wall reinforcement prosthesis – **France**
2012	o Support for Medical device registration in Japan – Orthopedic devices - **France** o Support for writing technical documentation for CE MARK – Orthodontic devices – **France**
2011	o Support for FDA Inspection – Packaging of medical devices - **France** o Support for writing technical documentation for CE MARK – Ophthalmology - **France** o Support for writing technical documentation for CE MARK – Spine - **France** o Support for writing 510[k] file and associated documentation – Spine – **France**
2010	o Support for preparation to ISO 13485 certification – Subcontractor for spinal implants manufacturing - **France** o Protocol of validation – Packaging process for sterile spinal implants – **France** o Risk management process related to the implementation of an activity of packaging in a controlled area – Subcontractor for implants treatment - **France** o Support for analysis and treatment of materiovigilance events / exchange with competent authorities –Implantable medical devices - **France**

77 rue des jars
17000 LA ROCHELLE – France
Tel : +33 (0)6 17 98 16 94
www.adequatexpertise.com

❒ TRAINING

ADEQUAT EXPERTISE is registered as a training organism (in France) : Number of activity declaration 54 17 01405 17 (under Poitou-Charentes administration representative).

YEAR	Trainings
2017	To conduct quality audits for internal and external program
2017	ISO 13485: 2016 – New requirements to implement and to audit
2017	21CFR Part 820 requirements
2016	To conduct quality audits for internal and external program
2016	ISO 13485: 2016 – New requirements to implement and to audit
2015	How to implement a risk Management process according to NF EN ISO 14971 v 2013
2015	Understanding the medical device regulation context: ISO 13485 – European directive – 21CFR PART 820
2014	To conduct quality audits for internal and external program
2014	How to implement a risk Management process according to NF EN ISO 14971 v 2013
2014	Industrial process: implementation of a strategy of validation IQ – OQ - PQ
2013	To conduct quality audits for internal and external program
2012	To conduct quality audits for manufacturing processes and subcontractors
2012	To conduct quality audits for internal and external program
2011	Quality Management: Comparison of requirements between the main applicable standards (US, Canadian and European standards)
2010	To conduct quality audits for internal and external program
2010	ISO 13485: 2016 – New requirements to implement and to audit
2010	How to implement a risk Management process according to NF EN ISO 14971 v 2013

77 rue des jars
17000 LA ROCHELLE – France
Tel : +33 (0)6 17 98 16 94
www.adequatexpertise.com

Sophie RENE

☐ Location: LA ROCHELLE [17] – France
☐ Date of birth:14 May 1971 – 46 years
☐ Mobile Phone:+33 6 17 98 16 94
☐ Email: s.rene@adequatexpertise.com
☐ Website: www.adequatexpertise.com

INDEPENDENT CONSULTANT WHICH PROVIDES QUALITY AND REGULATORY CONSULTING SERVICES TO MEDICAL DEVICES COMPANIES

15 YEARS EXPERIENCE IN MEDICAL DEVICES

EXPERIENCE

2009 to now — Owner/Consultant [ADEQUAT EXPERTISE – France]

- *Multiple quality and regulatory consulting services to medical devices companies, in the field of orthopedic devices, ophthalmology, orthodontics, cardiovascular application:*
  - ✓ *Management of quality and Regulatory affairs departments as outsourced resource*
  - ✓ *Support for regulatory affairs (EU, US and WW)*
  - ✓ *Training sessions*
- *Management of the company*
- *Auditor (IRCA) for internal audit programs or process or suppliers audits programs*

2002 - 2008 — Quality and Regulatory Affairs Director [MEDICREA TECHNOLOGIES - FRANCE]

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*

2000 - 2002 — Technical project manager - [IREPOLIA - FRANCE]
Development of new processes and industrialization of processes for industrial water

1993 - 2000 — Process project manager [VIVENDI ENVIRONNEMENT – FRANCE and AUSTRALIA]
Development of new processes for water treatment by filtration

77 rue des jars
17000 LA ROCHELLE – France
Tel : +33 (0)6 17 98 16 94
www.adequatexpertise.com

SKILLS

QUALITY	☐standards ISO13485 - ISO9001 - cGMP (FDA) ☐ process validation: design, inspection, manufacturing, logistic, purchasing,... ☐ implementation and management of quality systems ☐ support for certification ☐ subcontracting qualification ☐ medical device industrialization ☐ audits (Auditor IRCA) ; ☐ training
REGULATORY AFFAIRS	☐ medical device regulation : EUROPE MDD 93/42/CEE – ☐ USA 21CFR PART 820 – PARTS 801 / 803 / 806 ☐ CANADA CMDR DORS 98/282 –JAPAN Ordinance JPAL ordinance # 169 - BRAZIL BGMP: RDC 59 ☐ medical device registration ☐ 510[k] files ☐ labeling ☐ vigilance - ☐ medical device classification ☐ training
PROCESS VALIDATION	☐ Qualifications IQ/OQ/PQ ☐ special process validation ☐ protocol for testing ☐ Implementation of the process validation management system ☐ Training

BACKGROUND & QUALIFICIATION

2011	Medical device regulation : Canada, Australia [LNE – Paris]
2011	Medical device regulation in Japan – Requirements for a quality system [LNE – Paris]
2011	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]
2008	FDA Medical devices regulation [Idée Consulting – inter entreprise- France]
2005	To conduct internal audits [Idée Consulting – inter entreprise- France]
2005	Regulatory requirements related to design of medical devices – according to US 21CFR Part 820 ; Risk management ISO 14971 - [Idée Consulting – inter entreprise- France]
2005	Software validation [Idée Consulting – inter entreprise- France]
2005	American relation 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 management [ESC LA ROCHELLE- France]
1992	DUT Industrial process engineering [University Paul Sabatier Toulouse- France]

Adequat EXPERTISE
77 rue des jars
17000 LA ROCHELLE – France
Tel : +33 (0)6 17 98 16 94
www.adequatexpertise.com

DETAILLED EXPERIENCE AS AUDITOR

Data from 01/2005 to 12/2017