Adequat EXPERTISE

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

ADEQUAT EXPERTISE cooperates from now with companies which are looking for simple and useful solutions, in accordance with their strategy, their size and their economic constraints:

The main missions are the following:

❒ OUTSOURCED SERVICES

2009 to Now	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...).
2013 to Now	Quality and regulatory affairs manager (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. Preparation of the certification ISO 13485.
2010-2012	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 - 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.

❒ 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 / ISO 9001.

2014	o Internal audit : full quality system according to standards ISO 13485 – Manufacturer of intraocular lenses - **France** o Internal audit : full quality system according to standards ISO 13485 – Manufacturer of spinal implantable devices - **Denmark** o Internal audit : full quality system according to standards ISO 13485 – Subcontractor of electronic parts of medical devices - **France**

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- Supplier audit- Manufacturing, cleaning and packaging of electromedical devices – **Singapore / Malaysia**
- Supplier audit- Machining of metallic parts for medical devices - **Singapore**
- Internal audit : full quality system according to standards ISO 13485 & 21CFR Part 820 – Manufacturer of cardiovascular devices - **Switzerland**
- Supplier audit – Manufacturing process of instruments - **USA**
- Supplier audit – Sterilization process of medical devices - **USA**
- Internal audit : full quality system according to standards ISO 13485 & 21CFR Part 820 – Manufacturer of electromedical devices for vascular and cutaneous applications - **France**
- Internal audit – full quality system according to 21CFR part 820 and ISO 13485 – manufacturer of diagnostic equipment - **France**
- Supplier audit – Manufacturing process of implants – **Tunisia**

2013

- Internal audit : full quality system according to standards ISO 13485 – Manufacturer of intraocular lenses - **France**
- Internal audit : full quality system according to standards ISO 13485 – Manufacturer of spinal implantable devices - **Denmark**
- Internal audit : full quality system according to standards ISO 13485 – Manufacturer of spinal implantable devices – **France**
- Internal audit: full quality system according to standards ISO 13485, 21CFRpart 820 – Manufacturer of electro-medical devices - **France**
- Supplier audit- Manufacturing, cleaning and packaging of electromedical devices – **Singapore / Malaysia**
- Supplier audit – Sterilization process of medical devices - **France**
- Supplier audit – Manufacturing process of bones substitutes - **France**
- Supplier audit – Plastic injection process for medical devices - **France**
- Supplier audit – Manufacturing process of implants - **Tunisia**
- Supplier audit – Manufacturing process of instruments - **USA**

2012

- Internal audit : full quality system according to standards ISO 13485 – Manufacturer of electromedical devices for vascular and cutaneous applications - **France**
- Internal audit : full quality system according to standards ISO 13485 – Manufacturer of cardiovascular devices - **Switzerland**
- Supplier audit- Manufacturing, cleaning and packaging of electromedical devices – **Singapore**
- Supplier audit – Manufacturing process of orthopedic instruments - **USA**
- Internal audit – full quality system according to standards ISO 13485 and ISO 9001 – Manufacturer of Diagnostic in vitro medical devices - **France**

2011

- Supplier audit – Manufacturing process of components for In Vitro Diagnostic Medical Devices – **Mumbai - India**
- Internal audit – full quality system according to standards ISO 13485 and ISO 9001 – Manufacturer of Diagnostic in vitro medical devices - **France**

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	o Supplier audit : process of machining of implantable medical devices - **Tunisia**
2010	o Supplier audit : manufacturing process of metal tubes for instrumentation - **France** o Internal audit : Management, improvement and supply chain processes according to ISO 13485 – Manufacturer of instrumentation for cardiovascular devices - **Switzerland** o Internal audit : full quality system according to standards ISO 13485 – Manufacturer of cardiovascular devices - **Switzerland** o Internal audit – full quality system according to standards ISO 13485 and ISO 9001 – Supplier of implantable medical devices- **France** o Supplier audit- Manufacturing, cleaning and packaging of electromedical devices – **Singapore / Malaysia** o Supplier audit – ETO sterilization process – **France** o Internal audit – full quality system according to standards ISO 13485 and ISO 9001 – Manufacturer of Diagnostic in vitro medical devices - **France**
2009	o Internal audit – full quality system according to standards ISO 13485 and 21CFR Part 820 – Distribution of spinal medical devices - **USA**

❒ CONSULTING SERVICES

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**

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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**

❒ TRAINING

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

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	ISO 13485 : how to implement these requirements to an existing quality system for subcontracting company
2010	Risks management : application of the standard ISO 14971v2009 – France
2010	ISO 13485 : How to implement a quality system related to the requirements of manufacturers for subcontracting companies

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Sophie RENE

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

12 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

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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 – 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 quality and environment management – ESC LA ROCHELLE- France]
1992	DUT Industrial process engineering [University Paul Sabatier Toulouse- France]

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

9 YEARS EXPERIENCE IN MEDICAL DEVICES

EXPERIENCE

2013 to now — Consultant [ADEQUAT EXPERTISE - France]

Multiple quality and regulatory consulting services to medical devices companies, in the field of orthopedic devices, ophthalmology, robotic, software application:
- *Management of quality and Regulatory affairs departments as outsourced resource*
- *Support for regulatory affairs (EU, US and WW)*
- *Training sessions*

2009 – 2013 — Consultant [Free-lance – Japan/France]

- *Implementation of a quality system according to the requirements of the US and European regulations. Regulatory consulting support for Japan registration*

2006 – 2009 — Quality & Regulatory affairs Manager [SpineVision - France]

- *Quality System management according to ISO 13485, ISO 9001 and 21 CFR Part 820*
- *FDA inspection and European auditee*
- *Internal and sub-contractor auditor*
- *Regulatory clearances worldwide (Brazil, Venezuela, Mexico, Australia, Korea, India, Thailand, Malaysia…)*
- *Management of the quality control department*

2005 - 2006 — Quality Assurance Manager [Celogos – France]

- *Implementation of the Quality System according to ISO 9001:2000*

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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
REGULATORY AFFAIRS	☐ medical device regulation : MDD 93/42/CEE – 21CFR PART 820 – CMDR DORS 98/282 ☐ medical device registration ☐ 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 ☐ Software
BIOCOMPATIBILITY	☐ Training ☐ Bioburden follow-up ☐ Protocol for testing ☐ Sterilization (Oxyde Ethylen, vapor)

BACKGROUND & QUALIFICIATION

2013	ISO 14971:2012 Risk Management [BSI – Paris – France]
2008	Canadian Regulations & Europe/United States/Canadian vigilance [Demos - Paris-France]
2007	21 CFR Part 820 training [AAMI - Washington – United-States]
2006	Biocompatibility of Medical Devices ISO 10993-1:2004 [NAMSA - Zurich-Zwitzerland]
2006-2008	Master of Business Administration (MBA) [Business Administration Institute of Paris – La Sorbonne – Paris - France]
2004-2005	Master degree of *Total Quality and Biotechnologies* [ISSBA - Angers-France]
2002-2005	Master degree of Genetics, Biotechnologies and Microbiology [University of Paris-Sud - Paris France. 2nd year at McGill University (English-speaking University in Montreal, Canada)]