B. Eng. Ivano Oliveri

RA Manager & QA

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Work History

Head of Quality Assurance — Oct 2020 - Present

1MED sa

- Create, update, distribute and maintain 1MED Quality Management System (SOP and Modules) according to ISO 13485, ISO 14155 and GCP
- Train staff on the Company Quality Management System
- Manage the archive related to the 1MED Quality Management System (both paper and electronic)
- Plan and conduct of internal and on-site audits
- Assist Clinical Operations in the development of Clinical SOPs and other quality documents
- Perform QA review/QC processes
- Preparation and participation in sponsor audits
- Preparation and participation in sponsor audits of study sites
- Evaluate the opportunities of improvement of the company Quality Management System
- Perform the required auditing activities to ensure that studies are conducted in accordance with sponsor protocols, GCP, guidelines and regulations.
- Implementation of Quality Management Systems in accordance with the ISO 13485 standard and in accordance with the regulations (MDD/MDR) on Medical Devices and the FDA regulation.

Quality Assurance — Jan 2020 - Present

1MED sa

- Create, update, distribute and maintain the GCP quality system (SOP and Modules)
- Train staff on the SQ GCP
- Manage the archive
- Manage the sponsor's SOPs and ensure distribution to the staff involved
- Plan and conduct internal and on-site audits
- Carry out document control (QC)
- Prepare and participate in sponsor audits
- Prepare and participate in sponsor audits on study sites

Regulatory Affairs Manager — Nov 2015 - present

1MED sa

- Regulatory Strategy definition
- Application of Quality Management Systems (ISO 13485:2016; ISO 9001:2015)
- Auditing for ISO 13485:2016 compliance and supplier qualification for med-tech companies
- Support in Process Validation (IQ, OQ, PQ) according to Good Manufacturing Practice
- Software validation within Quality Management System according to ISO/TR 80002-2:2017
- Clinical Evaluations and Post-Market Clinical Follow Up in accordance with Annex X of Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EEC and based on MEDDEV 2.7.1:2016
- Technical File preparation in compliance with European Medical Device Directive
- Support in Project Management processes
- Support in Regulatory Pathway for medical device development
- Risk Analysis Dossier preparation in conformity with ISO 14971:2012

Skills

Technical File preparation

Setting up documents for MD Technical Files (w/ Clinical and Biological Evaluations, Risk Analysis report), support on test to be performed on the device prior to the submission of the TF to the Notified Body.

Application of ISO 13485, ISO 9001 and ISO 14155 Quality Systems and experience in auditing med-tech companies and suppliers

Regulatory Plan developement

Strategic consultant

Procedure and Modules customization, Internal audits, compliance verification, support during NB auditing

Risk Analysis preparation in compliance with ISO 14971

Standard operating Procedure implementation and customization, FMECA Table, Annex C Questionnaire

Clinical Evaluation and Post Market Vigilance

Clinical Evaluation Report, Post Market Surveillance Planning, Post Market Clinical Follow Up

Italian Ethics Committee and Competent Authorities Submissions, Clinical Trials management for medical devices

- Post Market Surveillance in compliance with MEDDEV Guidelines
- Support for Medical Device Clinical Trials Management in compliance with ISO 14155/GCP
- Tutor for MDR 2017/745, ISO 13485:2016 and Clinical Evaluation under MDR and MEDDEV 2.7.1

Quality Assurance and Regulatory Specialist — Jun 2011 - Oct 2015

Freelance

- European Medical Device Regulations for Clinical Data and Clinical Trials
- Medical device Clinical Trials Project Management and CA/EC notification,
- CE-Marking and Quality System Certifications (ISO 13485:2012; ISO 9001:2008) support Medical Devices registration in Italian MOH NSIS System Database
- Clinical Evaluations in accordance with Annex X of Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EEC and based on MEDDEV 2.7.1:2009
- Support in Project Management processes
- Support in Regulatory Pathway for medical device development
- Technical File preparation in compliance with European Medical Device Directive
- Risk Analysis Dossier preparation in conformity with ISO 14971:2012
- Support in Post Market Surveillance - Post Market Surveillance Plan based on MEDDEV 2-12.2
- Quality Assurance:
  Good Clinical Practice ISO 14155
  ISO 13485
  ISO 9001

Regulatory Specialist — Oct 2009 - May 2011

Freelance

- Clinical Trial submission process (EC and CA) for international companies
- Clinical Evaluations and Post-Market Clinical Follow Up in accordance with Annex X of Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EEC and based on MEDDEV 2.7.1 guidelines

Main activities and responsibilities:

Regulatory & Quality Assurance (technical dossier preparation and review, literature review, God Clinical Practice)

Project Engineer — Mar 2007 - Sep 2009

Infinity Tech. Solutions

Work in Information Tecnology as a Project Engineer. I was a part of the Developement Team of Infinity TS and of the SIST Team for Edison.

- C# and .NET development
- Advanced VBA Excel Reports for Microdoft Office Project 2003
- Oracle Db creation and managing.
- Graphic Pages developement in PI ProcessBook (Osisoft)
- Visual Basic developement for ESRI ArcMap Add-Ons

Education

Bachelor of Arts in Biomedic Engineering — Sep 1999 - Dec 2006

University of Genoa

G. Marconi College - Chiavari — Sep 1994 - Jun 1999

Qualifications

Qualification: Authorization to operate as Engineer

Area: Civil and industrial buildings, electronics, informatics

Date: 2006

Articles

Advanced Cardiac Therapeutics. August 02, 2010. Volume 10

Ablating with Irrigated RF Safely and Effectively Using Microwave Radiometry Sensing Technology

Interest

NLP - Neuro Linguistic Programming

Neuro-linguistic programming (**NLP**) is an approach to psychotherapy, self-help and organizational change. NLP is a model of interpersonal communication and a system of alternative therapy which seeks to educate people in self-awareness and effective communication, and to change their patterns of mental and emotional behaviour.

Photography; Martial Arts

Music; Archery

Languages

Italian: native speaker

English Listening : B1 Reading : B2 Speaking: B2 Writing : B1

Spanish Listening : A2 Reading : B1 Speaking: A2 Writing : A2

Courses performed or attended during the last 5 years

Last update: October 02, 2019

Title: MDR Conformity Assessment Routes

Trainer: BSI **Date**: July 16, 2019 **Duration:** 1 h

Title: MDR Day (Tutor for Clinical Evaluation and PMCF)

Trainer: 1MED SA **Date**: June 06, 2019 **Duration:** 5 h

Title: Clinical Evaluation Course (Tutor)

Trainer: 1MED SA @TUV Rheinland **Date**: Nov 22, 2018 **Duration:** 8 h

Title: Medical Device Single audit Program (MDSAP)

Trainer: TUV Rheinland **Date**: Oct 6, 2017 **Duration:** 8 h

Title: Le novità riguardo le prove di sicurezza sulle apparecchiature elettromedicali e i nuovi aggiornamenti normativi del settore Medical Device

Trainer:TUV Rheinland **Date**: Oct 20, 2017 **Duration:** 4 h

Title: Il Nuovo Regolamento per i Dispositivi Medici

Trainer:TUV Rheinland **Date**: Sept 28, 2017 **Duration:** 8 h

Title: Clinical Evaluation Course (Tutor)

Trainer: 1MED SA @TUV Rheinland **Date**: Sept 27, 2017 **Duration:** 8 h

Title: ISO 13485:2016 Lead Auditor Course

Trainer: BSI **Date**:August 28 - Sept 1st, 2017 **Duration:** 40 h

Title: Clinical Evaluation for Medical Device Course

Trainer: BSI **Date**: June 19, 2017 **Duration:** 8h

Title: implementing ISO 14971

Trainer: BSI **Date**: May 22-23, 2017 **Duration:** 16h

Title: Medical Device Regulation - Implications on manufacturers resources

Trainer: BSI **Date**: July 26, 2016 **Duration:** 1h

Title: Internal and External Audits

Trainer: 1MED sa **Date**: June 02, 2016 **Duration:** 8h

Title: ISO 13485 Sistema di Gestione Qualita per Dispositivi Medici – Contenuti generali, novità e tecniche di auditing

Trainer: TUV Rheinland **Date**: March 29, 2016 **Duration:** 8h

Software & Hardware Knowledge

Microsoft Windows 10, 8, 7, XP, 2000, 95, 98, MS-DOS, Ms Windows Server, Mac Os

Visual Studio (C#, .NET, Visual Basic), Visual Basic 6, VBA

Microsoft Office 365 and 2013 (Excel, Word, Access, MS Project , Visio, PowerPoint, Outlook)

Osisoft PI System

ESRI ArcMAp and ArcOjbect Developement

Photoshop CS5, CS6, CC, Lightroom, Gimp

VmWare (Workstation, Converter)

Oracle, SQL2005

Maya, Vue Xstream , EyesWeb, Labview, Matlab

Professional Area

Medical Device Technology

- Quality System Certifications (ISO 13485; ISO 9001)
- Technical File preparation in conformity with Medical Device Directive and ISO standards
- Risk Analysis (ISO 14971)
- Clinical Evaluation in conformity with MEDDEV guidelines
- US & European Medical Device Regulations
- Clinical Trials start-up and preparation of key documents for the clinical trial management
- CE Marking regulatory strategy
- FDA premarket notification

Title: New versions of ISO 13485 and ISO 9001, what do you need to consider?

Trainer: BSI **Date**: March 23, 2016 **Duration:** 1h

Title: Publication of the Medical Device International Standard ISO 13485

Trainer: BSI **Date**: March 09, 2016 **Duration:** 1h

Title: Direttiva Dispositivi Medici 93/42/EEC - Overview e Approfondimenti

Trainer: TUV Rheinland **Date**: Nov 04, 2015 **Duration:** 8h

(Teacher) ASSOBIOMEDICA Course: "Le indagini cliniche con i dispositivi medici: quadro normativo"

Trainer: Ivano Oliveri **Date**: September 29, 2015 **Duration:** 3h

Title: Clinical evaluation, clinical investigations, do you have enough evidence?

Trainer: BSI **Date**: July 07, 2015 **Duration:** 1h

Title: Aggiornamenti normativi per il settore dei dispositivi medici, Unannouced Audits – Clinical e Combination products

Trainer: BSI **Date**: July 02, 2015 **Duration:** 4h

MAIN PROJECTS

Period: March 2018 - ongoing

Therapeutic Area : minimally invasive surgery

Product: Surgical robotic system and accessories

Activities: Clinical Evaluation, Quality System

Period: May 2017 - ongoing

Therapeutic Area : radiotherapy ablation

Product: device for local radiotherapy ablation with beta-emitter

Activities: Quality System, Product Design&Development, Clinical Trial, Pre-Clinical Activities, Risk Management

Period: January 2016 - ongoing

Therapeutic Area : vascular surgery

Product: nitinol implant for EVAR devices

Activities: Product Design&Development, Pre-Clinical Activities, Risk Management, Clinical Evaluation

Period: April 2016 - ongoing

Therapeutic Area : tissue engineering

Product: vascular grafts, nerve grafts

Activities: Quality System, Product Design&Development, Clinical Trial, Pre-Clinical Activities, Risk Management, Clinical Evaluation

Period: June 2016 - ongoing

Therapeutic Area : dental care

Product: dental implants and related accessories

Activities: Clinical Evaluation , Risk Management, Quality System, Certification process

Period: September 2015 - June 2016

Therapeutic Area : wound management

Product: silk fibroin dressing

Activities: Quality System, Product Design&Development, Certification process, Risk Management, Clinical Evaluation

Period: January 2012 - ongoing

Therapeutic Area : wound management, dental care, dermatology

Product: wound management, oral care products, dermal care products

Period: October 2012 - June 2016

Therapeutic Area : neonatal monitoring

Product: wireless system for neonatal monitoring of vital parameters

Activities: Quality System, Product Design&Development, Pre-Clinical Activities, Risk Management, Clinical Evaluation

Period: September 2014 - November 2015

Therapeutic Area : cardiology - European project

Product: contactless System for non-invasive screening of the status of the vascular system

Activities: Quality System, Product Design&Development

Period: June 2011 - February 2015

Therapeutic Area : dental care

Product: dental implants

Activities: Quality System, Product Design&Development, Certification process, Pre-Clinical Activities, Risk Management, Clinical Evaluation

Period: January 2011 - January 2015

Therapeutic Area : dermal care, orthopaedics, otolaryngology, wound management

Product: wound dressing, dermal filler, viscosupplementation devices, products for management of respiratory diseases-

Activities: Quality System, Clinical Evaluation

Period: January 2010 - ongoing

Therapeutic Area : cardiology

Product: clip, annuloplasty rings and other devices for the treatment of mitral/tricuspid valve regurgitation

Activities: Clinical Evaluation, Clinical Trials StartUp

Agno, 08 Oct 2020