

**Medical Engineer, PRRC, Lean Six Sigma trained**

Pragmatic, *down-to-earth* implementation of commonly used quality standards and quality management systems. Able to interpret and translate these standards and systems to an operational level, based on operational needs while avoiding the introduction of overhead and bureaucracy. Shape the QAVRA organization to be able to sustain the future of quality management across all functions throughout the organization

WORK EXPERIENCE

- 12/22 – to date **Healthcare Category Manager – Consip SpA**  
 Via Isonzo, 19E - 00198 Roma, RM – [www.consip.it](http://www.consip.it)  
 Consip is the Italian national Central Purchasing Body. I am responsible for managing healthcare public procurement processes and defining innovative methods for remuneration by cooperating with national health authorities, KOLs, economic and legal experts
- 07/20 – to date **Consultant – CREA Sanità**  
 Piazza A. Mancini, 4 - 00196 Roma, RM– [www.creasanita.it/en](http://www.creasanita.it/en)  
 Author of the chapter dedicated to the healthcare personnel for the *Annual Report on Healthcare Status* issued by CREA Sanità
- 04/16 – 12/22 **PRRC, Person Responsible for Regulatory Compliance – COSMED The Metabolic Company**  
 Via dei Piani di Monte Savello, 37, 00041 Albano Laziale, RM – [www.cosmed.com](http://www.cosmed.com)  
 Involved in assuring quality compliance and design controls throughout whole projects according to EU MDD/MDR, US FDA requirements and international standards IEC 60601-1 series, IEC 62304 (Software Development Lifecycle), IEC 62366 (Usability), ISO 14971 (Risk Management) by providing also training and regulatory support to a team of 8 developers  
 Experience in interfacing and leading Notified Body and international regulatory agency audits to maintain the following certifications:

	<i>Total amount of third party audit experience</i>
Medical CE mark	60 hours
ISO 9001:2015	48 hours
ISO 13485:2016	48 hours
MDSAP	48 hours
Anvisa Brasil	24 hours

Involved in FDA's 510(k) submissions and directly responsible for the UDI – *Unique Device Identification* implementation for US, European and Chinese markets
- 10/15 – 03/16 **Project Manager Assistant – COSMED The Metabolic Company**  
 Via dei Piani di Monte Savello, 37, 00041 Albano Laziale, RM – [www.cosmed.com](http://www.cosmed.com)  
 Implementing *Lean* and *Agile* methodologies in company's Quality System: Voice of the Customer collection, VOC Tree analysis, CTQs translation, Quality Function Deployment for product performance optimization and Visible Planning (SIPOC, Swimlane diagram, Value Stream Mapping, 5S) for process optimization. This activity has led to the commercialization and marketing of a Class I medical device fully meeting requirements specified by relevant stakeholders (clinicians, academics)
- 05/11 – 08/11 **Medical Engineer – Tor Vergata General Hospital in partnership with Esaote SpA**  
 Viale Oxford, 81 - 00133 Rome  
 Running of certification tests and maintenance procedures on medical devices. Administration of the hospital medical device inventory using InfoHealth database software

EDUCATION

- 03/24 – to date **Training on Artificial Intelligence applications in Healthcare – Regulatory, economic and organizational aspects**  
 Catholic University of the Sacred Heart (<https://altems.unicatt.it/altems-tutti-i-master-competenze-e-servizi-giuridici-in-sanita/altems-corsi-di-alta-formazione-valutazione-delle-applicazioni-dell-intelligenza-artificiale-in-sanita>)

- 04/18 – 02/19 **Post Graduate Degree in Healthcare Economics and Management**  
University of Rome – Tor Vergata in partnership with CREA Sanità Consortium ([www.creasanita.it/en](http://www.creasanita.it/en))
- 10/12 – 07/15 **Master of Science in Medical Engineering – Final Grade: 110/110 cum Laude**  
University of Rome – Tor Vergata, Industrial Engineering Department
- 10/07 – 07/12 **Bachelor of Science in Medical Engineering – Final Grade: 106/110**  
University of Rome – Tor Vergata, Industrial Engineering Department
- 09/01 – 07/06 **Scientific High School Diploma – Final Grade: 100/100**  
Lyceum “Vito Volterra” – Ciampino (RM)

#### ADDITIONAL COURSES

---

- 12/20 **Health Technology Assessment – The University of Sheffield, [www.futurelearn.com](http://www.futurelearn.com) | 3 weeks**
- 12/20 **Measuring and Valuing Health – The University of Sheffield, [www.futurelearn.com](http://www.futurelearn.com) | 3 weeks**
- 03/20 **ISO 9001 Qualified Internal Auditor Training – ArealSO, online | 8 hours**
- 03/20 **ISO 9001 Third Party Auditor Training – TÜV Essen, online | 8 hours**
- 10/19 **Medical Devices in Europe: Clinical Evaluation & Post Marketing Surveillance – TÜV SÜD Headquarter, Bologna | 16 hours**
- 09/19 **The New Medical Device Regulation (MDR) 2017/745 – Lodi Consulting, Rome | 8 hours**
- 06/19 **Regulatory Workshop Focused on EU MDR 745/2017 requirements – Assobiomedica | 8 hours**
- 05/19 **Medical Device Technical File for EU MDR 745/2017 – Eurofins-Lab, Milan | 8 hours**
- 05/19 **How to Facilitate Regulatory Meetings – RAPS Webinar (1.5 RAC Credits) | 2 hours**
- 04/19 **Team Working Training – Mentorship provided by a FranklinCovey certified coach | 30 hours**
- 09/18 **European Medical Device Regulation EU 2017/745 – Kiwa, Bologna | 8 hours**
- 04/18 **Lean Six Sigma Green Belt training – TUM Technische Universität München MOOC | 90 hours**  
Certificate ID for part 1/3: <https://courses.edx.org/certificates/be0a421e7e2945c88429d5fb6615b925>  
Certificate ID for part 2/3: <https://courses.edx.org/certificates/836521e35732470ba1f07df4f33ec7ae>  
Certificate ID for part 3/3: <https://courses.edx.org/certificates/8063406b95d24478af25ea079769d83b>
- 07/17 **ISO 13485:2016 – TÜV SÜD Headquarter, Bologna | 8 hours**
- 05/15 **Lean Six Sigma Yellow Belt – Six Sigma Academy, University of Rome Tor Vergata | 16 hours**

#### ANNEXES

---

- Healthcare Economics and Management Post-Graduate Degree thesis  
Link: [Digital Health thesis](#)

Rome, 30/05/2024

