

## PERSONAL INFORMATION

## Alice ing. RAVIZZA



Sex F | Date of birth 18/12/1979 | Nationality Italian

## POSITIONS

- Founder, USE-ME-D srl and InsideAI srl ad GeneRa srl
- Registry Manager for “Medical Devices Responsible Person” Registry at AICQ- SICEV
- Medical Device Responsible Person article 15 MDR, Technogym spa and Advice Pharma srl
- Regulatory coordinator, DTx \_ Fondazione Smith Kline
- Board Member, bioPmed
- Member, Biomedical commission and Innovation Commission at Ordine degli Ingegneri, Torino
- Member, Centro Studi at AIIC Associazione Italiana Ingegneri Clinici
- Expert, EU Expert Horizon 2020 EX2014D182129

## WORK EXPERIENCE

## ● Teaching experience

- 2022- lecturer for MIP Politecnico di Milano Graduate School of Business.
- 2020- current: adjunct professor at Università di Pisa, for the Master “Teledidattica Applicata alle Scienze della Salute e ICT in Medicina”
- 2018 - current: lecturer for Osservatori Digital Innovation della School of Management del Politecnico di Milano
- 2017- current: invited professor at Università di Torino Master "Tecnologie Farmaceutiche e Attività Regolatorie"
- 2017- current: Course director for “Medical Devices Responsible Person” for Confindustria Dispositivi Medici Servizi- AICQ approved
- 2020-2019-2018: adjunct professor at Politecnico di Torino (INCARICO DIDATTICO A DOCENZA ESTERNA) for the courses Fondamenti di Normativa per Dispositivi Medici (01SRXMV), Ingegneria per la medicina rigenerativa (01QHGMV) and New advances in alternative pre-clinical trials (01UCQMV) sectors ING-IND/22, ING-INF/06, ING-IND/34
- 2013- current: Trainer of Auditors at Notified Bodies (Rina Services and DNV GL); Trainer at Auditor courses for ISO 9001:2015 and ISO 13485:2016- AICQ approved; trainer at Confindustria Dispositivi Medici Servizi and Bioindustry Park Silvano Fumero
- 2012- current: invited Lecturer at Politecnico di Milano, Politecnico di Torino, Università di Torino, Università di Bologna and Università di Pisa; UBORA First Design School – University of Nairobi, with Università di Pisa; lecturer and mentor at UBORA Second Design School –Università di Pisa

## ● Experience in CE marking of Medical devices

- 2022 - Founder, GeneRa srl an innovative startup company
- 2021- current: Founder, InsideAI srl an innovative startup company preincubated at I3P Politecnico di Torino

- 2018- current: Founder, USE-ME-D srl an innovative startup company preincubated at I3P Politecnico di Torino
- 2012- current: Regulatory consultant. CE marking and fully compliant ISO 13485 and GMP Quality Management System of multiple innovative devices
- 2016-2020 Regulatory and QA Manager Epygon s.r.l. designing an innovative mitral valve, bovine derived pericardium.
- 2014-2018 Regulatory consultant for Haemotronic s.p.a and Karolinska Hospital as part of the PVC Free Blood Bag programme
- 2013-2016 MDD technical Expert for DNV GL; Auditor at DNV GL Italy for ISO 9001:2015 and 13485:2012 and ISO 13485:2016
- 2008-2010 CTO at Medical Molding and manufacturing de Mexico, SRLdC, Reynosa Mexico ISO 13485:2003
- 2001-2012 R&D Manager at Haemotronic spa. CE Marking of 4 different classes of plastic medical devices; ISO 13485:2003 and ISO 13485:2012

Presentations  
Conferences  
Seminars

**Notified bodies**

- 8 June 2016; 2-3 July 2015 at DNV GL “Calibration Meeting”. In English and Italian.
- 10-11 September 2014 at DNV GL “Qualification course Medical Devices and ISO 13485”.
- 7-8 April 2016 at RINA Services “Auditor training: the technical file”. In Italian.
- 1-2 and 15-16 February 2017 course approved at AICQ for Medical Device Auditors
- 18 May 2017 at RINA Services “ISO 13485:2016”. In Italian.

**Universities:**

- 2014-2020 at Politecnico di Torino, corso “Ingegneria per la medicina rigenerativa” course “Introduzione ai dispositivi medici: le norme relative alla validazione dei dispositivi biomimetici.”
- 7 June 2018 and 24 June 2019: “Biocompatibility Standards” at Università di Bologna, Master in biomedical plastics
- 2018-2021: Introduction to Medical Device Regulation, at Università di Torino Master in affari regolatori,
- 23 May 2017: “Human Factors Engineering” at Politecnico di Milano, Progettazione di Sistemi di Supporto alla Vita
- 24 May 2016, 2 May 2017, 25 June 2018: “Introduction on Medical devices” and “Risk management” at Università di Pisa. In English and Italian
- 29 January 2016 “Introduction on Medical devices” at Centro di ricerca E. Piaggio, Università di Pisa. In English
- 18 May 2016; 13 and 20 May 2015; 12 April and 10 May 2013 ; 9 May 2014 and 16 May 2014 at Politecnico di Milano, Progettazione di Sistemi di Supporto alla Vita course “Medical devices design: from the laboratory to the production department”. In English and Italian.
- April 22nd and April 29th, 2013 At Dottorato in Tecnologie applicate alle scienze chirurgiche, , Università di Medicina e Chirurgia, Torino, course “I dispositivi medici nella pratica clinica e sperimentale”. In Italian. January 2013 At Dottorato in Scienze della Vita e della Salute, Politecnico di Torino, course: “Fabbricazione e certificazione dei dispositivi biomedici: dalla ricerca all’industria”. In Italian.

**Training for companies:**

- From 2012 multiple courses on Medical Devices at Bioindustry Park Silvano Fumero
- From 2014: multiple courses on Medical Devices for Quality Systems Srl- Training & Consulting;
- From 2020- current: multiple courses on Medical Devices for Confindustria Dispositivi Medici Servizi

Patents-

- 2021 “Dispositivo elettromagnetico di ablazione tissutale” n 102020000008518
- 2018 Metodo per la verifica dimensionale di modelli generati mediante fabbricazione additiva IT102018000002833
- 2017 “Dispositivo utilizzabile nel trattamento chirurgico di disfunzioni uro-ginecologiche” ITUA20163503A1 • 2017-11-17

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- 2010 “KIT FOR THE EXTRACORPOREAL TREATMENT OF A BIOLOGICAL FLUID OF A PATIENT, AND UNIT PROVIDED WITH SAID KIT” EP2160213 (A2) marketed as device Chiaraset
- 2008 ” CATHETER FLUSH AND FILL UNIT” WO2009147510 (A1) marketed as device Haemocatch
- 2007 “CHECK VALVE FOR A MEDICAL DEVICE “WO2009031018 (A2)
- 2005 Sacca a più compartimenti ITTO20050083

Publications See Annexed list

Auditing experience

- Third part: around 23 man/days of third party audits, including 9001; 13485, MDD class IIa and IIb
- Second part, supplier audits: around 80 man/days, including class IIa, class IIb, suppliers of raw materials, suppliers of pericardium, suppliers of sterilization services
- Internal audits: 10 man/days of internal audits at Medical Molding (class IIa), Biotechware (class IIa), Epygon (class III)
- Person Responsible Article 15 MDR Audits: 15 days at Technogym Spa

## EDUCATION

2003

BIOMEDICAL ENGINEERING MASTER DEGREE AT POLITECNICO DI MILANO

2016

Master di I livello in Bioetica e consulenza in Etica Clinica at Università di Torino

Affiliations Ordine degli Ingegneri della Provincia di Torino

## PERSONAL SKILLS

Mother tongue(s) Italian

Levels: A1/2: Basic user - B1/2: Independent user - C1/2 Proficient user  
COMMON EUROPEAN FRAMEWORK OF REFERENCE FOR LANGUAGES

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	Bilingual	Bilingual	Bilingual	Bilingual	Bilingual
Spanish	Bilingual	Bilingual	B2	B2	B2

Autorizzo il trattamento dei miei dati personali presenti nel cv ai sensi del Decreto Legislativo 30 giugno 2003, n. 196 “Codice in materia di protezione dei dati personali” e del GDPR (Regolamento UE 2016/679)