PERSONAL INFORMATION Silvia Ciampa

WORK EXPERIENCE

From Dec 2020 - ONGOING

Biomedical engineer officer – Medical devices assessor

Italian Ministry of Health, Department of Health Planning, Medical Devices, Drugs and Policies for the National Health Service, Medical Device and Pharmaceutical Service Directorate, Medical Device Clinical Investigations and HTA Office

Sector Public Health

- Investigational medical devices technical-regulatory assessor
- Technical validation, assessment and safety monitor of clinical investigation applications under MDR
- Member of the Secretariat of the National Steering Committee for HTA.
- Member of the Emerging Health Technologies subgroup of the HTA coordination group under the regulation EU 2021/2282
- Alternate member of the HTA Coordination group
- Alternate member of the Clinical Investigation and Evaluation Working Group within the Medical Device Coordination Group (MDCG). Main activities:
    - Co-leader of the task force for the development of the new MDCG clinical evaluation guidance under MDR
    - Participant in the Questions & Answers regarding clinical investigation task force

From Oct 1st 2022 to Dec 31st 2022

National Expert in Professional Training

European Commission- DG SANTE – Unit D3, Medical Devices (Brussels)

Sector Public Health

- Support activities in the clinical investigation and evaluation and Notified Bodies fields
- Preparatory work to start a task force dedicated to the development of a new guidance

From Oct 2012 to Dec 2020

Technical-sales engineer

Med-logix srl, Roma (www.albahyperthermia.com)

Business Medical Device Developer Company

TECHNICAL-SALES AREA

- Technical product specialist (Europe and Asia)
- Customers training and scientific support
- Tenders' technical documentation
- Clinical/technical marketing materials
- Organize and participate in international conferences, scientific meetings, seminars, and product demonstrations at key reference sites (clinical oncology and radiation oncology departments).

R&D AREA

- Monitor, analyse, and evaluate product performance and customer feedback to improve existing devices and develop new products
- Coordinate R&D projects in collaboration with academic hospitals and universities.
- Collaborate closely with the engineering team to contribute to products testing and development
- Research grant applications

REGULATORY AFFAIRS AREA

- Clinical evaluations and post-marketing surveillance.
- Provide support to the regulatory affairs department by assisting in the preparation of technical dossiers.

From May 2017 to Dec 2020

REGULATORY AFFAIRS FREELANCE CONSULTANT (occasional)

Author for medical device clinical evaluation reports, including a comprehensive literature review, data analysis and appraisal for various medical device categories.

Business Medical Device Regulatory affairs

From Apr 2012 to Sept 2012

RESEARCH INTERSHIP

AMSTERDAM UNIVERSITY MEDICAL CENTER – RADIOTHERAPY DEPARTMENT
Clinical validation of a treatment planning software for oncological deep hyperthermia

Sector Research

EDUCATION AND TRAINING

Form Mar 2021 to Jan 2022

II level post-graduation Master in Health technologies assessment and management

Università Cattolica del Sacro Cuore- Roma

Principles and practice of HTA; HTA methods; Principles and Practice of Systematic Review; Economic evaluation in healthcare; Management of health organizations and impact assessment Ethical, social and legal aspects of HTA; Health systems, HTA and policy making.
Vote: "Best project" award

Feb 2014

Qualification to exercise the profession of industrial engineer

Università di Roma Tor Vergata

AA 2005/2006 - AA 2011/2012

Master of science in Biomedical Engineering **(LM-21)**

Università di Roma Tor Vergata

Electronics, Biomedical Instrumentation, Signal processing, Medical imaging, Mechanics Bio-prosthesis, Modeling and simulation of physiological system, Fundamentals of Medicine, Biomaterials, informatics.
Finale vote: 110/110

Courses

Dec 2023 Course "Nuovo codice dei contratti pubblici"
Italian Ministry of Health

Dec 2022 Training for medical device National Experts involved in Notified Bodies Joint Assessment
European Commission, Dublin

Nov 2021 Intensive course in administrative law
Italian Ministry of Health

Feb 2016 Class IIb medical devices electric safety test
TEST SRL- Perugia

Jan 2016 Quality system management according to ISO 13485
Sistemir srl - Milano

PERSONAL SKILLS

Mother tongue(s) Italian

Other language(s)

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	C1	C1	C1	C1	C1

Speexx Live+1:1 - English certificate issued on 3-09-2021: **C1.1 PASS WITH MERIT**

Organisational and management skills

- Very good team leading skills gained through the past experience in coordinating projects and current experience of leading an international team of regulators
- Very good management skills gained thanks to the past work in a small company where I was used to manage multiple projects in different areas and to the current job where I'm used to manage multiple processes having strict deadlines

Communication skills

- Very good verbal and written communication skills gained through my experience as technical-sales specialist where I was used to communicate with different professionals in multicultural environments
  as well as through my current work experience
- Very good empathy and active listening skills due to my natural predisposition to personal relationships

Technical skills

- Medical device regulations and standards
- Clinical evaluation and clinical investigations of medical devices
- Health Technology Assessment
- Concept, development, marketing and launch of new medical products
- Drafting technical and marketing documentation (project specifications, test procedures, manuals, technical dossier, tender and research grant documents, brochure, presentations, etc.)
- Software functional analysis and validation

Computer skills

Excellent command of Microsoft Office tools and the Internet (ECDL license), Matlab, Balsamiq Mock-up, Use of CAD modeling software (SolidWorks) - basic level, Comsol Multiphysics - basic level

Driving licence

B

Teaching experience

- May 2017: Seminar on the development of a new medical device for deep hyperthermia treatments ALBA 4D, University La Sapienza, Rome, COURSE OF BIOMEDICAL EQUIPMENT, BIOMEDICAL ENGINEERING FACULTY
- July 2024: Lessons on clinical investigations under Medical Device Regulation, University La Sapienza, Rome, DEPARTMENT OF ODONTOSTOMATOLOGICAL AND MAXILLOFACIAL SCIENCES

Publications

- Kok HP, Ciampa S, de Kroon-Oldenhof R, Steggerda-Carvalho EJ, van Stam G, ZumVördeSiveVörding PJ, Stalpers LJ, Geijsen ED, Bardati F, Bel A, Crezee J. Toward online adaptive hyperthermia treatment planning: correlation between measured and simulated specific absorption rate changes caused by phase steering in patients. Int J RadiatOncolBiol Phys. 2014 Oct 1;90(2):438-45
- Toseroni I, Ciampa S, Cavagnaro M. Human body models for validation studies of deep hyperthermia. Int J RF MicrowComput Aided Eng. 2017
- Ferro M., Ciampa S., Cappelli F. R., Pagliaroli E., Sorlani A., Venditelli M. Marker-based registration for antenna positioning in superficial hyperthermia (13th International Congress of Hyperthermic Oncology 2021), https://proceedings.i-rfm.it/content/details/2019/4783841

Projects

- Development, test, certification and marketing of a new radiative system for oncological deep hyperthermia (ALBA 4D, https://albahyperthermia.com/project/alba-4d-precision-hyperthermia/)
- Development of an image-guided robotic superficial hyperthermia applicator position system (https://albahyperthermia.com/brochure_ALBAON4000D.pdf)
- Development of a treatment software and procedure for deep hyperthermia (https://albahyperthermia.com/project/alba-4d-precision-hyperthermia)
- Development of Human body models for validation studies of deep hyperthermia. Int J RF MicrowComput Aided Eng. quality assurance phantom for deep and superficial hyperthermia systems

Conferences

Regulatory Affairs DAY, Associazione Italiana Ingegneria Clinica; ESTRO (European Society for Radiotherapy & Oncology), ESTRO MEETS ASIA, ESHO (European Society for Hyperthermia in Oncology), AIRO (Società Italiana di radioterapia), DEGRO (German Society for Radiotherapy and Oncology), SASRO (Swiss Society for Radiotherapy and Oncology) dal 2013 al 2019

F.TO

Rome, 17/06/2025

Silvia Ciampa