Paolo Pescio, ERT

Skill profile

- European Registered Toxicologist (Regulatory Toxicology)
- Regulatory advice for medical devices
- Business Unit management

Work Experience

11/2020 – present	*Eurofins Biolab S.r.l.* *Vimodrone (MI) – Italy*	*B.U. Manager - Consultancy* Complete management of the Business Unit focused on consultancy services for healthcare products
06/2020 - present	*Fondazione Alma Mater – Bologna*	*Adjunct Professor* "Sicurezza dei biomateriali polimerici" at Master annuale di II livello in “Materiali e prodotti polimerici per il settore biomedicale”
03/2020 - present	*Eurofins Medical Device Testing – Europe*	*Senior Scientific Director* Scientific advice for medical devices testing and consultancy
2016 - present	*Scienze Del Farmaco - Università Degli Studi Di Milano* Milano – Italy	*Adjunct Professor* Regulatory aspects in toxicology - Legislation In European Union
08/2017 – 11/2020	*Eurofins Biolab S.r.l.* Vimodrone (MI) – Italy	*Senior Consultant - Medical Devices* RA/QA consultant – SME - Trainer
08/2016 – 07/2017	*Doctors with Africa CUAMM* Chiulo – Cunene – Angola	*Project Administrator* Financial and logistical project management
01/2014 – 08/2016	*Eurofins Biolab S.r.l.* Vimodrone (MI) – Italy	*B.U. Medical Devices Manager* *GLP Test Facility Manager* Complete management of the Business Unit focused on medical devices testing
2006 - 2013	*Eurofins Biolab S.r.l.* Vimodrone (MI) – Italy	*Medical Devices & Toxicology Manager* *Test Facility Manager*
2004 – 2005	*Barbieri s.r.l. (Gruppo Progettiamo Autonomia)* Reggio Emilia – Italy	*Coordinator “Lycra Project Italy”*: technical responsible for bespoke orthesis
2004 – 2005	*Politecnico di Milano* Milano – Italy	*Lab supervisor "Computer Science B"*

Since November 2018, RENTIC (Registro Nazionale dei Tossicologi Italiani Certificati) member. Since June 2018, SITOX member.
Since July 2021 (and from 2009 to 2018), **member of ISO TC 194 and CEN TC 206** about biological evaluation of medical device. Since July 2021 (and from 2006 to 2018), member (chairman from 2008 to 2016) of Medical Device Technical Commission U4220 of UNI (Italian Organization for Standardization).
From June 2018 to June 2021, **Healthcare Engineering HAS consultant** (managed by E&Y on behalf of the European Commission).

Academic

2014	*University of Surrey- Faculty of Health and Medicinal Sciences* *Surrey - UK*	Master of Science in Applied Toxicology
2004	*Politecnico di Milano* *Milano - Italy*	Master of Science in Biomedical Engineering

Professional Qualifications

2018	European Registered Toxicologist
2005	Professional Engineering qualification

Lectures / Speeches *(last 10 years)*

2022	*TÜV Rheinland Italia*	Chemical Characterisation of Medical Devices
	3rd Hybrid Conference Biocompatibility Testing In Medical Devices - BCF	Risk Management for Biocompatibility Evaluation
2021	*Conference E&L Europe 2021*	Going beyond the ISO 10993-18
	2nd Annual Extractables & Leachables Online Conference - BCF	ISO 21726: Biological Evaluation of Medical Devices - Application of the Threshold of Toxicological Concern
	Biological and Clinical Evaluations Conference for Medical Devices – Sweden	Safety is more than biocompatibility: MDR general requirements and ISO 10993 series
	2nd Online Conference Biocompatibility Testing In Medical Devices - BCF	2021 Updates on Test for Irritation Caused by Medical Device: Key Factors of Result Interpretation
2020	*Conference E&L Europe 2020*	ISO 10993 evolution: when 17 arrives after 18
	MedTech Meetup 2020 – Belgium	Chemical Characterisation: a prerequisite for the biological evaluation
2019	*3rd Symbioteq Biocompatibility of Medical Devices Conference 2019*	Harmonization under MDR: insights from an HAS consultant
	TÜV Rheinland Italia	*Valutazione biologica dei Dispositivi Medici: corso avanzato* Biological evaluation of medical devices: advanced course
2018	*TÜV Rheinland Italia*	*Biocompatibilità e ISO 10993-1: l'approccio e gli strumenti per una corretta applicazione ai dispositivi medici*
	Conference: "Sterilization validation and cleaning validation of MD" LiMed Israel	Cleaning & reprocessing validation
2017	*Conference: "Biological evaluation of medical devices" LiMed Israel*	ISO 10993 standard series: approaching biocompatibility within a risk management process
	CORSO DI PERFEZIONAMENTO "La gestione dei dispositivi medici e cosmetici: aspetti regolatori" Università degli Studi di Milano	*In vitro* testing
2015	*Asociación Española de Farmacéuticos de la Industria (AEFI)*	Cleaning validation: health based exposure limits in shared facilities
	Symbioteq Conference Biocompatibility of Medical Devices	How to conduct and plan a toxicological and biological evaluation when heading for a world-wide submission. What about global harmonization?
	9th annual E&L Europe Conference	Integrated approach for the toxicological evaluation of substance leaching out from medical devices
2014	*Eurofins Biolab S.r.l.*	Cleaning Validation: determinazione tossicologica dei criteri di accettabilità
	Ionisos Ibérica	Microbiological Approaches To Dose Setting
2013 - 2021	*Life Sciences Skillnet – Ireland*	Biological Evaluation of Medical Devices ISO 10993 (10 editions)

Articles

2022	Pescio, P. "Risk management for biocompatibility evaluation" Journal of Medical Device Regulation (2022) https://globalregulatorypress.com/product/risk-management-for-biocompatibility-evaluation
2018	De Jong, W.H., et al. "Round robin study to evaluate the reconstructed human epidermis (RhE) model as an in vitro skin irritation test for detection of irritant activity in medical device extracts" Toxicology in Vitro (2018), https://doi.org/10.1016/j.tiv.2018.01.001