Curriculum Vitae

General Information

Name Last name	**Enrico Perfler**
Title	**Biomedical Engineer**
Address	Via Lardirago 31, 27100 Pavia
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Nationality	Italian
Birth date	04/08/1976
Place of birth	San Giovanni Valdarno (AR)
Fiscal code	PRFNRC76M04H901E

Professional area

Medical Device Technology

Summary

Italian expert of International Organization for Standardization ISO/TC 194 Biological evaluation of medical devices - WG17 Nanomaterials

Member of the Medical Device Technical Committees of UNI (Italian Organization for Standardization) Commission U4201 “Non Active Medical Devices – Biological Evaluation” and Commission U4205 “Surgical Implants”

Member of AFI - Pharmaceutical Industry Association - WG "Medical Device Develeopment"

Regulatory expertise for cardiovascular percutaneous transcatheter technologies

Regulatory expertise for implantable devices

Professional experience

Date	01/09/2010 →
Name of company	Eudax s.r.l., via Cuzio 41, 27100 Pavia (Italy)
Job	Director
Area	Medical Device Technology
Main activities and responsibilities	Strategic, technical and quality support to medical device company to conduct clinical investigations in Europe. Regulatory assistance to medical device companies to obtain CE-marking or FDA premarket approval. Compliance assessment to GMP, GCP, and ISO 13485.
Date	21/03/2008 → 21/03/2010
Name of company	Meditrial s.r.l., via Savoia 78, 00198 Rome (Italy)

Job	Executive Manager, Regulatory & Quality Assurance
Area	Contract Research Organization: regulatory and quality assurance of medical technology companies, project management of clinical studies (drugs – medical devices), audit for compliance to GMP, GCP, ISO 14155, ISO 13485, ISO 9001, data management, data analysis and biostatistics.
Main activities and resposnibllities	Project managing and regulatory & quality assurance (risk analysis per ISO 14971 technical dossier preparation and review, literature review, data management and biostatistics), audit to check compliance to GMP, GCP, ISO 13485, ISO 9001, ISO 14155-1-2, FDA Cfr Part 820, MDD 93/42/EEC.
Dates	12/09/2007 →
Name of company	QEC Ltd. - Celab s.r.l., via maira snc 04100 Latina
Job	Lead Auditor for QMS ISO 9001 and ISO 13485
Area	Quality Assurance Certification
Main activities and responsibilities	Assessment of conformity to ISO standards and factory inspections.

Dates	01/12/2006 → 01/12/2007
Name of company	Anthen Ltd., 20-22 Bedford Row, London WC1R4JS
Job	Technical Director
Area	Technical Design for medical technology companies
Main activities and responsibilities	Project managing and regulatory & quality assurance (risk analysis per ISO 14971technical dossier preparation and review, literature review, data management and biostatistics), audit to check compliance to GMP, ISO 13485, ISO 9001, ISO 14155-1-2, FDA Cfr Part 820, MDD 93/42/EEC for a broad range of International companies: - SurfTable GmbH - Photon Ltd - Merlin Medical GmbH
Dates	01/02/2005 → 30/11/2006
Name of company	Piezosurgery s.r.l., via Portobello 12 16039 Sestri Levante (GE)
Job	Product Manager
Area	Ultrasonic medical devices for microsurgery
Main activities and responsibilities	Project managing and regulatory & quality assurance (risk analysis per ISO 14971technical dossier preparation and review, literature review, data management and biostatistics), audit to check compliance to GMP, ISO 13485, ISO 9001, ISO 14155-1-2, FDA Cfr Part 820, MDD 93/42/EEC for company products.
Dates	01/09/2003 → 31/12/2004
Name of company	University of Genova (ITALY) - Faculty of Engineering
Job	Researcher
Area	Biomechanics
Main activities and responsibilities	Gait analysis and biomechanics of human body - Laboratory experiments for student of Biomechanics 2.

Education	
Date	21/05/2003
Qualification	MD in Biomedical Engineering
Area	Biomedical Engineering, electronics, biomechanics
Institution	University of Genova (ITALY) - Faculty of Engineering
Date	11/07/2003
Qualification	Authorization to operate as Engineer
Area	Civil and industrial buildings, electronics, informatics
Institution	Ordine degli Ingegneri della provincia di Genova
Date	30/06/2006
Qualification	ISO9001:2000 Lead Auditor
Area	Quality Assurance System
Institution	QEC Ltd. – CELab srl
Date	11/12/2008
Qualification	Member of Techical Commission – U4220 Quality Management Systems
Area	Quality Assurance Systems
Institution	Ordine degli Ingegneri della Provincia di Genova
Date	11/12/2008
Qualification	Member of Techical Commission - Biomedical Engineering
Area	Biomedical Technologies
Institution	Ordine degli Ingegneri della Provincia di Genova
Date	16/12/2009
Qualification	RSPP Responsible for Protection and Prevention in Safety (Module C)
Area	D.L.81/2008 Safety on work environment
Institution	Confindustria (GE)
Date	20/02/2009
Qualification	Member of Technical Commission UNI U4220 “Quality Systems”
Area	Quality Assurance Systems
Institution	UNI - Italian Organization for Standardization
Date	01/01/2011
Qualification	Member of the SSFA Medical Device Workgroup
Area	Medical Devices
Institution	SSFA – Society for Applied Pharmacological Sciences
Date	28/09/2011
Qualification	Member of Technical Committees UNI U4201 “Non Active Medical Devices – Biological Evaluation” and U4205 “Surgical Implants”
Area	Medical Device – UNI-EN-ISO Standards
Institution	UNI - Italian Organization for Standardization
Date	13/10/211
Qualification	ISO/TC 194 Biological evaluation of medical devices - WG17 Nanomaterials

Area	Biological Evaluation of Medical Devices
Institution	ISO

Conferences, Meetings & Courses

Date	June 12-13, 2013
Event	*SPEAKER* at National Symposium AFI "Le imprese farmaceutiche ed i settori collegati: quale futuro?"
Location	Rimini (RN)
Topic	"Un nuovo dispositivo medico border-line: valutazione pre-clinica e clinica"
Date	May 23, 2013 (10:00 - 13:00)
Event	UNI - TC U4201 “Non Active Medical Devices – Biological Evaluation”
Location	Milano (MI)
Topic	"Standardization for medical devices"
Date	May 10, 2013 (14:00 - 17:00)
Event	Lecture, Master Universitario di II Livello "Trasferimento tecnologico, imprenditorialità e innovazione nei settori hihg tech"
Location	Genova (GE)
Topic	"La certificazione: norme, procedure e attori"
Date	April 22-26, 2013
Event	Meeting of ISO TC 194 "Biological Evaluation of Medical Devices" (Technical Expert WG17, WG15 and Event Manager)
Location	Pavia (PV)
Topic	"Standardization in the medical device sector"
Date	March 28, 2013 (10:00 - 13:00)
Event	Lecture, Politecnico di Milano, Industrial Design
Location	Milano (MI)
Topic	"Regulatory Affairs in Medical Device Development"
Date	February 15, 2013 (10:00 - 13:00)
Event	Presentazione master universitario di secondo livello
Location	Genova (GE)
Topic	"Trasferimento tecnologico, imprenditorialità e innovazione nei settori high tech"
Date	February 6, 2013 (09:30 - 12:45)
Event	L'Innovazione tecnologica nel settore dei dispositivi medici: le startup e il trasferimento tecnologico
Location	Milano (MI)
Topic	"Lo scenario italiano sulle startup e sull'innovazione nell'ambito biomedicale"
Date	January 11, 2013 (10:30 - 13:30)
Event	AFI - meeting WG "Medical Device"
Location	Milano (MI)
Topic	"Presentations at AFI National Symposium" open discussion
Date	November 8-9, 2012
Event	Meeting of ISO/TC 194 "Biological Evaluation of Medical Devices"
Location	Delft - NL
Topic	"WG17 Nanomaterials" - technical writing committee meeting
Date	November 6, 2012
Event	*TRAINER* at Eurofins-Biolab s.r.l.
Location	Vimodrone (MI)

Topic	"Indagini cliniche con dispositivi medici: approccio strategico alla gestione di studi pre e post marketing"
Date	October 12, 2012 (10:00 - 13:00)
Event	UNI - TC U4201 “Non Active Medical Devices – Biological Evaluation”
Location	Milan, Italy
Topic	"Review of ISO standards related to non active medical devices"
Date	October 2-4, 2012
Event	*SPEAKER* at Medical Device Group (MDG) Forum
Location	Boston, MA - USA
Topic	"Medical Device Clinical Evaluation: Regulatory Challenges for Compliance to EU Requirements"
Date	September 19, 2012 (14:30 - 18:00)
Event	AFI - meeting WG "Medical Device"
Location	Milan, Italy
Topic	"Borderline products: regulatory challenges"
Date	May 30-31, 2012
Event	*SPEAKER at 52° National Symposium AFI* (Avviamento indagini cliniche pre-market nei dispositivi medici borderline, Sala del Tempio II, ore 10:00)
Location	Rimini, Italy
Topic	"Ricerca, innovazione e nuove tecnologie: fattori essenziali per il progresso del settore farmaceutico"
Date	May 10, 2012
Event	*SPEAKER at PLG* Italy (Prospettiva sul rapporto tra mondo farmaceutico e quello del MD)
Location	Bologna, Italy
Topic	"Medical Device e settore farmaceutico: quali opportunità"
Date	April 24, 2012 (14:00 - 18:00)
Event	AFI - meeting WG "Medical Device"
Location	Milan, Italy
Topic	"Preview presentations for national symposium AFI 2012"
Date	April 17-20, 2012
Event	The 23rd meeeting of ISO/TC 194 "Biological Evaluation of Medical Devices"
Location	San Diego (CA), USA
Topic	"Review of ISO 10993 serie"
Date	March 30, 2012 (10:00 - 13:00)
Event	UNI - TC U4201 “Non Active Medical Devices – Biological Evaluation”
Location	Milan, Italy
Topic	"ISO 13485:2012 and recent review of ISO standards related to non active medical devices"
Date	March 27, 2012 (14:00 - 18:00)
Event	AFI - meeting WG "Medical Device"
Location	Milan, Italy
Topic	"Regulatory discussion re: medical device development"
Date	March 6-7, 2012
Event	4th Annual Medical Devices Summit
Location	Boston (MA), USA
Topic	"Key Issues in compliance, quality and innovation""
Date	February 17, 2012 (14:00 - 18:00)
Event	AFI - meeting WG "Medical Device"
Location	Milan, Italy
Topic	"Open discussion about italian regulatory authorities"
Date	January 26, 2012

Event	AIFA, Italian Medicines Agency
Location	Rome, Italy
Topic	"10 Anni di Osservatorio Nazionale sulla Sperimentazione Clinica dei Medicinali: uno sguardo al futuro"
Date	January 17, 2012 (14:00 - 18:00)
Event	AFI - meeting WG "Medical Device"
Location	Milan, Italy
Topic	"Presentations for national symposium AFI 2012"
Date	December 4-6, 2011
Event	*SPEAKER at ICI* – Innovations in Cardiovascular Interventions (Technology Parade II, December 5, 16:42 - "Straight to the CE-mark")
Location	Tel Aviv, Israel
Topic	Interventional Cardiology
Date	November 8 - 11, 2011
Event	TCT 2011
Location	San Francisco (CA), USA
Topic	Educational meeting in interventional cardiovascular medicine
Date	October 24, 2011
Event	UNI CEI EN ISO/IEC 17021 - Conformity Evaluation
Location	Milan, Italy
Topic	Requirements for conformity evaluation and audit of quality management systems
Date	October 13, 2011
Event	Technical Committee UNI U4201 “Non Active Medical Devices – Biological Evaluation”
Location	Milan, Italy
Topic	Biological Evaluation of Medical Devices - Standards
Date	October 6, 2011
Event	Investigator’s Meeting
Location	Genova, Italy
Topic	Clinical Validation and CE-marking (endosseous dental implant)
Date	September 28, 2011
Event	Development Team Meeting
Location	Cisano Bergamasco (BG), Italy
Topic	Development Plan & Pre-Clinical Validation (medical device for mitral annuloplasty)
Date	September 16, 2011
Event	Development Team Meeting
Location	Cisano Bergmasco (BG)
Topic	FEM Verification and ex-vivo model validation (medical device for mitral annuloplasty)
Date	July 28, 2011
Event	Investigator’s Meeting
Location	Cisano Bergamasco (BG), Italy
Topic	Development Plan & Pre-Clinical Validation (medical device for mitral annuloplasty)
Date	July 4-5, 2011
Event	Risk Analysis According to ISO 14971
Location	Cirè di Pergine (TN), Italy
Topic	Risk management for medical devices – dental implant risk analysis
Date	June 23, 2011
Event	Investigator’s Meeting

Location	Italian Cancer Institute - Milan, Italy
Topic	Clinical Study Feasibility (medical device for cancer of uterince cervix treatment)
Date	June 16, 2011
Event	Investigator's Meeting
Location	Milan, Italy
Topic	Clinical Investigational Plan for a phase I monocentric study (medical device for radiotherapy)
Date	June 15, 2011
Event	Investigator's Meeting
Location	Milan, Italy
Topic	Clinical Investigational Plan for a phase I multicentric study (medical device for tricuspid valve repair)
Date	May 23-25, 2011
Event	ILSI-BioMed Conference
Location	Tel Aviv, Israel
Topic	Lifescience Technology, Biotech & Medical Devices
Date	May 17, 2011
Event	EuroPCR – Cardiovascular Conference
Location	Paris, France
Topic	Medical Device – Cardiovscular Technologies
Date	May 11, 2011
Event	Investigator's Meeting
Location	Milan, Italy
Topic	Regulatory Pathway for Study Authorization in Italy – GCP study management (vascular closure device)
Date	April 27, 2011
Event	DEKRA meeting
Location	Arnhem, The Netherlands
Topic	Pre-clinical verification & validation testing, GCP study management
Date	March 25, 2011
Event	SORIN – TAVI Congress
Location	CNR Pisa, Italy
Topic	Transcatheter Aortic Valve Implantation
Date	March 3, 2011
Event	SSFA – Medical Device Workgroup
Location	Florence, Italy
Topic	Medical Device Directive 93/42/EEC as amended by 2007/47/EC, post-market vigilance
Date	December 5-7, 2010
Event	ICI – Innovations in Cardiovascular Interventions
Location	Tel Aviv, Israel
Topic	Interventional Cardiology
Date	December 6-8, 2009
Event	ICI – Innovations in Cardiovascular Interventions
Location	Tel Aviv, Israel
Topic	Interventional Cardiology
Date	May 19-22, 2009
Event	EuroPCR – Cardiovascular Conference
Location	Barcellona, Spain
Topic	Medical Device – Cardiovscular Technologies

Date	December 7-9, 2008
Event	ICI – Innovations in Cardiovascular Interventions
Location	Tel Aviv, Israel
Topic	Interventional Cardiology
Date	May 13-16, 2008
Event	EuroPCR – Cardiovascular Conference
Location	Barcellona, Spain
Topic	Medical Device – Cardiovascular Technologies
Date	August 19, 2011
Topic	ICH-GCP: "The European Clinical Trial Directives"
Organization	Scepter
Date	August 19, 2011
Topic	ICH-GCP: "Non-compliance, Scientific Misconduct and Fraud & Monitoring and Preparing for Audits and Inspections"
Organization	Scepter
Date	August 16, 2011
Topic	ICH-GCP: "Safety Reporting, Financial Disclosure, & Study Closeout, Trial Termination, and Record Retention"
Organization	Scepter
Date	August 16, 2011
Topic	ICH-GCP: "Investigational Product, Randomization, and Unblinding & Source Documents and Case Report Form Completion"
Organization	Scepter
Date	August 16, 2010
Topic	ICH-GCP: "Subject Informed Consent & Protocol Compliance"
Organization	Scepter
Date	August 14, 2010
Topic	ICH-GCP: "Clinical Investigator Obligations & Qualifications, Resources, IRBs/IECs"
Organization	Scepter
Date	August 13, 2010
Topic	ICH-GCP: "Overview of ICH Good Clinical Practice"
Organization	Scepter
Date	April 13-14, 2010
Topic	III National Conference on Medical Devices
Organization	Ministero della Salute - Italian Ministry of Health
Date	February 20, 2009
Topic	ISO 9001:2008
Organization	Ordine degli Ingegneri della Provincia di Genova - AICQ
Date	December 11-16, 2008
Topic	Quality Management & Safety on Work Environment
Organization	Confindustria - Genova
Date	June 22-23-27-28-29, 2006
Topic	ISO 9001:2000 Lead Auditor Course
Organization	Celab s.r.l.

Foreign Languages	Comprehension	Spoken	Written
English	Excellent	Good	Good
IT skills	Microsoft Office, Word, PowerPoint, Excel, Outlook, Windows, Mac/OS, MSProject, Adobe Acrobat Professional, Dreamweaver MX, MatLAB, Working Model.		

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Pavia - July 09, 2013

Ing. Enrico Perfler