Training Calendar

Courses

22 and 23 February 2022 *Online*	**IVDs: Get Started on the Right Foot** *How to be ready for IVDR: regulatory impact and milestones for CE marking* *IVDs (In-Vitro Diagnostics) / Regulatory*
21, 24 e 28 febbraio 2022 *Online*	**Comunicare Efficacemente con gli Operatori della Salute** *Corso Base di Comunicazione per Informatori Scientifici del Farmaco ed Agenti di Dispositivi Medici, Nutraceutici e Integratori* *Soft Skill*
22 and 24 February 2022 *Online*	**Medical Writing Course: Improve your Writing & Reviewing Skills** *Writing, editing & proofreading tips for medical writers: a standardised process to make your message effective; review & ensure document quality* *Medical Affairs / Medical Writing / Clinical Research*
24 and 25 February 2022 *Online*	**Clinical Evaluation for Medical Devices** *Understanding the clinical evaluation requirements for the MedTech industry in the context of MDR 2017/745* *Medical Device / Regulatory*
01 and 03 March 2022 *Online*	**How to Write a Clinical Evaluation Plan** *Find your way around the strategic kick-off of a medical device clinical evaluation* *Medical Device*
01, 03 e 08 marzo 2022 *Online*	**Hospital Meeting: dall' Ideazione alla Conduzione di una Riunione di Successo** Medical Affairs / Soft Skill

08 e 10 marzo 2022 *Online*	**ISO 14155/2020 - Come Svolgere uno Studio Clinico con Dispositivi Medici** *Implementazione, Ottemperanza e Chiavi per il Successo* *Medical Device / Regulatory / Clinical Research*
09 marzo 2022 *Online*	**Integratori Alimentari a Base di Botanicals** *Cosa sta cambiando nel panorama normativo europeo* *Regulatory*
15 e 16 marzo 2022 *Online*	**Strategia e Requisiti per Ottenere il Marchio CE dei Dispositivi Diagnostici in Vitro** *I passi da seguire e gli errori da evitare per arrivare alla registrazione con successo!* *IVDs (In-Vitro Diagnostics) / Regulatory*
16 March 2022 *Online*	**Setting Up and Delivering a Workshop** ***Confessions of a trainer!*** *Soft Skill*
17 and 18 March 2022 *Online*	**How to Globally Register a Medical Device** *Regulatory strategy, steps and timelines for global medical device market access with an eye on the Americas, the Asian pacific and China* *Medical Device / IVDs (In-Vitro Diagnostics) / Regulatory*
22 March 2022 *Online*	**“Attributability” in Pharmacovigilance: Still a Hot Topic** ***How to navigate the different algorithms and approaches used to evaluate the causality of an adverse event/reaction.*** *Pharmacovigilance*
24 March 2022 *Online*	**Classification of Medical Devices** *A comprehensive guidance on rules, practical relevance, borderline classification and procedures in the MDR system* *Medical Device / IVDs (In-Vitro Diagnostics)*
24, 28 e 31 marzo 2022 *Online*	**La Statistica Medica per Non Statistici** *I principi statistici dalla pianificazione della ricerca alla pubblicazione sulle riviste scientifiche* *Medical Affairs / Clinical Research / Statistics and Data Management*
25 marzo 2022 *Online*	**Terapie Geniche e Terapie Cellulari - Dalla Ricerca all’Impiego nel Real World** Medical Affairs / Regulatory / Clinical Research

05 and 07 April 2022 *Online*	**Searching the Medical Literature** *How and where to find the information you need* *Pharmacovigilance / Medical Affairs / Clinical Research*
06 e 08 aprile 2022 *Online*	**Il Responsabile del Servizio Scientifico** *Corso pratico per un ruolo complesso* *Medical Affairs*
12 and 14 April 2022 *Online*	**How to write a Clinical Evaluation Report from the MDR Perspective** Medical Device
26, 28 April and 03 May 2022 *Online*	**Safety in Clinical Trial under the Clinical Trial Regulation (EU) No 536/2014** *Regulatory expectations on safety documents, CTR assessment procedures and CTR Q&A document* *Pharmacovigilance / Regulatory*
26 e 28 aprile 2022 *Online*	**Normativa della Ricerca Clinica tra Presente e Futuro** *Pillole di regolatorio* *Clinical Research*
27 e 29 aprile 2022 *Online*	**La Conduzione di uno Studio Clinico con un Dispositivo Medico-Diagnostico in Vitro** *Dai requisiti regolatori per la sottomissione alla gestione dello studio* *IVDs (In-Vitro Diagnostics) / Clinical Research*
27, 29 aprile e 02 maggio 2022 *Online*	**Inside Real World Evidence (RWE)** *La generazione di evidenze dal 'pre' al 'post' lancio di un prodotto* *Evidence Generation / Market Access / Medical Affairs / Clinical Research*
03 e 05 maggio 2022 *Online*	**L'Arte di Ascoltare** *Mettersi nei panni dell'altro per comprenderne i bisogni e comunicare efficacemente* *Soft Skill*
03, 05 and 10 May 2022 *Online*	**Regulatory and Scientific Pathways for Global Advanced Therapy Medicinal Products Development (ATMPs)** *A broad scientific and regulatory overview of the current status and challenges facing ATMPs development* *Regulatory*

10, 12 e 17 maggio 2022 *Online*	**Promozione dei Brand nel Farmaceutico** *Come sfruttare al meglio i canali di promozione nuovi e tradizionali nel rispetto delle normative attuali* *Medical Affairs / Regulatory*
10, 12 e 16 maggio 2022 *Online*	**Patient Advocacy ed Engagement nell'Azienda Farmaceutica** *Ruolo e mission in un approccio inter-funzionale* *Medical Affairs*
11 e 12 maggio 2022 *Milano*	**Ricerca Clinica: Comunicare meglio per Lavorare meglio** *Strategie, competenze e ruoli per realizzare un lavoro di squadra efficace* *Clinical Research / Soft Skill*
17 and 19 May 2022 *Online*	**Knowing your Post-Market Clinical Follow-up (PMCF)** *How to program the life-cycle of your device under the MDR 2017/745 requirements* *Medical Device*
23 e 25 maggio 2022 *Online*	**Cosmetici - Aspetti Tecnico-Regolatori e Panorama Normativo** Regulatory
24 e 26 maggio, 07 e 09 giugno 2022 *Online*	**Selezione e Convalida di Una Soluzione Cloud in Ambito GxP** *Rischi e opportunità nella scelta di una soluzione Cloud a supporto di processi GXP* *Clinical Research*
25 maggio 2022 *Online*	**Come Produrre Dati Non Clinici e Comunicare Contenuti Scientifici in Poco Tempo? Elementare, Watson!** Medical Device / Evidence Generation / Medical Affairs
26 e 27 maggio 2022 *Milano*	**La Gestione dell'Advisory Board nei Progetti Life Science** *Modelli e strumenti* *Medical Affairs / Soft Skill*
30 e 31 maggio 2022 *Online*	**La Registrazione dei Dispositivi Medici presso FDA** *Le differenti tipologie di submission e la preparazione di una 510K* *Medical Device / Regulatory*
31 maggio 2022 *Online*	**Governare la Privacy nella Ricerca Clinico-Scientifica. I Limiti e le Eccezioni al Consenso dei Pazienti Interessati nelle Ricerche Clinico- Scientifiche e nel Trasferimento dei Dati a Soggetti Terzi** Medical Affairs / Regulatory / Clinical Research

07 June 2022 *Online*	**In-Vitro-Diagnostics: a Deep Dive into Clinical Evidence** *The IVD clinical evidence framework* *IVDs (In-Vitro Diagnostics) / Regulatory*
07, 09 e 14 giugno 2022 *Online*	**Patient Support Program (PSP) - Dalla Strategia al Management** Market Access / Medical Affairs
08, 10 and 13 June 2022 *Online*	**The Pharmacovigilance System Master File (PSMF): from GVPs to Inspections** *A practical, hands-on guide* *Pharmacovigilance*
09 June 2022 *Online*	**Great Topic – Shame About the Slides!** *Creating clear and professional-looking slide decks to communicate biomedical science* *Soft Skill*
14 e 15 giugno 2022 *Online*	**La Compliance Regolatoria nel Contesto dei Dispositivi Diagnostici in Vitro** *Dalla direttiva IVD (98/79/CE) al Regolamento europeo 2017/746, cosa cambia?* *IVDs (In-Vitro Diagnostics) / Regulatory*
14 and 16 June 2022 *Online*	**Fundamentals of European Cosmetics Regulatory Affairs** Regulatory
15 e 17 giugno 2022 *Online*	**Gli Ingredienti Essenziali per un Protocollo Clinico Efficace** *Come assicurare la riproducibilità di uno studio clinico attraverso la corretta preparazione del protocollo* *Medical Affairs / Medical Writing / Regulatory*
21 and 22 June 2022 *Online*	**The Summary of Safety and Clinical Performance (SSCP)** *Tools and techniques to help you in balancing regulator's expectations and manufacturers timelines* *Medical Device*
21 e 22 giugno 2022 *Online*	**Medical Reading** *Valutare, comprendere ed interpretare l'articolo scientifico* *Medical Device / Medical Affairs / Clinical Research*

23 and 24 June 2022 *Online*	**Combination Products under the EU Medical Devices Regulation (MDR)** *A targeted training to understand the regulatory pathway for device drug and drug device combinations in the European Union (EU). Updates from the MDR 2017/745 and EMA guidance* *Medical Device / Regulatory*
23 giugno 2022 *Online*	**Governare la Privacy nella Ricerca Clinico-Scientifica. La Qualifica e il Controllo sui Responsabili del Trattamento** Medical Affairs / Regulatory / Clinical Research
24 giugno 2022 *Online*	**Integratori Alimentari ed Advertising - Caratteristiche di una Corretta Comunicazione Commerciale e Vincoli Normativi** Regulatory
27 and 30 June 2022 *Online*	**Medical Writing Course: Improve your Writing & Reviewing Skills** *Writing, editing & proofreading tips for medical writers: a standardised process to make your message effective; review & ensure document quality* *Medical Affairs / Medical Writing / Clinical Research*
28 and 30 June 2022 *Online*	**Pharmacovigilance System: Audit & Inspection Readiness** Pharmacovigilance
30 June and 01 July 2022 *Online*	**New MDR/IVDR Requirement: the 'Person Responsible for Regulatory Compliance' (PRRC)** *Responsibilities & challenges for medical device companies within MDR & IVDR* *Medical Device / IVDs (In-Vitro Diagnostics) / Regulatory*
06 July 2022 *Online*	**Oral Presentations** *Skills to help you survive or even shine* *Soft Skill*
08, 11 e 15 luglio 2022 *Online*	**Computer System Validation - GxP Process Owner and Quality Assurance: In or Out?** *Il ruolo del QA e del Process Owner nella convalida dei sistemi computerizzati (CSV) GxP* *Regulatory / Clinical Research*

12, 14, 19 e 20 settembre 2022 *Online*	**Qualità, Compliance e Audit in GVP** *Come applicare le GVP (Good Pharmacovigilance Practices) alla gestione della Qualità ed all'Auditing in Farmacovigilanza* *Pharmacovigilance*
13, 15 e 19 settembre 2022 *Online*	**Signal Detection e Signal Management** *Ricerca, identificazione, interpretazione e gestione dei segnali di sicurezza* *Pharmacovigilance*
15 September 2022 *Online*	**Know your Instructions for Use Inside-Out** *Input documents and writing recommendations* *Medical Device*
20, 22 and 26 September 2022 *Online*	**Asking the Patient: Patient-Reported Outcomes (PRO) with focus on measuring Quality of Life (QoL)** *An attempt to turn what is subjective into objective data* *Evidence Generation / Pharmacovigilance / Market Access / Medical Affairs / Clinical Research*
20, 21 and 22 September 2022 *Online*	**Tips and Tricks to Improve your Technical/Scientific Writing** *Learn the basic techniques to effectively write technical/scientific documents* *Medical Writing*
20, 22, 27 and 29 September 2022 *Online*	**Pharmacovigilance Documents in the Life Cycle of a Medicinal Product: From Patients to Health Authorities** *Development Safety Update Report (DSUR), Risk Management Plan (RMP), Periodic Safety Update Report (PSUR) / Periodic Benefit-Risk Evaluation Report (PBRER), and Addendum to the Clinical Overview* *Pharmacovigilance*
26 September 2022 *Barcelona, Spain*	**Periodic Safety Update Report (PSUR)** *Are you ready to satisfy the regulator's expectations?* *Medical Device*
27 e 29 settembre 2022 *Online*	**Buone Pratiche per la Gestione dei Documenti Cartacei e dei Dati Elettronici in Ambito GxP** *Strumenti per la conformità alle Good Documentation Practice (GDP) e ai requisiti di Data Integrity* *Pharmacovigilance / Medical Affairs / Clinical Research*

28 e 30 settembre 2022 *Online*	**La Gestione del Case Processing in Farmacovigilanza** *Raccolta, gestione e trasmissione delle segnalazioni di sospette reazioni avverse* *Pharmacovigilance*
28 settembre 2022 *Online*	**Governare la Privacy nella Ricerca Clinico-Scientifica. Esperienze e Strumenti pratici per Mappare il Flusso Dati, Creare e Mantenere il Registro dei Trattamenti, Effettuare la Valutazione di Impatto e Formulare Istanze di Consultazione preventiva** Medical Affairs / Regulatory / Clinical Research
30 settembre e 04 ottobre 2022 *Online*	**Training di Successo** *Come creare un corso efficace e coinvolgente per il proprio team o per stakeholder esterni* *Soft Skill*
04, 05 and 06 October 2022 *Online*	**Clinical Study Protocols – Structure & Content** Medical Affairs / Medical Writing / Regulatory
04 and 06 October 2022 *Online*	**The Basics of Regulatory Affairs for Cosmetic Products in US and Canada** Regulatory
05 October 2022 *Online*	**Initiating the Development of Artificial Intelligence (AI) Medical Devices** *Developing AI medical devices considering the latest industry expectations* *Medical Device*
05 and 07 October 2022 *Online*	**Beyond PubMed** *Additional approaches and sources for cost-effective literature monitoring* *Pharmacovigilance / Medical Affairs / Clinical Research*
11 October 2022 *Online*	**An Introduction to Causal Inference in Clinical and Observational Trials** *Theory and practice* *Statistics and Data Management*
11 October 2022 *Online*	**Introduction to Patient Engagement in Clinical Drug Development** *Practical overview and insights on Patient Engagement from history, current status towards future perspectives* *Clinical Research*

13 and 14 October 2022 *Online*	**Clinical Study Reports – a 360° Perspective** *Planning and Authoring CSRs in Accordance with Public Disclosure Requirements* *Medical Writing / Clinical Research*
13 October 2022 *Online*	**Writing Science for Lay Audiences** *Ways to better get your message accross* *Medical Device / Medical Affairs / Medical Writing / Clinical Research*
13 October 2022 *Online*	**Management in the MedTech Industry** *Principles, duties and instruments of professional management* *Soft Skill*
13 e 18 ottobre 2022 *Online*	**Modelli Economici nel Dossier di Prezzo e Rimborso** Market Access
18 ottobre 2022 *Online*	**Off-Label, Uso Compassionevole ed Expanded Access Program - Come Orientarsi tra Normative, Studi, Ricerca e Realtà Clinica** Medical Affairs / Regulatory / Clinical Research
18 e 20 ottobre 2022 *Online*	**Introduzione al Problem Solving** *Il processo per trovare soluzioni* *Soft Skill*
19 October 2022 *Online*	**From Good to Excellence: State of the Art Section for Medical Devices Inside-Out** *Drafting a document that meets Notified Bodies expectations!* *Medical Device*
19 e 21 ottobre 2022 *Online*	**La Ricerca della Letteratura Scientifica: dalla Domanda ai Risultati** *Principali funzionalità delle banche dati biomediche e degli strumenti di gestione delle bibliografie* *Medical Affairs / Medical Writing / Clinical Research*
21 October 2022 *Online*	**Patient Engagement and Decentralized Clinical Trial Designs** *How to avoid hypes and create value for patients and sponsors* *Clinical Research*
24 e 25 ottobre 2022 *Milano*	**Le Good Manufactoring Practices (GMP) e il Sistema Qualità per i Farmaci Sperimentali** GMP (Good Manufacturing Practices) / Clinical Research

25 ottobre 2022 *Online*	**Preparazione del Dossier di Prezzo e Rimborso in Italia** *Come sviluppare un dossier di Prezzo e Rimborso integrando le funzioni chiave tra loro* *Market Access / Medical Affairs / Clinical Research*
25 e 27 ottobre 2022 *Online*	**La Visione Strategica del Market Access dei Dispositivi Medici** Medical Device / Market Access
26 ottobre 2022 *Online*	**Governare la Privacy nella Ricerca Clinico-Scientifica. I Trasferimenti dei Dati Personali extra UE** Medical Affairs / Regulatory / Clinical Research
27 and 28 October 2022 *Online*	**Medical Writing Course: Improve your Writing & Reviewing Skills** *Writing, editing & proofreading tips for medical writers: a standardised process to make your message effective; review & ensure document quality* *Medical Affairs / Medical Writing / Clinical Research*
30 novembre 2022 *Online*	**Governare la Privacy nella Ricerca Clinico-Scientifica. Attribuire Correttamente i Ruoli nelle Operazioni di Trattamento dei Dati e Presidiarli – Esperienze e Strumenti** Medical Affairs / Regulatory / Clinical Research
02, 04 and 07 November 2022 *Online*	**Inside Real World Evidence (RWE)** *Filling data gaps: methodology, updates and insights in RWE and Observational Studies* *Evidence Generation / Market Access / Medical Affairs / Clinical Research*
03 November 2022 *Online*	**Advertisement and Promotion Claims for Medical Devices** *How to ensure regulatory compliance of advertisement and promotion claims and activities in the MedTech industry* *Medical Device / IVDs (In-Vitro Diagnostics) / Medical Affairs / Regulatory*
08 e 10 novembre 2022 *Online*	**La Protezione dei Dati: un Ponte fra Good Clinical Practices (GCP) e General Data Protection Regulation (GDPR)** *Come condurre uno studio clinico adempiendo alla normativa GDPR* *Clinical Research*
08 novembre 2022 *Online*	**Progettare il Servizio Partendo dal Paziente: il Ruolo del Patient Experience Design** Market Access / Medical Affairs

08, 15 and 17 November 2022 *Online*	**How to Write a Clinical Evaluation Plan and Report** *Find your way around the clinical evaluation of a medical device from concept to market approval and beyond* *Medical Device*
09 November 2022 *Online*	**Patient Engagement and Clinical Trial Recruitment and Retention** *How to truly empower, enable and assist patients to fit their needs in clinical trial participation* *Clinical Research*
09, 16 and 23 November 2022 *Online*	**All You Need to Know to Understand Statistic if You are not a Statistician** *Statistical principles from research planning to publication in scientific journals* *Medical Affairs / Statistics and Data Management*
11 November 2022 *Online*	**What you Need to Know about Implant Cards and never Dared to Ask** *MDR Art.18 requirements on Implant Cards explained!* *Medical Device*
11 November 2022 *Online*	**Key Opinion Leaders (KOLs) Mapping & Engagement** *Identifying and establishing a KOL network* *Medical Affairs*
14, 18, 21 e 25 novembre 2022 *Online*	**Integrare la Cyber Security nel mondo dei sistemi GxP** *Conoscere i rischi sui dati per garantire adeguate strategie di controllo per prevenire danni di immagine e impatti sulla continuità del business e sulla compliance regolatoria* *Regulatory*
15 e 17 novembre 2022 *Online*	**La Gestione dei Reclami e della Vigilanza Post Market per i Dispositivi Medici** *Quando il reclamo deve essere notificato alle Autorità Competenti in Europa e in USA* *Medical Device / Regulatory*
15 and 17 November 2022 *Online*	**Writing Manuscripts for Peer-Reviewed Medical Journals** *Getting started on the right foot* *Medical Affairs / Medical Writing*

15 e 17 novembre 2022 *Online*	**La Ricerca della Letteratura Scientifica in PubMed: dalla Domanda ai Risultati – corso avanzato** *Le funzionalità avanzate della banca dati PubMed e la gestione dei risultati della ricerca* *Medical Affairs / Medical Writing / Clinical Research*
16 novembre 2022 *Online*	**Governare la Privacy nella Ricerca Clinico-Scientifica. La Gestione del Data Breach** Medical Affairs / Regulatory / Clinical Research
17 e 18 novembre 2022 *Online*	**Ispezioni GMP** *Guida pratica alla preparazione e gestione di un'ispezione regolatoria presso uno stabilimento di produzione farmaceutica* *GMP (Good Manufacturing Practices) / Clinical Research*
22 November 2022 *Online*	**IVDR Implementation & Audits** *IVDR readiness in the time of Corona Pandemic* *IVDs (In-Vitro Diagnostics)*
22, 24, 29 novembre e 01 dicembre 2022 *Online*	**Safety Management e Farmacovigilanza** *Aspetti normativi, clinici e metodologici della farmacovigilanza, gestione della safety nello sviluppo clinico del farmaco.* *Pharmacovigilance / Clinical Research*
22 November 2022 *Online*	**Patient Engagement and Enhancing Diversity in Clinical Trial Participation** *An introduction and suitable approaches using Patient Engagement to enhance diversity in clinical trials* *Clinical Research*
23, 25 and 28 November 2022 *Online*	**Patient Advocacy and Engagement in Pharmaceutical Companies** *Role and mission in a cross-functional approach* *Medical Affairs*
23 and 24 November 2022 *Online*	**Medical Reading** *The critical evaluation of scientific publications* *Medical Device / Medical Affairs / Clinical Research*
24 e 25 novembre 2022 *Online*	**Annex 1 e la Contamination Control Strategy** GMP (Good Manufacturing Practices)

28 e 30 novembre 2022 *Online*	**Integratori Alimentari - Aspetti Tecnico-Regolatori e Panorama Normativo** Regulatory
29 novembre 2022 *Online*	**Le Risorse Gratuite in Rete per Reperire la Letteratura Scientifica** *Dalla ricerca bibliografica alla gestione delle pubblicazioni* *Medical Affairs / Medical Writing / Clinical Research*
01 and 02 December 2022 *Online*	**Labelling Requirements for Medical Devices** *Understanding the regulatory labelling requirements for medical devices in the context of the MDR 2017/745* *Medical Device / Regulatory*
02, 05 e 12 dicembre 2022 *Online*	**Audit to Computer Systems** *Be ready!* *Clinical Research*
13 and 15 December 2022 *.Online*	**Benefit Risk Assessment in Pharmacovigilance** Pharmacovigilance
28 February and 01 March 2023 *Online*	**Clinical Evaluation for Medical Devices** *Understanding the clinical evaluation requirements for the MedTech industry in the context of MDR 2017/745* *Medical Device / Regulatory*
28 febbraio e 02 marzo 2023 *Online*	**L'Ingegneria dell'Usabilità applicata ai Dispositivi Medici** *Interpretazione della norma IEC 62366-1:2015 e della correlata IEC TR 62366-2:2016* *Medical Device / Regulatory*
28 febbraio e 02 marzo 2023 *Online*	**General Data Protection Regulation (GDPR), Ricerca Scientifica e Norme Locali** *L'impatto del GDPR sugli studi clinici a livello locale ed internazionale* *Clinical Research*
01 and 02 March 2023 *Online*	**Medical Writing Course: Improve your Writing & Reviewing Skills** *Writing, editing & proofreading tips for medical writers: a standardised process to make your message effective; review & ensure document quality* *Medical Affairs / Medical Writing / Clinical Research*

07 e 09 marzo 2023 *Online*	**ISO 14155/2020 - Come Svolgere uno Studio Clinico con Dispositivi Medici** *Implementazione, Ottemperanza e Chiavi per il Successo* *Medical Device / Regulatory / Clinical Research*
14, 16 and 21 March 2023 *Online*	**How to Write a Clinical Evaluation Plan and Report** *Find your way around the clinical evaluation of a medical device from concept to market approval and beyond* *Medical Device*
21, 23 e 28 marzo 2023 *Online*	**La Statistica Medica per Non Statistici** *I principi statistici dalla pianificazione della ricerca alla pubblicazione sulle riviste scientifiche* *Medical Affairs / Clinical Research / Statistics and Data Management*
22 March 2023 *Online*	**“Attributability” in Pharmacovigilance: Still a Hot Topic** *How to navigate the different algorithms and approaches used to evaluate the causality of an adverse event/reaction* *Pharmacovigilance*
22 and 23 March 2023 *Online*	**Medical Devices Periodic Safety Update Report (PSUR)** *What’s behind the MDCG guidelines* *Medical Device*
23 marzo 2023 *Online*	**Terapie Geniche e Terapie Cellulari** *Dalla Ricerca all’Impiego nel Real World* *Medical Affairs / Regulatory / Clinical Research*
28, 29, 31 marzo 2023 *Online*	**Struttura e Contenuti del Protocollo di uno Studio Clinico** *Come prepararlo in modo efficace* *Medical Affairs / Medical Writing / Regulatory*
28 marzo 2023 *Online*	**Governare la Privacy nella Ricerca Clinico-Scientifica. I Limiti e le Eccezioni al Consenso dei Pazienti Interessati nelle Ricerche Clinico- Scientifiche e nel Trasferimento dei Dati a Soggetti Terzi** Medical Affairs / Regulatory / Clinical Research
29 marzo 2023 *Online*	**I Radiofarmaci** Medical Affairs / Regulatory / Clinical Research
30 March 2023 *Online*	**Providing Homecare Visits for Patients Enrolled in Clinical Trials** *Overview of an established process* *Clinical Research*

30 marzo e 04 aprile 2023 *Online*	**Utilizzo dei Dati Derivanti dai PSP: Confini e Opportunità** Evidence Generation / Market Access / Medical Affairs
04 e 06 aprile 2023 *Online*	**Il Responsabile del Servizio Scientifico** *Consapevolezza di un ruolo articolato* *Medical Affairs*
04 April 2023 *Online*	**Writing Science for Lay Audiences** *Ways to better get your message across* *Medical Device / Medical Affairs / Medical Writing / Clinical Research*
05 April 2023 *Online*	**Great Topic – Shame About the Slides!** *Creating clear and professional-looking slide decks to communicate biomedical science* *Soft Skill*
06 April 2023 *Online*	**Advertisement and Promotion Claims for Medical Devices** *How to ensure regulatory compliance of advertisement and promotion claims and activities in the MedTech industry* *Medical Device / IVDs (In-Vitro Diagnostics) / Medical Affairs / Regulatory*
18 e 20 aprile 2023 *Online*	**Normativa della Ricerca Clinica tra Presente e Futuro** *Pillole di regolatorio* *Clinical Research*
18 e 19 aprile 2023 *Online*	**La Conduzione di uno Studio Clinico con un Dispositivo Medico-Diagnostico in Vitro** *Dai requisiti regolatori per la sottomissione alla gestione dello studio* *IVDs (In-Vitro Diagnostics) / Clinical Research*
19 and 21 April 2023 *Online*	**Patient Registries as a Source of Real-World Evidence not only for Pharmaceuticals but also for Medical Devices** Evidence Generation / Medical Affairs / Clinical Research
20 and 21 April 2023 *Online*	**How to Globally Register a Medical Device** *Regulatory strategy, steps and timelines for global medical device market access with an eye on the Americas, the Asian pacific and China* *Medical Device / IVDs (In-Vitro Diagnostics) / Regulatory*

26 and 28 April 2023 *Online*	**Knowing your Post-Market Clinical Follow-up (PMCF)** *How to program the life-cycle of your device under the MDR 2017/745 requirements* *Medical Device*
03 e 04 maggio 2023 *Online*	**La Registrazione dei Dispositivi Medici presso FDA** *Le differenti tipologie di submission e la preparazione di una 510K* *Medical Device / Regulatory*
04, 09 and 11 May 2023 *Online*	**Pharmacovigilance and Safety in Clinical Trials under the Clinical Trial Regulation (EU) No 536/2014** *First experience with CTR/CTIS, regulatory expectations for safety documents, CTR assessment procedures and CTR Q&A document, typical issues and how to avoid it.* *Pharmacovigilance / Regulatory*
09 e 12 maggio 2023 *Online*	**Il Processo di Gestione dei Rischi applicato ai Dispositivi Medici** *Interpretazione della norma ISO 14971:2019 e della correlata ISO/TR 24971:2020* *Medical Device / Regulatory*
09 e 11 maggio 2023 *Online*	**La Pubblicità del Farmaco** *Dall'informazione scientifica alla pubblicità al pubblico* *Regulatory*
10 maggio 2023 *Online*	**Integratori Alimentari a Base di Botanicals** *Cosa sta cambiando nel panorama normativo europeo* *Regulatory*
11 May 2023 *Online*	**The Summary of Safety and Clinical Performance (SSCP)** *Tools and techniques to help you in balancing regulator's expectations and manufacturers timelines* *Medical Device*
16 maggio 2023 *Online*	**Come Produrre Dati Non Clinici e Comunicare Contenuti Scientifici in Poco Tempo? Elementare, Watson!** Medical Device / Evidence Generation / Medical Affairs
16, 18, 23 e 25 maggio 2023 *Online*	**Selezione e Convalida di Una Soluzione Cloud in Ambito GxP** *Rischi e opportunità nella scelta di una soluzione Cloud a supporto di processi GXP* *Clinical Research*

17 e 18 maggio 2023 *Online*	**La Sorveglianza Post-Market dei Dispositivi Diagnostici in Vitro** *Come implementare le corrette procedure per la gestione post-vendita* *IVDs (In-Vitro Diagnostics)*
17, 19 e 22 maggio 2023 *Online*	**Patient Advocacy ed Engagement nell'Azienda Farmaceutica** *Ruolo e mission in un approccio inter-funzionale* *Medical Affairs*
18 and 19 May 2023 *Online*	**New MDR/IVDR Requirement: the 'Person Responsible for Regulatory Compliance' (PRRC)** *Responsibilities & challenges for medical device companies within MDR & IVDR* *Medical Device / IVDs (In-Vitro Diagnostics) / Regulatory*
23 maggio 2023 *Online*	**Qualifica dei Vendor nella Ricerca Clinica - Approfondimenti** *Esempi e aspetti pratici* *Clinical Research*
24 and 26 May 2023 *Online*	**Medical Reading** *The critical evaluation of scientific publications* *Medical Device / Medical Affairs / Clinical Research*
24, 26 and 31 May 2023 *Online*	**The Pharmacovigilance System Master File (PSMF): from GVPs to Inspections** *A practical, hands-on guide* *Pharmacovigilance*
25 e 26 maggio 2023 *Milano*	**La Gestione dell'Advisory Board nei Progetti Life Science** *Modelli e strumenti* *Medical Affairs / Soft Skill*
30 May 2023 *Online*	**Oral Presentations** *Skills to help you survive or even shine* *Soft Skill*
31 May 2023 *Online*	**How to Create Effect Visuals for Better Communicating your Science** Medical Writing
06, 08 e 13 giugno 2023 *Online*	**Patient Support Program (PSP) - Dalla Strategia al Management** Medical Affairs

07 e 09 giugno 2023 *Online*	**Cosmetici - Aspetti Tecnico-Regolatori e Panorama Normativo** Regulatory
08 June 2023 *Online*	**From Good to Excellence: State of the Art Section for Medical Devices Inside-Out** *Drafting a document that meets Notified Bodies expectations!* *Medical Device*
12 and 14 June 2023 *Online*	**Medical Writing Course: Improve your Writing & Reviewing Skills** *Writing, editing & proofreading tips for medical writers: a standardised process to make your message effective; review & ensure document quality* *Medical Affairs / Medical Writing / Clinical Research*
20 and 22 June 2023 *Online*	**Fundamentals of European Cosmetics Regulatory Affairs** Regulatory
21 and 22 June 2023 *Online*	**Combination Products under the EU Medical Devices Regulation (MDR)** *A targeted training to understand the regulatory pathway for device drug and drug device combinations in the European Union (EU). Updates from the MDR 2017/745 and EMA guidance* *Medical Device / Regulatory*
27 June 2023 *Online*	**How to Become a Successfully Published Author - Practical steps to make the publication process as smooth and as successful as possible** Medical Device / Medical Affairs / Medical Writing / Clinical Research
28 and 30 June 2023 *Online*	**Pharmacovigilance System: Audit & Inspection Readiness** Pharmacovigilance
05 luglio 2023 *Online*	**Integratori Alimentari ed Advertising - Caratteristiche di una Corretta Comunicazione Commerciale e Vincoli Normativi** Regulatory
19, 20 and 21 September 2023 *Online*	**Tips and Tricks to Improve your Technical/Scientific Writing** *Learn the basic techniques to effectively write technical/scientific documents* *Medical Writing*

26 and 28 September 2023 *Online*	**How Are You? – Asking the Patients - Patient-Reported Outcomes (PRO) with focus on measuring Quality of Life (QoL)** Evidence Generation / Medical Affairs / Clinical Research
04, 05 and 06 October 2023 *Online*	**Clinical Study Protocols – Structure & Content** Medical Affairs / Medical Writing
10 and 11 October 2023 *Online*	**Medical Writing Course: Improve your Writing & Reviewing Skills** *Writing, editing & proofreading tips for medical writers: a standardised process to make your message effective; review & ensure document quality* *Medical Affairs / Medical Writing / Clinical Research*
17 and 19 October 2023 *Online*	**The Basics of Regulatory Affairs for Cosmetic Products in US and Canada** Regulatory
18 and 19 October 2023 *Online*	**Clinical Study Reports – a 360° Perspective** *Planning and Authoring CSRs in Accordance with Public Disclosure Requirements* *Medical Writing / Clinical Research*
October 2023 TBD *Online*	**What you need to know about Medical Device Software and never dared to ask** *More than just apps – An introduction to Medical Device Software* *Medical Device*
09 November 2023 *Online*	**Advertisement and Promotion Claims for Medical Devices** *How to ensure regulatory compliance of advertisement and promotion claims and activities in the MedTech industry* *Medical Device / IVDs (In-Vitro Diagnostics) / Medical Affairs / Regulatory*
14 e 16 novembre 2023 *Online*	**La Vigilanza Post Market per i Dispositivi Medici secondo MDR e FDA** *Dalla gestione del reclamo alla sua notifica alle Autorità Competenti in Europa e in USA* *Medical Device / Regulatory*

Corso on demand *TBD*	**Comunicare con l'Intelligenza Relazionale - La Flessibilità nelle Relazioni per Comunicare, Guidare e Motivare Colleghi e Interlocutori, in Presenza e da Remoto** *Soft Skill*
Corso on demand *Online*	**Revisioni Sistematiche e Meta-Analisi: Guida all'Uso!** *Come leggere, utilizzare e condurre Revisioni Sistematiche e Meta-Analisi* *Evidence Generation / Market Access / Medical Affairs / Clinical Research*

Training Paths

From 24 February to 22 June 2022 *Online*	**Medical Devices: a 5-Step Clinical Evaluation Masterclass** Medical Device
Dal 09 marzo al 18 maggio 2022 *Online*	**GMP Project Management** *Il ruolo del Project Manager nella gestione di progetti nei siti produttivi farmaceutici* *GMP (Good Manufacturing Practices) / Soft Skill*
Dall'11 marzo al 07 maggio 2022 *Online*	**Clinical Quality Assurance: un Ruolo Chiave nella Ricerca Clinica** *Percorso di alta specializzazione per lo sviluppo delle competenze peculiari del Clinical Quality Assurance (QA)* *Clinical Research*
From 16 March to 08 June 2022 *Online*	**The Soft Skills You Need to Advance Your Scientific Leadership** *A 3-step soft skill training path* *Soft Skill*
dal 04 maggio al 16 novembre 2022 *Online*	**Governare la Privacy nella Ricerca Clinico-Scientifica** Medical Affairs / Regulatory / Clinical Research
Dal 23 settembre al 26 novembre 2022 *Online*	**Medical Affairs: Prepararsi alle Sfide Future di un Ruolo Complesso** *Corso di alta specializzazione per lo sviluppo delle competenze tecnico-scientifiche peculiari del Medical Advisor (MA) e del Medical Science Liaison (MSL)* *Medical Affairs*

From 11 October to 22 November 2022 *Online*	**Patient Engagement in Clinical Development** *A practical guidance towards making patient engagement in clinical development relevant for patients* *Clinical Research*
Dal 17 febbraio al 01 aprile 2023 *Online*	**Clinical Quality Assurance: un Ruolo Chiave nella Ricerca Clinica** *Percorso di alta specializzazione per lo sviluppo delle competenze peculiari del Clinical Quality Assurance (QA)* *Clinical Research*
From 28 February to 11 May 2023 *Online*	**Medical Devices: a 4-Step Clinical Evaluation Masterclass** Medical Device
Dal 01 marzo al 07 giugno 2023 *Online*	**Percorso Formativo GMP Project Management** *Il ruolo del Project Manager nella gestione di progetti nei siti produttivi farmaceutici* *GMP (Good Manufacturing Practices) / Soft Skill*
Dates TBD *Online*	**Pharmacovigilance Masterclass** *A-10 modules journey into the field of Drug Safety and Good Pharmacovigilance Practices (GVP)* *Pharmacovigilance*
Dates TBD *Online*	**Vaccine Safety and Pharmacovigilance** Pharmacovigilance

Conferences

12 and 13 September 2022 *Madrid, Spain*	**International Pharmacovigilance Day** *Pharmacovigilance Today: Back to Business!*
27 September 2022 *Barcelona, Spain*	**MedDev Day** *MDR 2017/745 Reality Check – Readiness of the EU System*
13 October 2022 *Copenhagen, Denmark*	**Nordic Pharmacovigilance Day** *Current Challenges and Emerging Trends in Pharmacovigilance: a Focus on the Nordic Countries*

25 October 2022 *Barcelona, Spain*	**European Statistical Forum** *Statistical Reasoning in Drug Development*
15 novembre 2022 *Roma, Italia*	**Italian Pharmacovigilance Day** *La Trasformazione della Farmacovigilanza: come le Novità Normative e l'Evoluzione del Contesto impattano la Comunicazione dei Rischi e la Gestione delle Attività?*
26 September 2023 *Vienna, Austria*	**MedDev Day**
18 ottobre 2023 *Milano*	**Italian Pharmacovigilance Day**
08 November 2023 *Copenhagen*	**Nordic Pharmacovigilance Day**
November 2023 *Munich, Germany*	**European Statistical Forum**