Digital Quality in Clinical Trials — A Training on GCP, Data Integrity, and System Validation Aligned with ICH E6 (R3)

VIENNA, AUSTRIA, October 28, 2025 /EINPresswire.com/ -- As the clinical research landscape continues its digital transformation, regulatory agencies such as EMA, MHRA, and FDA are tightening expectations on the validation, integrity, and oversight of electronic systems used in clinical trials.

The long-awaited update to ICH E6 (R3) places stronger emphasis on electronic data capture, system validation, and vendor oversight. Understanding and applying these principles in a compliant way is now critical for sponsors and CROs to ensure inspection readiness and maintain GCP compliance.

To address these evolving needs, Fleming Events will host a two-day professional training program, “Digital Quality in Clinical Trials,” on 22–23 April 2026 in Vienna, Austria.
The course will be led by a former MHRA Group Manager and member of the ICH E6 (R3) Expert Working Group, together with a Digital Clinical Trials Innovator, offering a blend of regulatory insight and practical, real-world experience.

Participants will gain practical understanding on how to:
• Apply ICH E6 (R3) principles across digital workflows.
• Avoid common data integrity and validation pitfalls.
• Strengthen vendor oversight and ensure audit readiness.
• Understand essential requirements for eConsent, IRT, ePRO, EMS, and eTMF systems.
• Learn from real EMA, MHRA, and FDA inspection findings.

The training also includes an interactive workshop on data integrity, AI/ML tools, and Critical-to-Quality factors, helping participants translate new regulatory expectations into actionable practices.
Each participant will receive a Certificate of Completion recognizing their updated knowledge in

digital trial compliance.

About Fleming Events
For over two decades, Fleming has been a global leader in organizing high-level conferences, summits, and training courses across industries including Pharma, Healthcare, Energy, and HSE. With a strong focus on knowledge exchange and professional development, Fleming's events bring together top industry experts, regulators, and business leaders to share insights that drive compliance, innovation, and operational excellence.

For media inquiries or further information about the Digital Quality in Clinical Trials training, please contact:

Karthik Naik
Fleming Events
+421 911 820 365
karthik.naik@fleming.events
Visit us on social media:
LinkedIn

This press release can be viewed online at: https://www.einpresswire.com/article/862277453

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.
© 1995-2025 Newsmatics Inc. All Right Reserved.