GxP AI - How Quality Systems Can Responsibly Control AI to Enhance Productivity and Streamline Operations

Speakers

Bryan Ennis
President & Co-Founder
Sware

Madhavi Ganesan
Director, Lifesciences Advisory
KPMG

Jamie Hijmans
President & Strategic CTO
Global Exponential Technologies (GxT)

Michelle Vuolo
Head of Quality
Tulip Interfaces, Inc.

Resources

See below for a curated list of resource from the speakers panel the audience may find useful.

From the FDA

1. Artificial Intelligence / Machine Learning in Drug Development Notification
2. Using Artificial Intelligence & Machine Learning in the Development of Drug and Biological Products (Discussion Paper & Request for Feedback, published 11May2023)
3. Artificial Intelligence in Drug Manufacturing (Discussion Paper)
4. FDA Releases Two Discussion Papers to Spur Conversation about Artificial Intelligence and Machine Learning in Drug Development and Manufacturing (Discussion Papers)
5. Good Machine Learning Practice for Medical Device Development: Guiding Principles (SAMD)
6. Joint US FDA/Health Canada/UK MHRA Good Machine Learning Practice for Medical Device Development

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From the ISPE

1. The Road to Explainable AI in GXP – Regulated areas (Jan/Feb 2023)
2. Machine Learning Risk and Control Framework (Jan/Feb 2024)
3. AI Maturity Model for GxP Application: A Foundation for AI Validation (April 2022)
4. ISPE GAMP® 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems (2022)
   - → Figure 11.3 Typical Use of Risk-Based Decision Making, p. 112
   - → Figure 31.1 GAMP 5 Life Cycle with ML Sub-System, Appendix D11, p. 271
5. Application of principles included in Risk Analysis and Mitigation Matrix (RAMM) – A Risk Tool for Quality Management (2012) (Page 26)
6. ChatGPT, BARD and other Large Language Models Meet Regulated Pharma (July/Aug 2023)
7. AI Governance and QA Framework: AI Governance Process Design (July/Aug 2022)
8. Note: ISPE has created an AI Community of Practice

EMA

1. Software and AI as a Medical Device Change Programmme-Roadmap (Guidance, June 2023)
2. The use of Artificial Intelligence (AI) in the medicinal product lifecycle (Reflection paper, Nov 2023)
3. Proposal for Laying down the rules for regulation in AI

Additional Resources

1. Regulators Face Novel Challenges as Artificial Intelligence Tools Enter Medical Practice
2. Preparing a Framework for AI / ML Validation: A 3 Step Process
   - → A succinct article that outlines 3 main points aligned with the Validation 4.0 approach but with a focus on AI/ML specific concepts.
3. AI Integration in Drug Manufacturing - GMP Insights for Operational Excellence
4. Hugging Face – Learn
5. Intro to AI Ethics
6. Natural Language Processing (for those who want to learn how GenAI for text works)