

- **COMPUTER SYSTEMS VALIDATION (CSV)**
- **GOOD PRACTICE UPDATE - GAMP RELEASE 2**
-  **28 NOV 2022 (MONDAY)**
8:30AM - 11.15AM



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GAMP5 RELEASE 2: WHY CHANGE?

- The initial version of GAMP was published in 2008, since then there have been continuous changes in the way that software is developed and deployed and the prevalence of IT in Pharma has grown dramatically.
- In August 2022 the ISPE published a new GAMP release 2 that contains major updates through the guide to capture the differences in today's systems and ways of working. The objective is to ensure GAMP continues to be relevant and the de facto industry best practice for IT systems GxP compliance

AGENDA

- Overview of applicable regulations
- Good Automated Manufacturing Practice (GAMP)
- What has changed in GAMP Release 2?
- What is Computer Software Assurance (CSA)?
- CSV/CSA approaches for new technology

VENUE

Zoom Platform

REGISTRATION FEES

FREE of Charge

SPEAKER:



David Margetts

David is the CEO and co-founder of Factorytalk and focuses his advice, consulting and technical experience for our clients in the Pharmaceutical and Biotech industries on quality, technology capability and process performance.

David has lived in Asia since 2004, and has worked extensively across the globe on key assignments to build businesses, ideas, client relations and to deliver projects and develop successful teams and talent. David is an active contributor to ISPE through GAMP and the Validation 4.0 Special Interest Group.

CLOSING DATE

26 NOV 2022