



GAMP Italia EDPM M I L A N O

Electronic Document and Business Process Management

Date: 25th September 2014

Location: Hotel Michelangelo
Piazza Luigi di Savoia, 6, Milano

GAMP® Italia organizes a one-day seminar about Electronic Document and Process Management in order to discuss applicable regulation framework, business opportunities and best practices. Representatives from Life Sciences industries (pharmaceuticals, medical devices, biotech etc.), suppliers and subject matter experts will share useful indications and good practices to progressively implement a paperless management of critical process documentation, improving both quality and business efficiency.

During the seminar, the first draft of a practical implementation guide for electronic document and processes management systems will be presented by GAMP® Italia EDPM (Electronic Document and Process Management) Working Group.

The draft Guide and all the supporting material for presentations will be prepared in English language.

Morning

Chairman – Sandro De Caris, Gamp Italia Chair

- 9.00 Attendee Registration
- 9.30 Welcome by the President of ISPE Italian Affiliate
- 9:40 Industry needs & Initiatives of GAMP EDPM (*Pederzini Grünenthal-Formenti, Michele Gragnani, K2C*)
- 10:00 EDPM Guideline initiative - Overview, scope and content (*Sandro De Caris, Gamp Italia Chair*)
- 10:10 Analysis of business opportunities and criticalities (*Teresa Minero, Life Bee*)
- 10.40 Business Process Management as a way to discover the value of human resources (*Claudio Rondelli, CRE Microsistemi*)
- 11.00 Coffee Break
- 11.30 Project Lifecycle and Project Management (*Michele Gragnani, K2C*)
- 12.00 V-Model vs. Agile: new opportunities to be faster, leaner, cheaper. (*Gianfranco Pugno, GSK*)
- 12.30 Technology considerations (*GAMP EDPM Group member tbc.*)
- 12:50 Questions and Answers
- 13.00 Lunch (buffet)

Afternoon

Chairman – Michele Gragnani, GAMP Italia EDPM Working Group Chair

- 14.00 Short presentations by Sponsors
- 14.15 Compliance and validation approach (*Sandro De Caris, consultant*)
- 14.35 Electronic Records and Signatures (*Giorgio Civaroli, CTP*)
- 14.55 Case Study: Business Process Remodeling for QC Analytical Methods management (*Roberto Pace and Stefano Dini, Indena*)
- 15.25 Coffee Break
- 15.50 Case Study: Business Process Remodeling for SOPs' and QMS management (*Emanuele Rossi, Cosmo Pharmaceuticals*)
- 16.20 Case Study: Corporate Enterprise Quality Management System (*tbd., Zambon*)
- 16.50 Questions and Answers
- 17.00 End of seminar