



E05 GAMP[®]5: Enabling Innovation and Technological Advance **(Launch of GAMP[®]5)**

ISPE Conference on Manufacturing Excellence, Tampa, FL
Wednesday (09.00-17.00) and Thursday (08.00-16.00), 27-28 February 2008

Wednesday, 27 February

07.30-09.00	Breakfast
	What's New in GAMP[®]5 / Main Body Summary
09.00-09.10	Welcome and Introduction (Perez)
09.10-10.00	Keynote: Ensuring Efficient Compliance within the Scope of Industry Best Practice (Wingate)
10.00-10.30	Networking Break
10.30-11.15	Evolution of GAMP: New Material and Enhanced Business Benefit (Wyn)
11.15-12.00	Organizational Issues, Including Role of Quality Assurance and Users (Kane)
12.00-13.00	Lunch
	Management Appendices / Special Appendices
13.00-13.10	Welcome and Introduction (Wingate)
13.10-13.50	Holistic Approach to Science-based Risk Management in Developing Compliance Solutions (includes new categorization) (Perez)
13.50-14.30	Hot Topic Appendices (Robertson)
14.30-15.00	Networking Break
15.00-15.40	Getting the Most from Leveraging Supplier Work (Cappucci)
15.40-16.20	Risk-based Management of Outsources or Off-shore Suppliers (Morton)
16.20-17.00	Inspection Readiness: Master Plans, System Registers, Inspection Trends and Regulatory Developments (EU, US and Japan), (Wingate)
17.00	Seminar Adjourns for the Day, Reception

Thursday, 28 February

07.00-08.00	Breakfast
	GAMP[®]5 and Development of Compliant Systems
08.00-08.10	Welcome and Introduction (Robertson)
08.10-08.50	Melding GAMP [®] 5 with ASTM Processes (Buffi)
08.50-09.35	GAMP [®] 5 Development Appendix Highlights (Kane)
09.35-10.00	Introduce Workshop (Selby)
10.00-10.30	Networking Break
10.30-12.00	Workshop: Applying GAMP [®] 5 Principles to Scaling Validation Decisions (Buffi, Cappucci, Perez, Selby)
12.00-13.00	Lunch

	Appropriately Scaled Operational Controls the <i>GAMP</i>[®] 5 Way
13.00-13.05	Welcome and Introduction (Perez)
13.05-13.35	New Approach to Appropriately Scaled Operational Controls (Wyn)
13.35-14.05	Fitting <i>GAMP</i> [®] 5 Operational Controls into the ITIL Framework (Cappucci)
14.05-14.30	Workshop: Applying Risk Management to Change Control (Kane, Perez, Selby)
14.30-15.00	Networking Break
15.00-16.00	Workshop continued (Kane, Perez, Selby)
16.00	Seminar Adjourns