

Krakow Conference, April 24-25th 2008

Day I

8:00 Registration and coffee – welcome reception

9:00 Opening of the conference – ISPE Poland and Pliva Krakow

9:15 CEO Pliva Kraków presents the factory and opens the conference.

12:15 Coffee

12:45 ISPE Poland – change catalyst

13:15 Challenges for pharmaceutical manufacturers – Barbara Walenciuk, Main Pharmaceutical Inspectorate

14:00 Lunch

15:00 Development of the Quality Management Systems – Andrzej Szarmanski, Polpharma

15:45 ICH, Quality Systems and Quality Systems integration - Gilda D'Incerti, PQE

16:30 Coffee

16:45 From Performance Indicators to Risk Management Tools in Pharmaceutical Equipment Design - case study - Claudio Rolandi

17:30 End of day I

19:30 Dinner – networking

Day II

8:45 Welcome coffee

8:30 Software supporting newest Quality Management Systems - Rafal Buczek, Grzegorz Karolczyk, Pliva Krakow

9:15 Risk Analysis in ERP / MES systems validation processes - Roman Nowicki, RAN

10:00 Coffee

10:30 MES systems and GAMP5 - Paul Irving, Aptitude UK

11:15 Electronic Asset Management - Tomasz Hartuna and Medard Krzyżyński, Polpharma S.A.

12:00 Coffee

12:30 How to assure Data Quality in an e-CRF systems - Massimiliano M. Borelli, PQE

13:15 End of day II and lunch