

## **Transfer of Analytical Methods**

10<sup>th</sup> to 11<sup>th</sup> May 2012

Berlin, Germany

Course No. 6430

- Regulatory Requirements (FDA/Europe)
- How to Perform an Analytical Method Transfer
- Transfer Plan, Transfer Report
- Statistical Methods to Evaluate the Results
- Out of Specification Handling
- Examples, Possible Issues

## **Quality by Design Driven Development of Coated Dosage Forms**

From Simulations to Setting-up of DoEs and Design Space Definition

19<sup>th</sup> to 20<sup>th</sup> June 2012

Renaissance Barcelona Airport Hotel, Barcelona, Spain

Course No. 6431

Umetrics textbook "Design of Experiments, Principles and Applications" is supplied with the training material

- Critical Quality Attributes, Critical Formulation & Process Parameters for Coated Dosage Forms, Risk Assessment
- Simulations, Design of Experiments, PAT & Design Space - From Theory to Practical Experience
- Hands on Workshop in small groups with expert instructors – To set up and analyse DoEs for real cases study data, working with MODDE 9.1 software on your own computer