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**An On-Site 2-Day Workshop in
Engineering The Pharmacometric Enterprise**

**A Workshop For Improving the Efficiency and
Effectiveness of Model-Based Drug Development**



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Workshop Synopsis

This workshop has been developed in response to the growing recognition that increasing the efficiency and effectiveness of the pharmacometric analysis process is a critical prerequisite for the successful transition to model-based drug development. The mutually dependent goals of commercial and regulatory success will require an emphasis on the reliable delivery of timely information at critical milestones. Achieving these goals will require new skills in corporate leadership, technical prowess, and new levels of cooperation and communication across departments to successfully implement (or strengthen) the pharmacometric process and its interface with the larger drug development enterprise.

The workshop has been designed to provide pharmaceutical and biotechnology industry scientists, managers, and support staff with the strategy and tools they need to strengthen lines of communication amongst the stakeholders of model-based development, including pharmacometricians, pre-clinical and clinical development teams, senior managers, and regulatory affairs personnel. The material is structured to impart both the theoretical and practical aspects of pharmacometric process definition, implementation, and governance. Course participants will gain an appreciation for the importance of informatics, analysis purpose-identification, analysis planning, analysis dataset requirements, internal communication and education strategies, team structure and alignment considerations, and process standardization as the critical elements in maximizing the value derived from pharmacometric modeling and simulation.

Course material may include hands-on exercises if desired. A step-by-step plan will be provided along with specific suggestions

for exercises that can be performed within the participant's organization to ensure organization-specific considerations are accommodated and that the implementation plan is realistic and actionable. Compliance with the FDA's Guidance for Industry on Population PK, Exposure-Response Guidance, and the EMEA Guideline on Reporting the Results of Population PK Analyses will be reviewed and emphasized.

Learning Objectives

Following the workshop, the participant should be able to:

- Understand the technological, process, and communication needs that must be addressed in an optimal implementation of model-based drug development
- Understand the essential infrastructure elements required for optimal implementation of a pharmacometric service
- Identify the critical scientific, logistical, and practical issues encountered in improving the efficiency of model building efforts
- Understand the importance of a comprehensive analysis planning approach and the value of exploratory data analysis (EDA)
- Identify strategies to reduce costs associated with performing modeling and simulation activities
- Understand ways to increase the quality and consistency of pharmacometric results and work products

- Have insight into best practices in documenting pharmacometric analyses intended for regulatory submission
- Identify strategies to increase the understanding and acceptance of model-based approaches within their organization and the effectiveness of pharmacometric results in influencing decision-making

Workshop Topics

The Pharmacometric Analysis Process: Inputs, Outputs, and Deliverables

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The Transition to Model-Based Drug Development: Understanding the Need of Pharmacometrics

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Pharmacometric Analysis Planning: A Critical Component of Efficient and Effective Project Implementation

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Model Feasibility Assessment: A Tool for Formalizing Communications During the Model-Building Process

* * *

Overcoming the Challenges of Real-Time Data Assembly

* * *

A Lean Six Sigma Approach to Data Assembly Requirements Definition and Improving Communication with Data Programmers

* * *

Effective Communication of
Pharmacometric Analysis
Deliverables to Company Decision-
Makers

* * *

Pharmacometric Reporting Practices
to Achieve Compliance with FDA
and EMEA Guidelines

* * *

Introduction to Canonical
Documents and the Creation of a
Canonical Document Library

* * *

Strategies for Governance and
Monitoring Productivity in
Pharmacometric Analyses

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Scientific Workflows: The
Information Technology Backbone
of the Knowledge-Generating
Process

Registration Details

There is a minimum requirement of
ten attendees for on-site training.

Call for scheduling information

ABOUT COGNIGEN

Cognigen is a state-of-the-art scientific, technical, and strategic partner for our clients in the pharmaceutical and biotechnology industry. Our focus is on providing scientific support for dose selection and justification at all drug development and regulatory milestones.

Our vision

To advance the science and engineer the systems for model-based drug development.

Our mission

- To help our clients understand the determinants of safety and efficacy of new medicines in order to:
 - Increase stakeholder confidence at decision-making milestones
 - Improve the chances for success with innovative therapies
 - Enhance the value of new medicines for patients and providers
- To provide a challenging and rewarding work environment for the professional growth and development of our scientists and staff.

We provide pharmacometric services for approximately 20 to 30 drugs per year. In 2007, 4 of the 17 NDAs submitted to the FDA incorporated our work as a basis for dose selection and justification. We have had experience in most therapeutic areas and have worked on projects in all phases of drug development from

pre-clinical to clinical development, from discovery to commercialization and post-marketing surveillance. We have a well-established reputation for the credibility of our work and track record of successfully utilizing pharmacokinetic and pharmacodynamic modeling and simulations to influence regulatory and clinical decision-making.



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