

# DIA/CDE Quantitative Science Forum (QSF) - advancing data driven regulatory decision making



October 20-21, 2013  
Xinjiang Plaza, Beijing, China

This event, held by DIA China and CDE, aims at providing a forum to discuss quantitative science (including statistics, data management, programming, and related disciplines) related topics in pharmaceutical product development in a regulatory context. It is expected that a dialogue among professionals from industry, government, and academia will examine top challenges and opportunities in the quantitative science areas.

## FEATURED TOPICS

- ▶ Local and multi-regional clinical development
- ▶ E-source in clinical data management
- ▶ Challenges in traditional Chinese medicine development
- ▶ Innovative approaches and technology in clinical trial data management
- ▶ Innovative statistical approaches and technology in drug development
- ▶ Electronic submission & data standards: CDISC, and implementation
- ▶ Statistical issues in development of biosimilar products
- ▶ Application of surrogate endpoints and biomarker in drug development
- ▶ DMC and interim analysis
- ▶ Endpoints in clinical development

## LEARNING OBJECTIVES

At the conclusion of this training, you should be able to:

- ▶ To gain a better understanding of quantitative science and its roles in the regulated environment of pharmaceutical product development
- ▶ To discuss key quantitative science issues in pharmaceutical product development, impacts of regulations, guidance and practices, technologies and standards
- ▶ To improve collaboration and communication among industry, academia, and regulatory agencies.

## WHO SHOULD ATTEND

- ▶ Statisticians
- ▶ Clinicians
- ▶ Data management professionals
- ▶ Regulatory scientists
- ▶ Quantitative scientists in academia
- ▶ Quantitative scientists in regulatory agencies

## PROGRAM CO-CHAIRS



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## CO-SPONSORS

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