



**Recent  
regulatory  
movements  
and a  
practical  
approach**

**4th Charles River Symposium in Japan**

**Friday 24 April 2009**

**Room 605/606, Tokyo Big Sight, Tokyo, Japan**

# Recent regulatory movements and a practical approach

## Programme

**10:00 Welcome Drink**

**10:45 Mr. Yuji Fujii**

Managing Director, Charles River Laboratories Preclinical and Clinical Services Japan Inc.

Welcome Greeting

**11:00 Dr. Howard Goodall**

Clinical Research Physician, Edinburgh, UK

ICH M3(R2) and FDA MIST: New Horizons in Clinical Development

**11:45 Dr. Tim Callahan**

Chief Scientific Officer, Biomedical Systems, USA

Practical Applications of the ICH E-14  
Guideline to Thorough and Intensive QT Trials

**12:30 Lunch**

**13:15 Dr. Elise Lewis**

Director, Reproductive and Neurobehavioural Toxicology, Horsham, PA, USA

Reproductive Toxicity Testing for Biological Products

**14:00 Mr. Keith Robinson**

Scientific Director, Reproductive and Juvenile Toxicology, Montreal, Canada

Specialized Procedures in Reproductive and Juvenile Toxicology Testing

**14:45 Coffee Break**

**15:15 Dr. Lynne LeSauteur**

Director, Immunology, Montreal, Canada

Immunotoxicity Evaluation for Biologic Products

**16:00 Mr. Alun Morgan**

Safety Pharmacologist, Edinburgh, UK

*In vivo* Safety Pharmacology to support pre-clinical drug development:  
Regulatory perspectives (ICH Guidelines S7A/B) and study conduct

**16:45 Break**

**17:00 Dr. Douglas Learn**

Principal Research Scientist, Horsham, PA, USA

Photosafety: How to Address International  
Safety and Regulatory Concerns in Drug Development

**17:45 Dr. Yoshiro Shibasaki**

Business Development Manager - Asia Market, Edinburgh, UK

Closing Remarks

**18:15 - 20:00 Reception & Whisky Tasting**

For information on how to register please contact: [infopcc@jp.crl.com](mailto:infopcc@jp.crl.com)