



# Industry and Academic Perspectives

Michael Golden (Pearl Therapeutics) and David Cipolla (Aradigm), Chairs

- **Synopsis of the RDD/PQRI PK Workshop**
  - Dennis O'Connor (Boehringer Ingelheim, *USA*)
- **Dose-Response and Related Mathematical Considerations**
  - Gur Jai Pal Singh (Axar Pharmaceuticals, *USA*)
- **Equivalence of OIPs in Europe: Present and Past Approval Principles**
  - Anders Fuglsang (Consultant, Former Regulator, *Denmark*)
- ***3:00-3:30 PM Coffee/Networking Break***
- **Subject Populations and Study Designs**
  - Richard Ahrens (University of Iowa, *USA*)
- **Review of the EMEA Guidelines' In-Vitro Equivalence Criteria for Cascade Impaction Data**
  - Dennis Sandell (S5 Consulting, *Sweden*)
- **Use of In Vitro vs In Vivo Data To Conclude Equivalence of Two Inhaled Products**
  - Dave Parkins (GSK, *United Kingdom*)
- **Some unresolved issues in the use of PK for equivalence of OIPs**
  - Günther Hochhaus (*University of Florida, USA*)