

# Perspectives for Validation and Qualification from the Regulatory and Science Communities

Scientific  
Knowledge  
and  
Technology



Clinical  
Practice

# Challenges

- Scientific
- Procedural and practical
- Regulatory
- Cultural

# Collective Responsibility

**Academia**



**Industry**

**Regulators**

**Payers**

# Perspectives

1. European Perspective: Changing the paradigm for safety testing of Pharmaceuticals?  
- **Beatriz Silva Lima**
2. Update on EMA and ICH activities  
- **Sonja Beken**
3. FDA Evaluation perspective on new toxicology testing system  
- **David Jacobson-Kram**