EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

BOS1 Regulatory Expectations

Regulatory Expectations

EUROPEAN MEDICINES AGENCY

Define the role of M&S in improving / accelerating development and in optimising animal experimentation (3R principle)

Utility of M&S in translation from pre to clinical

- What is done internally in the industry?
- FIM: current practice and potential improvements based on M&S

Systems pharmacology as a new paradigm in drug development

- How mature is the field?

How to share data in a competitive environment?

Qualification of novel methodologies

- Share with all stakeholders the need for qualifying M&S approaches
- Qualification of novel methodologies procedure as a platform for discussion
- Retrospective analysis of failed studies

Role of regulators as seen by industry / academia and review of the tools made available for interaction