Visualizing the Future: Microphysiological Systems

B. R. Berridge on behalf of the IQ MPS WG
IQ Annual Symposium
5 October 2016
MPS = human-relevant complex in vitro modeling platforms
“Tissue chip devices are designed as accurate models of the structure and function of human organs, such as the lung, liver and heart. Once developed and integrated, researchers can use these models to predict whether a candidate drug, vaccine or biologic agent is safe or toxic in humans in a faster and more cost-effective way than current methods.”
IQ LGs and WGs

Microphysiological Systems WG

Multi-disciplinary team of pharmaceutical scientists representing expertise and interests in drug metabolism and distribution, safety and the 3Rs of judicious animal use for research

- 22 members
- 15 pharma organizations
**MPS Roadmap**

**Phase 0**
- Defining context of use and performance standards

**Phase I characterization**
- Cell/tissue composition
- Physiologic function
- Response to injury/perturbation
- Pharmacologic response

**Phase II validation**
- Throughput capability
- Intra- and inter-laboratory reproducibility
- Process integration
- Data management

*Pharma strategy TBD*

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**Workshop 1** - context of use, building confidence, partnerships (manuscript in revision)

**Workshop 2** - organotypic standards (manuscript in prep)

**Workshop 3** - analytical testing strategies

**NCATS Investigators**

**IQ**

**Tissue Chip Testing Centers**

**Investigator labs**

**Validation lab centers**

**Pharma/CRO/Incubator**

**Industrial Application**
Challenges of applying MPS to drug development

• Balance of biological complexity/in vivo relevance and adequate throughput
• Accounting for the biology not in the platform (complex in vitro platforms, though less reductionist, will be reductionist)
• Most impactful context of use now and in the future
• Performance measures- what’s the gold standard?
• In vitro to in vivo extrapolations
• Interpreting more mechanistic endpoints
• Considering rapid changes in scope of drug modalities (small molecules, Ab therapies, oligonucleotides, cell/gene therapy)
• Asking different questions
• Impacts on cost and time
• Building a reason to believe!
Key messages

- There is significant room for improvement in our current approaches to drug discovery and development

- Technology innovation could have a valuable impact on improving the clinical predictivity of our preclinical modeling and decrease animal use

- Decision time- what impact do we want these systems to have, when do we want it and what are we willing to do to get it?
IQ MPS Working Group = Cross-LG Collaboration

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• 15 pharma organizations
IQ MPS Panel Members

Peggy Guzzie-Peck, Global Head of Investigative Safety Sciences; J&J

Jeetu Eswaraka- Head, Investigative Toxicology, Cell and Molecular Biology; Amgen

Szczepan Baran- Global Head of Animal Welfare and Compliance Training; Novartis