

IQ MPS Affiliate

# 2019 Year-End Report



IQ Microphysiological Systems (MPS)



INTERNATIONAL CONSORTIUM *for*  
**INNOVATION & QUALITY**  
*in* PHARMACEUTICAL DEVELOPMENT

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## MISSION AND OBJECTIVES

Microphysiological systems (MPS) are potentially transformative models designed to mimic physiologically relevant functions of human or animal organs and tissues. Yet, despite rapid evolution, a number of challenges remain before these technologies can be fully incorporated into drug discovery and development. Focused efforts to characterize performance and assess the analytical validity of new tissue platforms will be needed to build a high level of confidence in the technologies in order to drive industrialization, advance regulatory acceptance and fully realize the promise of MPS.

IQ MPS was established as an Affiliate within the International Consortium for Innovation and Quality in Pharmaceutical Development to provide a venue for cross-pharma collaboration and data-sharing, to facilitate industry qualification of MPS, and to establish a focused point of engagement for regulators and other stakeholders to evolve best practices on MPS implementation in drug development.

## LEADERSHIP

**Chair** – Will Proctor, Genentech

**Vice Chair** – Monicah Otieno, Janssen

**Vice Chair Elect** - Terry Van Vleet, AbbVie

*\*Congratulations to our incoming 2020 leaders: **Terry Van Vleet**, AbbVie (Chair), **Jason Ekert**, GlaxoSmithKline (Vice Chair), and **Szczepan Baran**, Novartis (Vice Chair Elect)*

The **Steering Committee** provides strategic oversight of the initiative's portfolio and is the primary decision-making body for the IQ MPS Affiliate. The Steering Committee has representation from all member companies and acts on the recommendations of working groups and member companies to establish objectives, policies, and plans of action on a consensus basis.

The **Executive Committee** provides leadership and guidance in the management of the business and affairs of the consortium between meetings of the Steering Committee, implements strategic plans recommended by the Steering Committee, and provides general counsel and tactical advice in support of IQ MPS's Working Groups.

## MEMBER COMPANIES

AbbVie • Amgen • Alnylam • AstraZeneca • Astellas • Biogen • Bristol-Myers Squibb

Celgene • Eisai • Eli Lilly • Genentech • GlaxoSmithKline • Janssen • Merck

Merck Healthcare KGaA • Mitsubishi Tanabe • Novartis • Pfizer • Sanofi • Seattle Genetics

Takeda • Theravance • Vertex

## KEY ACCOMPLISHMENTS

June 2018 the Consortium is established

23 member companies with 56 active participants

6 new work-streams launched:  
Gap Survey 2.0  
Communications and External Outreach  
Regulatory Outreach  
Pilot Project Aim 1  
Pilot Project Aim 2  
Pilot Project Aim 3

3 surveys conducted:  
MPS Landscape Assessment & Gap Analysis  
IQ MPS Affiliate Member Census of Retrospective MPS Data  
IQ MPS Affiliate Member Census of Near Term MPS Projects

3 groups focused on data-sharing and joint MPS evaluation pilot projects

4 manuscripts published in Royal Society of Chemistry's 'Lab on a Chip'

8 presentations at 7 conferences

Successfully secured engagement for in-person workshop with FDA (Feb 26, 2020)

Developed external outreach plan for implementation in 2020

Exploring potential collaborations with Predictive Safety Testing Consortium Kidney Biomarkers Team and University of Pittsburgh MPS Database

Launched website ([www.iqmps.org](http://www.iqmps.org))



### ESTABLISHING INDUSTRY REQUIREMENTS FOR MPS CHARACTERIZATIONS

In 2019, IQ MPS supported the development of 10 manuscripts – 4 of which were published – outlining contemporary pharmaceutical industry considerations for developing, evaluating, and characterizing MPS models to support drug discovery and development. The characterization criteria proposed will inform the Affiliate's joint-testing efforts and also help guide discussions at an upcoming workshop with FDA on overcoming barriers to industry implementation.

**Next steps:** In 2020, summaries of these manuscripts will be communicated to external stakeholders and serve as a starting point for engagement with MPS developers.



### SURVEYING THE LANDSCAPE OF DRUG DEVELOPMENT INDUSTRY

#### Applications of MPS

IQ MPS conducted a thorough assessment of how pharmaceutical companies are currently using complex in vitro models (CIVM) and the overarching challenges to realizing this technology's full potential. The survey collected information from 28 companies on industry experiences, rational for and applications of CIVM, organ model priority, resource allocation, as well as perception of its promise and inclusion in regulatory filings.

**Next steps:** The Affiliate is preparing a publication offering an industry assessment of the state of the field and commentary on changes needed to accelerate adoption of CIVM. A Gap Survey 2.0 team is developing a follow-up survey focused on more advanced CIVM/MPS systems.



## DATA SHARING AND JOINT TESTING

Central to IQ MPS's mission is establishing collaboration and data sharing efforts that will enable industry to jointly characterize MPS performance. Three teams were established to identify near-term collaboration opportunities, each with a different approach to collecting and sharing MPS data.

### Retrospective Data Sharing (Aim 1 Pilot Project)

The Aim 1 Pilot Project team was convened to develop a mechanism and framework enabling members to share, collate, and analyze existing MPS data. The group identified numerous studies that companies might be able to share either publically or within IQ MPS. The team is defining data-sharing opportunities focused on individual organ systems and contexts of use, and is currently evaluating potential data sharing platforms.

**Next steps:** In 2020, the Aim 1 team will continue to develop the framework for retrospective data-sharing.

### Joint Characterization of MPS (RFI/RFP) (Aim 2 Pilot Project)

The Aim 2 Pilot Project team is developing a request for information (RFI) and Request for Proposal (RFP) process to enable prospective and collaborative projects to characterize MPS platforms. In 2019, this subteam identified two high-priority organ systems for prospective model evaluation - gastrointestinal (GI) and kidney—and devised an initial framework to identify and select model systems for prospective evaluation. The team will soon release a RFI for GI models (expected Q1/2 2020), and has identified the Predictive Safety Testing Consortium (PSTC) as a potential collaborator to evaluate a kidney model. Aim 2 is currently actively engaged in setting up collaborative agreements between the two organizations.

**Next steps:** The team will release RFIs for joint characterization of kidney and GI MPS within the Affiliate.

### Prospective Project Alignment (Aim 3 Pilot Project)

The objective of Aim 3 is to identify collaboration and alignment opportunities for ongoing projects within individual member

companies. In 2019, the team gathered information on 54 studies planned in the 12 months to follow. The team has reviewed the data and identified opportunities to initiate discussions on potential company-managed partnerships.

**Next steps:** In 2020 the team will convene organ-centric discussion groups, which will be led and managed by individual member companies to discuss opportunities to collaborate and align on planned projects.



## OUTREACH TO STAKEHOLDERS

A Communications team was organized to develop a comprehensive communications strategy and resources for engaging with non-regulatory stakeholders. The team has since launched a website (<https://www.iqmeps.org/>), implemented a social media strategy and developed collateral material to provide up-to-date and accurate information on the Affiliate's accomplishments.

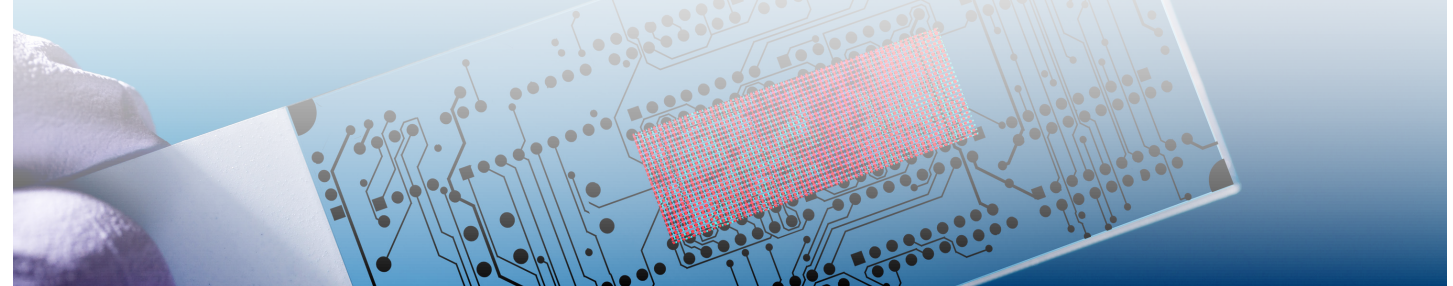
**Next steps:** In 2020, the team will implement IQ MPS's outreach strategy to initiate dialogue and establish connections with key external stakeholders.



## REGULATORY ENGAGEMENT

The Regulatory Engagement team has been planning a day-long workshop at FDA's main campus to take place in February 2020. The event, which is expected to be attended by up to 100 industry leaders and representatives from across FDA's divisions, will focus on overcoming hurdles to the adoption and acceptance of MPS technologies in safety, ADME, and pharmacology studies and opportunities to overcome barriers to submitting MPS data in regulatory submissions and gain acceptance for specific contexts of use. The meeting will include presentations on FDA's experience with MPS, industry case studies, and small group breakout discussions.

**Next steps:** In 2020, the Affiliate will continue to work with FDA to build on the progress made at the workshop and will also explore opportunities to establish similar relationships with other global regulatory agencies.





IQ MPS Members, Washington, D.C.



## PRESENTATIONS

(March 2019) **Update IQ Microphysiological Systems (MPS) Affiliate.** 14th National Center for Advancing Translational Science (NCATS) Tissue Chip Consortium Meeting. Bethesda, MD.

(April 2019) **Microphysiological Systems in Pharma: Evolving a Paradigm.** Investigative Toxicology Northern California Society of Toxicology (SOT) Spring Symposium. San Francisco, CA.

(May 2019) **Application of iPSC-Derived Neural Spheroids In Drug Discovery / IQ MPS Update.** Applied Pharmaceutical Toxicology (APT). San Francisco, CA.

(May 2019) **Industry Perspective on the use of MPS in Drug Safety Assessment.** Applied Pharmaceutical Toxicology (APT). San Francisco, CA.

(June 2019) **Implementation of multi-dimensional cellular tumor models with increase translational relevance in pre-clinical Oncology drug development.** World Preclinical Congress. Boston, MA.

(September, 2019) **Microphysiological Systems in Pharma: Evolving a Paradigm.** 9th China Society of Toxicology (SOT) National Congress. Taiyuan, China.

(October 2019) **Update on IQ Microphysiological Systems (MPS) Affiliate.** 15th Tissue Chip Consortium Meeting. Bethesda, MD.

(October 2019) **IQ Consortium- Latest Developments & Challenges.** Predict: 3D Models Summit. Boston, MA.



## PUBLICATIONS

Ainslie, G. R., Davis, M., Ewart, L., Lieberman, L. A., Rowlands, D. J., Thorley, A. J., ... & Ryan, A. M. (2019). **Microphysiological lung models to evaluate the safety of new pharmaceutical modalities: a biopharmaceutical perspective.** *Lab on a Chip*, 9(19), 3152-61. DOI: 10.1039/C9LC00492K

Hardwick, R.N., Betts, C.J., Whritenour, J., Sura, R., Thamsen, M., Kaufman E., Fabre K., (2019) **Drug-induced skin toxicity: gaps in preclinical testing cascade as opportunities for complex in vitro models and assays.** *Lab on a Chip*, 20(2), 199-214. DOI: 10.1039/c9lc00519f

Baudy, A.R., Otieno, M.A., Hewitt, P., Gan, J., Roth, A., Keller, D., Sura, R., Van Vleet, T.R., Proctor, W.R., (2019) **Liver microphysiological systems development guidelines for safety risk assessment in the pharmaceutical industry.** *Lab on a Chip*, 20(2), 215 - 225. DOI:10.1039/c9lc00768g

Fowler, S., Chen, W.L.K., Duigan, D., Gupta, A., Hariparsad, N., Kenny, J., Lai, G., Liras, J., Phillips, J., Gan, J. (2019) **Microphysiological systems for ADME-related applications: current status and recommendations for system development and characterization.** *Lab on Chip*, Epub ahead of print. DOI: 10.1039/c9lc00857h

## MEMBER BENEFITS AND SECRETARIAT SUPPORT

IQ MPS is an Affiliate of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ). The law firm of Faegre Drinker Biddle & Reath, LLP serves as Legal Counsel and Secretariat to IQ.

Composed of attorneys, scientists, and project managers, Faegre Drinker Biddle & Reath's Consortium Management Team forms and supports life sciences industry collaborations that help companies throughout the world address topics of mutual interest. For the past 25 years, the team's work with these collaborations has yielded new scientific knowledge, sound, data-driven policies, and technological advances that improve the drug development process.

### The Secretariat Supports the Affiliate By:

- Developing consensus positions on strategic initiatives and projects by facilitating member company decision-making processes within the IQ MPS
- Ensuring antitrust compliance by providing training, oversight, and ad hoc legal counsel
- Providing broad scientific, project management, legal, and administrative support
- Providing the Steering Committee with robust strategic, operational, and planning support, to include agendas, minutes, and presentations for meetings and teleconferences
- Supporting the exploration and scoping of data-sharing initiatives
- Reviewing manuscripts under development to ensure antitrust compliance
- Facilitating IQ MPS' external collaborations
- Managing internal and external communications
- Managing IQ MPS' website
- Providing venue and logistical support for in-person meetings

### Member Companies Are Entitled To:

- Two seats on the Steering Committee
- Participate in all in-person meetings and teleconferences of the IQ MPS Affiliate
- Shape data-sharing and prospective collaboration projects
- Access to the IQ MPS Collaboration Site
- Nominate representatives to all workstreams and project teams, including the Gap Survey and Pilot Project (open to all company representatives)
- Contribute to ongoing organotypic manuscripts and propose new topics (open to all company representatives)

For further information regarding IQ MPS and membership opportunities please contact:



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