IQ MPS
IQ Microphysiological Systems Affiliate

INTERNATIONAL CONSORTIUM for INNOVATION & QUALITY in PHARMACEUTICAL DEVELOPMENT

2025 YEAR-END REPORT

ABOUT IQ MPS

IQ MPS (www.iqmps.org) is a collaboration of pharmaceutical and biotechnologies companies created as an Affiliate within the International Consortium for Innovation and Quality in Pharmaceutical Development (www.iqconsortium.org) to provide a venue for appropriate cross-pharma collaboration and data sharing to facilitate the industry implementation and qualification of MPS models.

26 MEMBER COMPANIES

AbbVie, Inc.
Amgen, Inc.
Astellas Pharma US, Inc.
AstraZeneca
Biogen
Boehringer Ingelheim
Bristol-Myers Squibb
Daiichi Sankyo
Eisai, Inc.
Eli Lilly and Company
F. Hoffmann-La Roche
Genentech, Inc.
GSK
Incyte
Janssen Pharmaceuticals, Inc.
Merck & Co., Inc.
Merck Healthcare KGaA
Novartis
Novo Nordisk
Pfizer
Servier
Sanofi
Takeda
UCB Pharma, Inc.
Vertex
Zoetis

150 Active Participants

with expertise in Drug Safety, 3Rs, ADME, and PK/PD

WORKSTREAMS

Regulatory Engagement Workstream

Mission:

Advance shared industry-regulator understanding of complex in vitro models (CIVM) and microphysiological systems (MPS) and build confidence in their use by aligning on how MPS data are generated, interpreted, and incorporated into regulatory submissions.

Strategic Partnership and Communications Workstream

Mission:

Position IQ MPS as the partner of choice for education, alignment, and engagement on the pharmaceutical use of MPS by:

- Disseminating IQ MPS positions and technical learnings
- Creating venues to bring novel scientific and regulatory insights into IQ MPS to educate member companies
- Supporting adoption of MPS techniques among the next generation of scientists

Organotypic Manuscripts

Mission:

Benchmark design features, performance standards, and qualification criteria that MPS developers should consider when building scientifically relevant models fit for use in drug development.

Pilot Project (RFI/RFP) Workstream

Mission:

Provide a collaborative, cross-pharma venue for data sharing and collective problem-solving that accelerates industry-wide implementation and qualification of CIVM/MPS models.

Active Projects:

Gastrointestinal (GI): Collaboration with Altis using a jejunum model to measure toxicology biomarkers across cellular expansion, differentiation, and fully differentiated tissue states

ALTIS BIOSYSTEMS

Kidney: Collaboration with Newcells using a proximal tubule model to evaluate cross-species differences in common toxicology biomarkers

NEWCELLS

Position and Benchmarking Workstream

Mission:

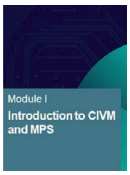
Benchmark design features, performance standards, and qualification criteria to support development of fit-for-purpose, scientifically relevant MPS for drug development.

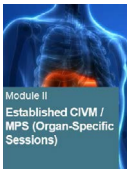
2025 **ACCOMPLISHMENTS**

Regulator Reviewer Training Course

Building global regulatory confidence in complex in vitro models

From 2023-2025, IQ MPS partnered with FDA to deliver a multi-year training program for PharmTox reviewers focused on best practices for evaluating and applying CIVM data in regulatory submissions.





Course Modules

Module I - Introduction to CIVM and MPS

Module II -Established CIVM / MPS (Organ-Specific Sessions)

2025 Highlights

- Developed a **3-hour workshop** for China's NMPA Center for Drug Evaluation, in coordination with RDPAC, based on prior course materials
- Expanded access to **MHRA**, strengthening international regulatory engagement

3Rs Collaborative Webinar Series

Connecting MPS developers and end-users around emerging science

Since 2022, the 3Rs Collaborative-MPS Initiative (3RsC-MPS) and IQ MPS have partnered to host workshops that facilitate communication between MPS technology developers, industry end-users, and other stakeholders. In 2025, IQ MPS supported four webinars with model developers:

- Retina & Ocular MPS Workshop
- Using AI/ML with MPS Workshop
- Multi-Organ MPS - Part 1 Workshop
- Multi-Organ MPS - Part 2 Workshop

Technical Learnings Seminars

Peer-to-peer knowledge sharing and problem solving for MPS implementation

IQ MPS Technical Learnings Seminars are short, focused sessions addressing real-world technical challenges in qualifying and implementing MPS for drug development. Members present case studies or practical scenarios, followed by open discussion with IQ MPS members and colleagues.

In 2025, IQ MPS organized six seminars:

Date	Topic
March 2025	Qualification of lung MPS: Muntasir Mamun Majumder, AstraZeneca
April 2025	Prediction of absorption and intestinal first-pass elimination utilizing a human 3D intestinal microtissue: Stephanie Kourula, Johnson & Johnson
April 2025	Employing a physiologically relevant 3D in vitro model for safety evaluation of T cell-based therapies: May Freag Takeda
June 2025	Human intestinal organoids predict clinical diarrhea for small molecule inhibitors in the oncology pipeline: Mike Beshiri, AstraZeneca
June 2025	Differentiation state of intestinal organoids impacts viability assays and predictive outcome for drug-induced diarrhea: Julie Co, Genentech
Oct 2025	Prediction of drug-induced kidney injury by biomarker response in a proximal tubule MPS: Anna-Karin Sjögren, AstraZeneca

2025 **ACCOMPLISHMENTS** *CONTINUED*

Position Papers and Organotypic Manuscripts

Shaping policy and best practices that facilitate CIVM and MPS adoption

Since its establishment in 2018, the IQ MPS Affiliate has consistently published benchmarking analyses and consensus perspectives that articulate industry needs, define fit-for-purpose complex in vitro models (CIVMs), and support broader qualification and adoption.

2025 Publications

Stresser, David M., et al. "Towards In Vitro Models for Reducing or Replacing the Use of Animals in Drug Testing." *Nature Biomedical Engineering*, vol. 8, no. 8, 2024, pp. 930-935, doi:10.1038/s41551-023-01154-7.

- Position paper developed with DruSafe, 3Rs TPS, and TALGs in response to the FDA Modernization Act 2.0.

Devine, Patrick J., et al. "Pharmaceutical Industry Perspective on the Utility of Animal Cell-Based Microphysiological Systems to Support Human Drug Development." *ALTEX*, 2025, doi:10.14573/altex.2407122.

- IQ MPS white paper outlining the role of animal cell-based MPS models in building confidence for human cell-based MPS applications.
- Complemented by an FDA-authored perspective: **Brown, Paul C., et al.** "Potential Value of Animal Microphysiological Systems." *ALTEX*, vol. 42, no. 4, 2025, pp. 692-699, doi:10.14573/altex.2311141.

Candarlioglu, Pelin L., et al. "Application of Microphysiological Systems for Nonclinical Evaluation of Cell Therapies." *ALTEX*, vol. 41, no. 3, 2024, pp. 469-484, doi:10.14573/altex.2402201.

- Manuscript outlining considerations for developing, evaluating, and characterizing MPS to support cell therapy discovery and development.

Celauro, Emanuele, et al. "Exploring the Synergy of CRISPR and Microphysiological Systems." *ALTEX*, vol. 42, no. 3, 2025, pp. 468-478, doi:10.14573/altex.2403251.

- Manuscript describing key considerations for applying MPS to emerging gene-editing modalities, including model performance and characterization.

New Workstreams

Strengthening the MPS Ecosystem

In 2025, IQ MPS launched new working groups to strengthen engagement with technology developers and early-career scientists through recurring "Office Hours" sessions.

New!

Office Hours for MPS Developers

Provides a forum for MPS and CIVM developers to receive direct industry feedback–offering a clear "voice of the customer" to guide technology development and support qualification and adoption.

New!

Office Hours for Early-Career Scientists

Offers open sessions to help early-career scientists understand industry expectations and build relevant skills, supporting a stronger future talent pipeline for IQ MPS member companies.

STEERING COMMITTEE

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

AbbVie Inc.
- Rita Ciurlionis
- Soumya Mitra

Amgen Inc.
- Alexander Sternjak

Astellas Pharma US
- Sowmya Balasubramanian
- Qun Li

AstraZeneca
- Kainat Khan
- Rhiannon David

Biogen
- Chris Hinckley
- Colin Choi

Boehringer Ingelheim International GmbH
- Luke Coyle
- Tom Chan

Bristol-Myers Squibb
- Patrick Devine
- Rhiannon Hardwick

Daiichi Sankyo
- Thomas Fischer

Eisai Co., Ltd.
- Raku Shinkyo
- Tushar Kokate

Eli Lilly and Company
- Mike Mohutsky
- Thomas Baker

F. Hoffmann-La Roche
- Remi Villenave
- Wen Li Chen

Genentech, Inc.
- Aaron Fullerton
- Kimberly Homan

GSK
- Josie McAuliffe
- Prabhakar Pandian
- William Proctor

Incyte
- Manti Guha

Janssen Pharmaceuticals, Inc.
- Onyi Ofoma
- Raymond Evers

Merck & Co., Inc.
- John Gleeson
- Wen Kang

Merck Healthcare KGaA
- Philip Hewitt
- Sakshi Garg

Novartis
- Francesca Moretti
- Julia Riede

Novo Nordisk, Inc.
- Rachelle Baun
- Sara Toftegaard Hjuler

Pfizer, Inc.
- Anna Kopec
- James Gosset

Sanofi
- Dimitrios Bitounis

Servier
- Amélie Moreau
- Chloe Korlowski

Takeda
- Matthew Wagoner
- May Freag

UCB, Pharma, Inc.
- Jason Ekert
- Benoit Cox

Vertex Inc.
- Arek Raczynski
- Bo Feng

Zoetis
- Charli Fant
- Logeswari Ponnusamy

SECRETARIAT

Mary Devlin Capizzi

MBA: Legal Counsel

SECRETARIAT

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JD: Legal Counsel

SECRETARIAT

Jillian Brady

MS: Senior Manager, Science, Regulation, & Policy

SECRETARIAT

Catherine Mattia

Project Manager

SECRETARIAT

John Peter (JP) Cortez

Analyst, Research & Policy