2022 YEAR-END REPORT

IQ MICROPHYSIOLOGICAL SYSTEMS AFFILIATE

INTERNATIONAL CONSORTIUM for INNOVATION & QUALITY in PHARMACEUTICAL DEVELOPMENT

IQ MPS
IQ Microphysiological Systems Affiliate

LETTER FROM THE CHAIR AND VICE CHAIR

We are impressed by the many accomplishments of the MPS Affiliate during another unpredictable and challenging year. In 2022, the MPS Affiliate focused on rounding out early foundational work and activating the next phase of work, including multiple collaborations with regulators and developers, with the goal to overcome challenges in building confidence in MPS technologies and realize their potential to improve preclinical predictivity.

The Affiliate made great strides in educating MPS developers on how to tailor their models and qualification data sets to meet industry needs by continuing to expand their collection of organotypic manuscripts. Three new manuscripts were published as of early January 2023. The MPS Affiliate also completed a draft manuscript summarizing insights revealed by two comprehensive surveys assessing the landscape of industry applications and experience with MPS models in 2019 and 2021. The information gathered from these surveys has also helped inform the MPS Affiliate's discussions with stakeholders, including the FDA, on the hurdles the field still faces.

In 2022, the Affiliate also advanced two pilot projects to the final study design phase, one characterizing complex in vitro model for predicting gastrointestinal toxicity and the other evaluating drug-induced proximal tubule injury across species. However, perhaps one of the most significant developments of 2022 was the planning and execution of an international regulatory and pharmaceutical industry workshop, which focused on addressing the need for standardization of MPS to accelerate model utilization in the context of regulatory decision-making. This was the Affiliate's second workshop with the FDA but the first with global regulators in attendance and has led to other opportunities, such as the development of another joint publication with the FDA and another workshop on the use of animal-based MPS models which took place in April 2023.

The completion of these pivotal milestones, some years in the making, has laid the foundation for the next phase of the MPS Affiliate's work, which in the near term will focus on collaborating with the FDA on a multi-series training course to provide PharmTox reviewers with considerations for MPS qualification and good practices for MPS study design, controls, and interpretation of results under general and organ-specific contexts.

The Affiliate ended 2022 with optimism. We've welcomed two new members – Incyte and UCB — and continue to attract interest from many companies considering membership. We also finally had the opportunity to reconnect and reengage for an in-person meeting in Washington, D.C.! After several years of exclusively remote participation due to the pandemic and travel restrictions, our Q4 2022 in-person meeting energized the community and sparked many new ideas for advancing the field, including a commentary on the readiness of New Approach Methodologies, like MPS, to replace animal models, which will be published in 2023.

As the IQ MPS Affiliate approaches its fifth anniversary in mid-2023, we are grateful for the generous collaboration of this special community. We encourage you to stay in touch in 2023 by following the MPS Affiliate on LinkedIn and staying informed regarding our progress via the website (iqmps.org).

We congratulate and thank all the MPS Affiliate participants and member companies for their terrific engagement and support. We are inspired by your commitment and enthusiasm and eager to see all the future holds for the important work we are accomplishing together!

Rhiannon Hardwick PhD, DABT
Chair (2022-2023)
Scientific Associate Director,
Bristol Myers Squibb

Anna Kopec, PhD
Vice Chair (2022-2023)
Director, Investigative Toxicology
Research & Development, Pfizer

MICROPHYSIOLOGICAL SYSTEMS (MPS)

Models that go beyond traditional 2D culture and include several of the following design aspects:

- A multi-cellular environment within biopolymer or tissue-derived matrix
- A 3D structure
- Mechanical factors such as stretch or perfusion/flow
- Primary or stem cell derived cells
- Immune system components

Microphysiological systems (MPS) have promising applications in drug discovery and development that could ultimately improve the translational success of drug candidates with the additional potential benefit of impacting the 3Rs (replacing, reducing and refining animal use). However, for the full potential of these technologies to be realized, there are many hurdles to overcome, including qualifying these tools for clearly defined contexts of use and generating the data needed to ensure end-user and regulatory confidence. To address these challenges, a group of pharmaceutical and biotechnology companies came together under the International Consortium for Innovation and Quality in Pharmaceutical Development to establish the IQ MPS Affiliate.

OUR MISSION

Serve as a thought leader for both MPS developers and stakeholder organizations in the industry implementation and qualification of MPS models.

Create focused engagement between industry and regulatory agencies on the status and evolving field of MPS in an industry setting.

Provide a venue for appropriate cross-pharma collaboration and data sharing to facilitate industry implementation and qualification of MPS models.

Develop external partnerships and collaborations to help enhance the inclusion of industry priorities.

23
member companies

115+
active participants

60+
meetings

3
publications

6
presentations

1,783
new website visitors from...

47 countries

NEW
IQ MPS LinkedIn Page

245 added followers

11 posts with more than...

14,000 total views

5 WORKSTREAMS

Landscape Assessment Survey

Organotypic Manuscript Series

Series 1.0 Introduction, Lung, Skin, Liver, Kidney, ADME, Biologics, Cardiovascular, Gastrointestinal. Cited 163 times.

Series 2.0 Introduction, Oligos (published in 2022), Immune System (published in 2022), Disease Models (published in 2023), Ocular, Gene Editing, Cell Therapies, Reproductive

MPS Characterization Pilot Projects

GI RFI/RFP Team

Kidney RFI/RFP Team

Strategic Partnership and Communication (SPAC)

Partnerships

National Center for Advancing Translational Sciences (NCATS)

Critical Path Institute (C-Path) Predictive Safety Testing Consortium (PSTC)

North American 3Rs Collaborative (NA3RsC)

2 Liver Webinars
featuring presenters from two academic institutions and nine commercial developers

2 Neuro Webinars
featuring presenters from one academic institution, one pharmaceutical company, and 13 commercial developers

Webinar Available Here

2 Kidney Webinars
featuring one academic institution

Webinar 1 Available Here
Webinar 2 Available Here

Regulatory Outreach

2022 IQ MPS/FDA/Global Health Authorities Workshop and Manuscript
on "Establishing Performance Criteria and Standards for MPS"

Attended by representatives from PDMA, Health Canada, MHRA, EMA, OECD, Japan AMED, NCATS, NIH, EURL ECVAM, NIST, NIHS, EUROoCS, and NICEATM

Planning Committee: 2023 IQ MPS/FDA Workshop and Manuscript
on "The Value of Animal Cell Based MPS and 3Rs Applications of MPS"

Planning Committee: Training Series for FDA PharmTox Reviewers

White Paper: The Readiness of New Approach Methodologies
to Replace Animal Models and Commentary on the FDA Modernization Act 2.0

LANDSCAPE ASSESSMENT SURVEY

To gain a better understanding of how pharmaceutical companies within the IQ MPS Affiliate and broader IQ consortium are currently using MPS models, the IQ MPS Affiliate conducted two comprehensive benchmarking surveys — one in 2019 and one in 2021. For each survey, IQ members answered more than 100 questions providing insight into technical characteristics of the models they have worked with, including resourcing, organs of interest, type of compound modalities tested and cell types, as well as current applications of MPS technologies in internal decision-making. The 2021 survey also included questions aimed at revealing more granular details about company experiences building confidence in model performance and translatability and perceived obstacles to utilizing MPS data in regulatory filings.

Comparing the results of these comprehensive surveys has not only provided valuable insight into the current state of the science of MPS technologies and the pace of progress, but has also revealed common challenges that need to be overcome to realize the full potential of MPS in the context of drug discovery and development. These insights have been used to inform IQ MPS Affiliate priorities and facilitate discussions with regulators on the datasets needed to satisfy end-user confidence for drug development applications. In 2022, a small team came together to prepare a manuscript summarizing the results and offering insights into what they reveal about the future direction of the field. They anticipate the manuscript will be published in 2023.

Organs of Greatest Interest:

- Liver
- Gut
- Kidney
- CNS/BBB
- Cardiovascular

Multi-Organ Systems of Greatest Interest:

- Liver-Gut
- Liver-Cardiovascular
- Liver-Kidney
- Tumor-Immune

ORGANOTYPIC MANUSCRIPT SERIES

Over the past few years, the IQ MPS Affiliate has prepared a collection of manuscripts outlining the pharmaceutical industry perspective on organ- and modality-specific best practices for designing, developing, and qualifying MPS models for various applications in drug discovery and development. To date, there are a total of twelve manuscripts, each providing important consideration for MPS developers and end-users, including essential model functions and measures for establishing baseline performance, exemplar drugs to assess predictive capacity and mechanisms of toxicity, standard 2D models for comparison, and likely contexts of use.

As this collection of manuscripts has grown, so has its impact. Since the first series of manuscripts was published, they have collectively been cited more than 163 times. The recommendations outlined in these manuscripts have been referenced by various stakeholders as a valuable guide for the core design features, datasets and other pharmaceutical end-user requirements needed to make MPS models fit for use.

In the coming year, the team looks forward to rounding out their collection of organ-specific manuscripts with the submission of Ocular and Reproductive manuscripts. A BBB-focused manuscript is also in preparation. In 2023, the team also plans to add two more therapeutic-specific manuscripts focusing on MPS applications for cell and gene editing therapies.

2022 Accomplishments

- Published two manuscripts in ALTEX (Oligos and Immune System) and submitted a third manuscript (Disease Models), which was accepted in early 2023.
- Presented manuscript summaries at five conferences.

Next Steps

- Publish manuscripts on Ocular models, Reproductive models, and applications of MPS in the development in cell therapies and gene therapies.
- Prepare a manuscript on Blood Brain Barrier (BBB) models.

2022 Publications

- Ramsden, D., Belair, D. G., Agarwal, S., Andersson, P., Humphreys, S., Dalmas, D. A., ... & Cichocki, J. A. (2022). Leveraging microphysiological systems to address challenges encountered during development of oligonucleotide therapeutics. ALTEX-Alternatives to animal experimentation. Available here.
- Wang, X., Kopec, A., Collinge, M., David, R., Grant, C., Hardwick, R., Navratil, A., Patel, N., Rowan, W. and Marshall, N. (2022) “Application of Immunocompetent Microphysiological Systems in Drug Development: Current Perspective and Recommendations”, ALTEX - Alternatives to animal experimentation. Available here.

MPS CHARACTERIZATION WORKSTREAM

The MPS Characterization Workstream provides a forum for members to explore opportunities to collaborate on proof-of-concept (POC) studies focused on characterizing and qualifying MPS models for specific COUs. In the past few years, this workstream has quickly evolved from pressure-testing different pathways for facilitating collaboration to developing and executing a stepwise process for soliciting information and proposals from interested parties. The Workstream currently has two active subteams — one focused on gastrointestinal (GI) models and the other focused on kidney models. In 2022, both substeams successfully solicited proposals from three GI MPS developers and two Kidney MPS developers.

The GI subteam has designed a study to evaluate toxicology biomarkers in GI MPS and GI stem cell toxicity that will help lay the foundation for more in-depth studies in the future, such as evaluating assay sensitivity and specificity. In the coming year, they anticipate confirming the parameters of their study design and initiating the project with their chosen GI model.

In collaboration with the C-PATH Predictive Safety Testing Consortium, the Kidney subteam has designed a study using an MPS kidney model to compare drug-induced renal proximal tubule injury and the resulting toxicology biomarker profile across 4 species. This would be one of the first MPS studies to investigate kidney toxicity and biomarkers across multiple species. Similar to the GI subteam, the Kidney subteam also anticipates confirming the parameters of their study design and initiating the project in 2023.

2022 Accomplishments

Gastrointestinal MPS Characterization Project

- Released draft GI Toxicology RFP and received responses from three MPS developers.
- Based on RFP responses, identified opportunity to assess two contexts-of-use in one study (toxicology biomarkers and stem cell toxicology).
- Developed comprehensive study design, including test compounds, biomarkers and readouts.
- Performed extensive cost evaluation analysis.

Kidney MPS Characterization Project

- Released Kidney RFP and received responses from two MPS developers.
- Conducted a thorough review of RFP responses and collaborated with PSTC to develop a study design to explore toxicology biomarkers in the context of drug-induced proximal tubule injury in models across four species.
- Performed extensive cost evaluation analysis.

Next Steps

Gastrointestinal MPS Characterization Project

- Finalize study design and initiate with selected MPS developer.

Kidney MPS Characterization Project

- Finalize study design and initiate with selected MPS developer.

RFI/RFP Workstream General

- Develop data management and publication strategy.
- Continue streamlining RFI/RFP workflow.
- Identify organ system for new RFI/RFP.

Shuyan Lu, MS
Principal Scientist
Janssen

What Our Members Are Saying

In 2022 , I was involved in the kidney and GI MPS project teams and it's been very exciting to see both teams make significant progress towards their goals. The results of these upcoming studies will provide much needed knowledge to help implement MPS models in our testing cascade. The forum the IQ/MPS Affiliate has provided has been invaluable and has allowed us to leverage expertise and resources from different companies for a better and more comprehensive study design.

STRATEGIC PARTNERSHIPS AND COMMUNICATIONS WORKSTREAM

In 2022, the Strategic Partnerships and Communications (SPAC) Workstream continued to support the dissemination of IQ MPS priorities and positions to the broader scientific community by refreshing core materials and establishing a LinkedIn page, which quickly acquired more than 245 followers. Members of the SPAC team also led the development of a workshop session on 'New Approach Methodologies in the Pharmaceutical Sciences: Novel Strategies Challenging the Traditional Testing Paradigm to Increase Regulatory Confidence', which was accepted to the 2023 Society of Toxicology Annual Meeting." In 2023, the SPAC team will aim to further strengthen and diversify the IQ MPS Affiliate's external communications by identifying conferences and symposia where IQ MPS should be represented to support the continued growth of the field.

In addition to communications, another core objective of the SPAC team is to develop external partnerships and collaborations to bring novel information into the affiliate and enhance the inclusion of industry priorities. To that end, in 2022, the SPAC Workstream worked closely with North American 3Rs Collaborative (NA3RsC) to deliver three webinars and three workshops on new developments in commercial liver, CNS, and kidney MPS. These events provided IQ MPS members with a comprehensive overview of commercially available MPS models, with an emphasis on recent developments. The series will continue in 2023 with webinars on BBB, vascular systems, GI and Lung.

To encourage greater knowledge sharing and communication among the IQ MPS Affiliate membership, the SPAC team established Technical Learnings Seminars to facilitate the sharing of learnings around overcoming challenges to qualifying or integrating MPS into drug development. The SPAC team organized its first discussion in 2022 and looks forward to facilitating more discussions in 2023.

2022 Accomplishments

- Refreshed IQ MPS Affiliate website and master slide deck.
- Established LinkedIn page.
- Partnered with NA3RsC to deliver three webinars and two workshops on liver, CNS, and kidney MPS.
- Led the successful development of a 2023 Society of Toxicology (SOT) Workshop.
- Established internal discussion series to facilitate sharing of technical learnings around MPS characterization.

Next Steps

- Support foundational activities by refreshing website content, curating core presentation materials and regularly posting on LinkedIn.
- Build on NA3RsC success with additional workshops and greater access.
- Continue to build networks that promote and facilitate the use of MPS by maintaining relationships with EUROoCS, HESI, NC3Rs, NA3RsC, ARMI, and NCATS and reaching out to newly identified organizations.
- Facilitate internal information exchange with Technical Learnings Seminars.

REGULATORY ENGAGEMENT WORKSTREAM

In 2022, the Regulatory Engagement team kicked off the year with the successful publication of the proceedings from their 2020 workshop with the FDA in ALTEX. The 2020 workshop was a critical step in laying the groundwork for the many ongoing collaborations with FDA, and the publication of the workshop proceedings reaffirmed the areas of need that are now being addressed through ongoing collaborations with the FDA.

One area of need discussed at the 2020 workshop was identifying the barriers to applying MPS in drug development and finding ways to encourage the incorporation of MPS data in regulatory submissions. To that end, the Regulatory Engagement team and FDA agreed that a follow-up workshop to discuss those challenges and explore the potential benefits of aligning on standards for MPS qualification would be of value. In May 2022, the IQ MPS Affiliate and more than 200 representatives from FDA, IQ MPS Affiliate, and global regulatory organizations and standards-setting organizations from Europe, Japan and Canada convened for a virtual workshop on this topic. The outcomes from that workshop have been summarized in a publication and are expected to be available in 2023.

As a follow-up to those discussions, the FDA invited the IQ MPS Affiliate to develop a course for PharmTox reviewers to inform them on industry practices for selecting, qualifying and integrating MPS into their drug discovery and development process. The course will consist of multiple sessions conducted over the course of the year, with the first sessions planned for Q2 2023.

Another essential area identified at the 2020 workshop was the need to align on the value of preclinical species MPS to build greater confidence in species concordance and clinical translatability. That was addressed in an April 2023 workshop. As with the first two workshops, a manuscript will follow.

Finally, at the end of 2022, in response to the passage of the FDA Modernization Act 2.0 and subsequent public anticipation of an acceleration in the adoption of New Approach Methodologies (NAM), such as MPS, in drug development, members of the Regulatory Engagement team agreed to develop a commentary to provide the industry's perspective on the Act and the current readiness of NAMs to replace animal models. That manuscript is anticipated to be published in 2023.

2022 Accomplishments

- 2020 IQ MPS FDA workshop proceedings published in ALTEX.
- Successfully executed 2022 IQ MPS FDA virtual workshop on the Development of Performance Standards and Guidelines for MPS in Drug Development. The workshop was attended by more than 200 representatives from industry, FDA, international regulatory agencies, and standards setting organizations attended.
- Initiated planning for a 2023 IQ MPS FDA virtual workshop on Animal Cell Based MPS and 3Rs Applications of MPS. Continued to develop draft commentary on the value of animal cell based MPS.
- Initiated planning of a four-module course to inform FDA PharmTox reviewers on best practices for qualifying and applying MPS models in drug discovery and development.
- Initiated work on a commentary on the Readiness of New Approach Methodologies to Replace Animals in Drug Testing.
- Expanded outreach to global regulatory agencies.

Next Steps

- Publish the proceedings of the 2022 IQ MPS FDA Workshop on "Considerations from an International Regulatory and Pharmaceutical Industry (IQ MPS Affiliate) Workshop on the Standardization of Complex In Vitro Models in Drug Development.
- Execute a successful workshop in 1Q 2023 with FDA and global regulatory agencies on Animal Cell Based MPS and 3Rs Applications of MPS.
- Publish a manuscript on the outcomes of the 2023 workshop.
- Complete Module I of the PharmTox Reviewer Training Course - Introduction to CIVM and MPS. Develop content for Module II - Established CIVM/MPS (Organ-Specific Sessions).

2022 Publications

- Baran, S. W., Brown, P. C., Baudy, A. R., Fitzpatrick, S. C., Frantz, C., Fullerton, A., ... & Ekert, J. E. (2022). Perspectives on the evaluation and adoption of complex in vitro models in drug development: Workshop with the FDA and the pharmaceutical industry (IQ MPS Affiliate). ALTEX-Alternatives to animal experimentation. Available here.

WHAT OUR MEMBERS ARE SAYING

Saket Agarwal, MS
Senior Scientist,
Investigative Toxicology
Alnylam Pharmaceuticals

Participation in the IQ MPS Affiliate has been a great experience and has permitted me personally, and us as a group, to tap into the knowledge and experience of other experts in the field. It has been particularly exciting to see some of the objectives come to fruition this year, including multiple publications. IQ MPS Affiliate is one of the most engaged and collaborative group that I've had the pleasure of working with

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Qun Li, PhD
Science Director, Research
Program Management
Astellas Research Institute
of America LLC

Participating in IQ MPS Affiliate has provided a valuable opportunity to discuss with other subject matter experts and then advise internal MPS activities. Picking up the role of a liaison between IQ Translational & ADME Leadership Group and IQ MPS Affiliate made me appreciate furthermore the importance of continued cross-disciplinary interactions in promoting application of Complex In Vitro Models in drug discovery and development process. I particularly enjoyed the open, insightful discussions in IQ MPS/FDA workshops this year. I feel I have a better understanding on the unmet needs, and the strong sense of collaboration between IQ and FDA is also very encouraging.

OUR MEMBERS AT A GLANCE 2022

EXECUTIVE COMMITTEE

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 working groups.

Past Chair (2022-2023)	Chair (2022-2023)	Vice Chair (2022-2023)	Vice Chair Elect (2022-2023)
Jason Ekert UCB	**Rhiannon Hardwick** Bristol Myers Squibb	**Ania Kopec** Pfizer	**Rhiannon David** AstraZeneca

STEERING COMMITTEE

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.

Prathap Mahalingaiah · AbbVie
David Stresser · AbbVie
Saket Agarwal · Alnylam Pharmaceuticals, Inc.
Sarah Hyde · Alnylam Pharmaceuticals, Inc.
Xiaoting Wang · Amgen
Qun Li · Astellas
Kainat Khan · AstraZeneca
Rhiannon David · AstraZeneca
Chris Hinckley · Biogen, Inc.
Sandra Engle · Biogen, Inc.
Gaurav Kaushik · Boehringer Ingelheim
Thomas Chan · Boehringer Ingelheim
Rhiannon Hardwick · Bristol Myers Squibb
Sei Kameoka · Bristol Myers Squibb
Raku Shinkyo · Eisai Inc.
Tushar Kokate · Eisai Inc.
Michael Mohutsky · Eli Lilly and Company
Thomas Baker · Eli Lilly and Company
Kimberly Homan · Genentech, Inc.
Aaron Fullerton · Genentech, Inc.
Josie McAuliffe · GSK

Alejandro Amador Arjona · Incyte
Manti Guha · Incyte
Onyi Irrechukwu Ofoma · Janssen Research & Development, LLC
Raymond Evers · Janssen Research & Development, LLC
John Gleeson · Merck & Co., Inc
Wen Kang · Merck & Co., Inc
Philip Hewitt · Merck Healthcare KGaA
Sakshi Garg · Merck Healthcare KGaA
Maria Moalli · Novartis
Tomas Joachim Mow · Novo Nordisk
Christian Pehmøller · Novo Nordisk
Ania Kopec · Pfizer Inc.
James Gosset · Pfizer Inc.
Karissa Adkins · Sanofi
Piyush Bajaj · Sanofi
Matthew Wagoner · Takeda
Reiner Class · UCB
Jason Ekert · UCB
Arek Raczynski · Vertex Inc.
Sanjeev Kuma · Vertex Inc.

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 and its affiliates.

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 (open to all company representatives)
- Contribute to ongoing organotypic manuscripts and propose new topics (open to all company representatives)

Mary Devlin Capizzi, JD, MBA
Legal Counsel
Secretariat
mary.devlincapizzi@faegredrinker.com

Reed Abrahamson, JD
Legal Counsel
Secretariat
reed.abrahamson@faegredrinker.com

Jillian Brady, MS
Senior Manager, Science, Regulation & Policy
Secretariat
jillian.brady@faegredrinker.com

Catherine Mattia
Project Manager
Secretariat
catherine.mattia@faegredrinker.com

IQ MPS Affiliate Membership Inquiries

2023 membership in the IQ MPS Affiliate is open to all members of the IQ Consortium. For questions about the IQ MPS Affiliate and its priorities and membership, please email **Catherine Mattia** at catherine.mattia@faegredrinker.com

IQ MPS AFFILIATE 2022 PARTICIPANTS

With sincere gratitude to all 2022 participants

ABBVIE
David Stresser*
Prathap Mahalingaiah*
Brian Enright
Christian Grant
David Belair
David Kukla
Garrett Ainslie
Keith Luhrs
Margaret Ramos
Rita Ciurlionis
Ronnie Yeager
Sharma Abhinav
Terry Van Vleet
Wayne Buck

ALNYLAM PHARMACEUTICALS, INC.
Saket Agarwal*
Sarah Hyde*
Chris MacLauchlin

AMGEN
Xiaoting Wang*
Sara Humphreys

ASTELLAS PHARMA, INC.
Qun Li*

ASTRAZENECA
Kainat Khan*
Rhiannon David*
Amer Saleh
Amy Pointon
Asli Akidil
Diane Ramsden
Emanuele Celauro
Kenneth Pryde
Louis Gall
Louise Delsing
Mick Fellows
Patrik Andersson
Roberto Nitsch
Simone Stahl

BIOGEN
Chris Hinckley*
Sandi Engle*
Colin Choi
Ilona Sunyovszki
Zhonghua Zhu

BOEHRINGER INGELHEIM
Gaurav Kaushik*
Thomas Chan*

BRISTOL MYERS SQUIBB
Rhiannon Hardwick*
Sei Kameoka*
Alexa Murray
John Szilagyi
Kyle Kolaja
Lauren Lewis
Myrtle Davis
Patrick Devine
Silvi Chacko

EISAI INC.
Raku Shinkyo*
Tushar Kokate*

ELI LILLY AND COMPANY
Michael Mohutsky*
Thomas Baker*
Aaron Thomas Smith
Kathleen Hillgren

GSK
Josie McAuliffe*
Banupriya Sridharan
Deidre Dalmas
Dinesh Stanislaus
Julianna Deakyne
Lisa Mohamet
Mirella Georgouli
Nikki Marshall
Pelin Candarlioglu
Taraka Sai Pavan Grandhi
Wendy Rowan

INCYTE CORPORATION
Alejandro Amador Arjona*
Manti Guha*
Brian Sayers

JANSSEN RESEARCH & DEVELOPMENT, LLC
Onyi Irrechukwu Ofoma*
Raymond Evers*
Ferran Jardi
Stephanie Kourula
Shuyan Lu

MERCK & CO.
John Gleeson*
Wen Kang*

MERCK HEALTHCARE KGaA
Philip Hewitt*
Sakshi Garg*

NOVARTIS
Maria Moalli*
Adi Wasserkrug
Birk Poller
Georgia Maria Rouseti
Juan Patarroyo
Magali Ferro

NOVO NORDISK
Christian Pehmøller*
Tomas Joachim Mow*

PFIZER, INC.
Anna Kopec *
James Gosset*
Alanna Sedgwick
Duc Phan
Julie Harney
Lindsay Tomlinson
Luping Qiu
Mark Collinge
Roshan Ashoor
Wenyue Hu

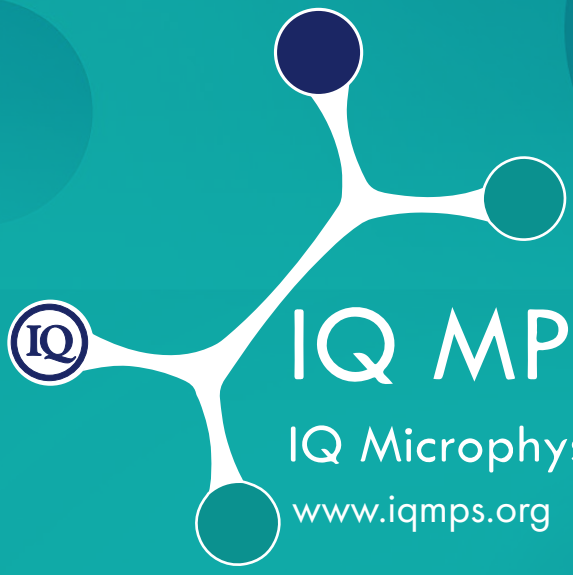
SANOFI
Piyush Bajaj*
Karissa Adkins*
Nirav Patel

TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.
Matthew Wagoner*
Anitha Saravanakumar
Diane Ramsden
George Papadopoulos
Lauren Gauthier

UCB
Jason Ekert*
Reiner Class*

VERTEX PHARMACEUTICALS, INC.
Arek Raczynski*
Sanjeev Kumar*
Jeffrey Willy
Joseph Cichocki
Sean Sheehy
Yoojin Shin

* 2022 Steering Committee Member



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INTERNATIONAL CONSORTIUM *for*
INNOVATION & QUALITY
in PHARMACEUTICAL DEVELOPMENT