Contents

Welcome to the IQ Annual Report • 1
Vision, Mission, Strategic Objectives • 2
2018 Year in Review • 3
The Power of Collaboration • 5
IQ Events • 7
IQ’s Impact • 8
What Our Members Are Saying • 12
IQ Membership • 13
IQ Board of Directors • 14
Leadership Groups • 15
Secretariat Support • 16
Welcome to the IQ Annual Report.

After launching in 2010, IQ grew steadily and now ranks among the most influential scientific- and regulatory-focused consortia in the life sciences industry. We are a vibrant and dynamic group that continues to grow. We look forward to maintaining—even accelerating—our momentum.

The following annual report was created in response to an opportunity identified by IQ’s Board of Directors to communicate how IQ is impacting our industry and the value it generates for its member companies. IQ’s achievements would not be possible without the passion, hard work, and commitment of all IQ participants and our government and academic partners. Together, we are advancing innovation and quality in pharmaceutical development in truly inspiring ways.

We rely on member engagement to drive IQ’s success. Recently, we completed a comprehensive Participant Engagement Survey. The overall input was significant and the survey results are already informing constructive changes across IQ. Over the past few years, the Board’s careful attention to membership feedback led to the creation of a Biologics CMC Leadership Group, a unified Quality Leadership Group, an enhanced database agreement, and affiliated groups focused on drug-induced liver injury (DILI) and microphysiological systems (MPS). IQ will continue to adapt and change to meet the new challenges presented by evolving science, regulations, and our members’ needs.

It is also important to share our work with the rest of the pharmaceutical community. We are establishing ties with the American Association of Pharmaceutical Scientists (AAPS), the International Society for Pharmaceutical Engineering (ISPE), the Pharmaceutical Research and Manufacturers of America (PhRMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the American Society for Clinical Pharmacology and Therapeutics (ASCPT), and other like-minded organizations to raise awareness of our achievements and objectives.

To remain a strong and vital organization, we must continue to identify and empower emerging leaders within the IQ community. The recent elevation of Carl McMillian (Eli Lilly) and the election of Margaret Faul (Amgen) as our next chair and vice chair, respectively, bode well for our ability to attract innovative and dynamic thinkers to lead our organization. In addition, our commitment to attracting a broader range of our colleagues to engage in IQ activities, including the annual IQ Symposium, ensures that the impact and value of IQ will be sustained.

In reading this report, you’ll find that IQ proudly offers a compelling value proposition and remains dedicated to identifying and adapting to our membership’s needs. There is no greater prerequisite for the effectiveness of our consortium. As we approach a second decade of IQ activities, I want to take this opportunity to thank you for your past support and your commitment to what is sure to be a bright and exciting future.

PIERRE BOULAS (BIOGEN) • IQ Consortium Chair
Vision

The vision of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ Consortium or IQ) is to be the leading science-based organization advancing innovative solutions to biomedical problems and enabling pharmaceutical companies to bring quality medicines to patients.

Mission

As a technically focused organization of pharmaceutical and biotechnology companies, IQ advances science and technology to augment the capability of member companies to bring transformational solutions that benefit patients, regulators, and the broader research and development (R&D) community.

Strategic Objectives

Collaborate across IQ member companies to create cross-functional data sets, scientific positions, and conclusions with greater scope and impact than possible by any member company alone.

Advance relationships with global professional organizations, other consortia, academics, and government research institutes to ensure scientific excellence and harmonization.

Proactively engage global regulators on issues and opportunities to advance science-based regulations in pharmaceutical development.

Share the results of IQ’s initiatives with international scientific and regulatory communities.

Ensure the continued value of IQ through committed leadership, focused and clear priority setting, productive cross-disciplinary collaborations, and active engagement by a diverse talent pool to plan for leadership succession.
2018 YEAR IN REVIEW

1,411 PARTICIPANTS

27 CONFERENCE PRESENTATIONS AND POSTERS

10 MEETINGS WITH INTERNATIONAL REGULATORY BODIES

16 PUBLICATIONS

18 COMMENTS ON REGULATORY GUIDANCES AND STANDARDS

8 WEBINARS

40 MEMBER COMPANIES
IQ provides valuable opportunities to address important scientific and regulatory challenges with colleagues in the industry.

98% Benchmarking exercises conducted through IQ help me to stay current on industry practices and trends.

96% IQ gives me valuable opportunities to learn about emerging scientific and regulatory issues.

86% IQ provides me with the opportunity to advance innovative ideas.

97% IQ helps me to meet new people and build my professional network.

92% Data-sharing activities have helped us to expand our knowledge of specific topics.

88% IQ provides an effective platform for engaging regulatory authorities on important regulatory science issues.

89% IQ provides valuable professional development opportunities for our scientists.

Data Sourced from 2018 IQ Participant Engagement Survey
The Power of Collaboration

With more than 40 members—including some of the world’s leading pharmaceutical and biotechnology companies—and 80 scientifically driven working groups, IQ provides a science-focused venue to facilitate drug research and development. Our collaborative structure and culture foster powerful benefits.

Shared Technical Expertise
Members draw on the intellectual capital of more than 1,400 scientists in a pre-competitive space. Member company representatives engage collaboratively in a range of initiatives addressing timely and critical drug-development issues.

Shared Research
IQ members leverage a unique database and data-sharing framework. Voluntarily contributed data is categorized and analyzed in formulating scientific positions, conclusions, and recommendations. Survey results, white papers, conference proceedings, and other materials are shared Consortium-wide.

Benchmarking & Analytics
IQ employs careful analysis of R&D data to assess performance, examine industry trends, answer critical business questions, establish best practices, and identify opportunities for innovation and scientific development.

Managed Risk
Two or more members frequently sponsor cooperative research projects. This approach, even when it does not result in discovery, often provides data and insights that inform better decisions and further mitigate risk.
Regulatory Engagement
Consortium members enjoy a valuable platform from which they can engage with the FDA and with European, Latin American, and Asian regulatory bodies.

Professional Development
Members enter into pilots and other work streams that might not be available to them through their individual companies. Industry leaders can harness the potential of IQ to build professional networks and hone “softer” team-building, emotional intelligence, and communications skills.

Affiliated Groups
As the market and our clients’ interests warrant, IQ creates affiliated groups to explore distinct pharmaceutical and biotechnological issues, reducing redundancies and generating potential cost savings. Currently, scientists representing a cross-section of companies are focused on drug-induced liver injury (DILI) and microphysiological systems (MPS).

Legal & Administrative Resources
The Consortium’s Secretariat provides legal, compliance, and technical support for IQ’s activities, fostering compliance with antitrust laws and assisting with the combination of data sets across companies for use in defined research projects. The Secretariat also handles various administrative tasks, allowing IQ participants to maintain a scientific focus.

Cost Efficiencies
The 40+ members of the IQ Consortium enjoy substantial economies of scale. Annual fees are reasonable, administrative costs are well controlled, resource redundancy is minimized, and costly “dead ends” are often avoided.

External Partnerships
IQ focuses on constructive scientific exchange through publications, conferences, workshops, and roundtables. Our 80 working groups frequently include representatives from government and academia, eliciting immediate and ongoing feedback from key opinion influencers and thought leaders.
IQ Events

IQ provides a pre-competitive, science-focused venue to facilitate drug research and development. As part of this mission, IQ hosts educational events to facilitate technical expertise, research, and best-practice sharing; encourage networking opportunities; and engage with regulators.

IQ Symposium

To date, IQ has held seven members-only full-day symposia focused on a cutting-edge theme, emerging trend, or industry challenge. Each year, these pivotal events are attended by hundreds of representatives of IQ member companies actively engaged on the IQ Board of Directors, Leadership Groups, and Working Groups.

IQ Symposium themes have focused on innovation through pre-competitive collaboration, new horizons in drug development, industry approaches to medical challenges in an aging population, and the development of new therapies for underserved populations. Each IQ Symposium features gifted thought leaders and renowned speakers from the biopharmaceutical industry, international regulatory bodies, and patient populations. Attendees cultivate crucial connections through a combination of interactive speaker presentations, team-building exercises, and breakout sessions.

Participants return to their organizations with enlightened perspectives and fresh ideas for addressing industry challenges, and they bring value-added best practices that benefit not only their companies but also the broader R&D community.

IQ CMC Summit

The IQ Chemistry, Manufacturing, and Controls (CMC) Summit is an annual event that brings together subject-matter experts from the IQ CMC Leadership Groups and Working Groups for a full day of inspired presentations, in-depth discussions, and a holistic review of the Consortium’s CMC portfolio.

The CMC Summit features plenary talks on contemporary topics and fosters an environment where members can explore collaborative topics, coordinate existing efforts, and launch new initiatives across Leadership Groups. Members emerge from the CMC Summit with operational plans and strengthened connections; many new Working Groups and joint efforts have originated from CMC Summit discussions. This venue generates continuous collaborative dialogue and helps fulfill IQ’s mission of advancing innovative solutions through pharmaceutical development.
IQ’s Impact on Professional, Scientific, and Regulatory Communities in 2018

IQ Consortium participants have contributed to a number of deliverables over the past year through the benchmarking activities, information exchange, data sharing, and other joint initiatives pursued across our membership. Below is a list of select key deliverables developed by the IQ Consortium in 2018.

Publications


Presentations, Posters, and Webinars

IQ 3RLeadership Group (2018, March). The 3Rs in North America. Presentation at the PRIM&R 2018 Institutional Animal Care and Use Committee Conference, Columbus, OH.


IQ DruSafe Leadership Group (2018, November). The IQ Consortium Nonclinical to Clinical Translational Database and Predictive Value. Presentation at American College of Toxicology’s 39th Annual Meeting, West Palm Beach, FL.


What our members are saying...

IQ participants share perspectives on their engagement in the consortium

See the full interviews at iqconsortium.org/annual-report-2018

“We’re a global organization. All of our companies are multinational. We’re working with regulatory agencies not only here in North America but also in Europe and Asia.”

Akintunde Bello
Bristol-Myers Squibb

“IQ allows us to share data in a pre-competitive manner so we can advance the science in a way that we wouldn’t be able to do easily within our own companies.”

Nancy Agrawal
Merck & Co.

“IQ has an excellent structure that manages all of the working and leadership groups, as well as a website that contains relevant, timely information.”

Jing-Tao Wu
Alnylam

“Often we don’t have a large enough data set to make a breakthrough or try to improve upon a process or science, and IQ gives all members a way to bring that data together to look at it across companies.”

Jack Cook
Pfizer

“IQ creates a common pre-competitive space in biomedical research that facilitates intelligent, effective, and safe innovation for all.”

Tracy Williams
Eli Lilly

“It’s a one-stop shop where, whether you’re involved in late-stage drug development or very early in discovery, you can work in a pre-competitive space with colleagues to solve some really challenging problems.”

Leon Carayannopoulos
Celgene

“IQ has it all: It’s a pre-competitive space where the scientific and technical developers can share data and ideas; access relevant, timely information; work with colleagues to solve challenging problems; and open and maintain a dynamic dialogue with the FDA, EMA, and other regulatory agencies. Done and done!”

Mark Rogge
Takeda
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IQ Board of Directors

CHAIR: PIERRE BOULAS • BI Owen

VICE CHAIR: CARL MCMILLIAN • ELI LILLY

VICE CHAIR ELECT: MARGARET FAUL • AMGEN

Hafez Abdel-Kader • Sanofi
Leslie Anthony • Eli Lilly
Phil Bonasia • Sunovion
Francois Brackman • Pierre Fabre
Alexander Bryant • Ironwood
John Burkhardt • Pfizer
Leigh Ann Burns • Gilead
Anne Chester • Gilead
Patrick Cullinan • Takeda
Donna Dambach • Genentech
Kelly Davis • Baxter
Myrtle Davis • Bristol-Myers Squibb
Olympe Depelchin • UCB Pharma
Paul Deutsch • UC B Pharma
Craig Dunbar • Ironwood
Joseph Dybowski • Alnylam
Philip Floyd • GlaxoSmithKline
Michael Garvin • AstraZeneca
Theresa Goletz • EMD Serono
Peggy Guzzie-Peck • Johnson & Johnson/Janssen
Takayuki Hara • Mitsubishi Tanabe
Timothy Hart • GlaxoSmithKline
Ling He • Daiichi Sankyo
Marcel Hop • Genentech
Keith Horspool • Boehringer Ingelheim
Elisabeth Husar • Roche
Vivek Kadambi • Blueprint Medicines
Douglas Keller • Sanofi
Belinda King • Eisai
Steve King • AbbVie
Brent Kleintop • Bristol-Myers Squibb
Gondi Kumar • Celgene
Sanjeev Kumar • Vertex
Hue Kwon • Roche
Daniel Lapadula • Novartis
Qun Lu • Celgene
Suresh Mallikaarjun • Otsuka
Jim McShane • Eisai
Mark Milton • Novartis
Thomas Monticello • Amgen
Dale Morris • Biogen
Mark Mowery • Merck
Brad Mueller • Incyte
Dennis O’Connor • Boehringer Ingelheim
Palani Palaniappan • Sarepta
Alexandre Passiouglov • Pierre Fabre
Lakshminarasimhan Pranatharthiharan • Sunovion
Arash Raoufinia • Otsuka
Mark Rogge • Takeda
Wendy Saffell-Clemmer • Baxter
Marlowe Schneidkraut • Astellas
Anita Shah • Bayer
Dana Shuey • Incyte
Lee Silverman • Agios
Wataru Takasaki • Daichi Sankyo
Srini Tenjarla • Shire
Kimberly Treinen • Sunovion
Yoshifumi Uno • Mitsubishi Tanabe
Csanad Varga • Blueprint
Thomas Visalli • Eisai
Timothy Watson • Pfizer
Markus Weigandt • EMD Serono
Devin Welty • Shire
Philip Worboys • Theravance
Danlin Wu • Vertex
Jing-Tao Wu • Alnylam
Paul Wu • Bayer
W. Peter Wulfing • Merck
Mehran Yazdanian • Teva
Gorm Yoder • Johnson & Johnson/Janssen
Tong Zhu • Astellas
For more information about IQ membership and its benefits, please contact Mary Devlin Capizzi or Maureen Cruz at the IQ Secretariat.

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Leadership Group Leads

CMC

Analytical LG
Mark Argentine • Eli Lilly  
Brian Regler • Merck  
Dennis Stephens • AbbVie

Active Pharmaceutical Ingredient LG
Timothy Curran • Vertex  
John Traverse • Celgene  
Kevin Seibert • Eli Lilly

Drug Product LG
Qun Lu • Celgene  
Ahmad Almaya • Eli Lilly  
Robert Ternik • Eli Lilly

Biologics CMC LG
Saroj Ramdas • GlaxoSmithKline  
Barbara Rellahan • Amgen

Statistics

Statistics LG
J. David Christopher • Merck

Life Sciences

Clinical Pharmacology LG
Sandhya Girish • Genentech  
Vikram Sinha • Merck  
Tong Zhu • Astellas  
Akintunde Bello • Bristol-Myers Squibb

Translational and ADME Sciences LG
Nancy Agrawal • Merck  
Jens Sydor • AbbVie

DruSafe LG
Donna Dambach • Genentech  
Thomas Monticello • Amgen  
Mazin Derzi • Pfizer  
Timothy Hart • GlaxoSmithKline

3Rs Translational and Predictive Sciences LG
Szczechan Baran • Novartis  
Natalie Bratcher • AbbVie  
Sean McGuire • GlaxoSmithKline  
Norman Peterson • MedImmune

Quality

Quality LG
Dennis O’Connor • Boehringer Ingelheim  
Chris Turner • Celgene  
K. Scott Dunham • Merck  
Jeff Beebie • Pfizer  
Mark Butchko • Eli Lilly  
Chris Grosso • Merck

Secretariat Support

The law firm of Drinker Biddle & Reath LLP serves as Secretariat and Legal Counsel to the IQ Consortium. Comprising attorneys, scientists, and project managers, Drinker Biddle’s Consortium Management Team executes central legal and administrative tasks. Team support includes:

- Facilitating member company decision-making processes to develop consensus positions on strategic initiatives and projects
- Ensuring antitrust compliance by providing training, oversight, and ad hoc legal counsel
- Providing broad scientific, project management, legal, and administrative support
- Providing the Board of Directors with robust strategic, operational, and planning support
- Supporting the Board of Directors with robust strategic, operational, and planning support
- Supporting the exploration and scoping of various data-sharing initiatives
- Implementing and executing data-sharing projects through custom-designed databases and surveys
- Reviewing manuscripts under development to ensure antitrust compliance
- Facilitating external engagements with key stakeholders
- Managing internal and external communications
- Managing the public website and internal collaboration portal
- Providing venue and logistical support for in-person meetings