Consortia Management

Guiding collective efforts to advance science and policy for the pharmaceutical, biotechnology, and medical device industries.
<table>
<thead>
<tr>
<th>Contents</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A HISTORY OF COLLABORATION</td>
<td>5</td>
</tr>
<tr>
<td>REPRESENTATIVE CONSORTIA</td>
<td></td>
</tr>
<tr>
<td>IQ</td>
<td>9</td>
</tr>
<tr>
<td>PML CONSORTIUM</td>
<td>10</td>
</tr>
<tr>
<td>RX 360</td>
<td>13</td>
</tr>
<tr>
<td>IPPC</td>
<td>15</td>
</tr>
<tr>
<td>IPAC-RS</td>
<td>17</td>
</tr>
<tr>
<td>ADDITIONAL CONSORTIA AT DRINKER BIDDLE</td>
<td>18</td>
</tr>
<tr>
<td>OUR TEAM</td>
<td>20</td>
</tr>
<tr>
<td>CONTACT US</td>
<td>23</td>
</tr>
</tbody>
</table>

“As I survey the issues facing the world of biomedical innovation, it is clear that no single organization... can muster all of the knowledge, talent, creativity, and resources required to decipher our continuously expanding knowledge... I cannot agree more ... about the need for creating a common precompetitive space in biomedical research that should facilitate intelligent, effective, and safe innovation for all.”

- Elias Zerhouni

Peer-to-peer sharing spurs scientific innovation.
To Our Clients and Colleagues:

For the past 20 years, our team has been privileged to work with pharmaceutical, biotechnology, and medical device companies on a variety of joint endeavors promoting the development and manufacture of safe and effective drug products and medical devices. Through the sharing of knowledge, experience, and resources, these endeavors have advanced the science of drug products and medical devices and built consensus on critical issues of safety, quality, and innovation.

It seems clear that industry’s prospects will only be enhanced by greater collaboration. Joint initiatives that marshal the best thinking of scientists across the industry are often the best means for overcoming scientific and regulatory hurdles that cannot be effectively addressed through the efforts of individual firms. Such initiatives also build confidence among regulators and the medical and patient communities.

Our team’s legal, scientific, project management, and administrative expertise provides an effective method for coordinating these efforts. This brochure provides information about a variety of the consortia we currently support. We look forward to continuing to work with them as the industry strives to promote public health through new and advanced medicines and medical devices.

The DBR Consortia Management Team
Myriad Challenges

Today’s pharmaceutical, biotechnology, and medical device companies face myriad challenges. Among these are the pressing needs to accelerate innovation, safeguard supply chains and distribution networks, address rare diseases, build consensus on scientifically based standards, ensure the safety of products and devices, protect the privacy of patients and research subjects, and achieve compliance with applicable laws and regulations.

Empowering Partnerships

To meet these challenges, consortia working with our team have not only built partnerships across industry but also with the patient, medical, scientific, academic, and regulatory communities. In some cases, these crucial stakeholders serve on advisory panels that provide the consortia with perspective and expert guidance. In other instances, they participate as observers and attend meetings to remain abreast of activities. In all cases, the contributions of those outside industry have greatly increased the ability of these consortia to accomplish their goals.

A sampling of consortia represented by Drinker Biddle follows.

“Consortia supported by DBR bring together some of the best minds in the industry. The opportunity to collaborate with these individuals to address critical issues is invaluable.”

- Terrence Tougas, PhD
Highly Distinguished Research Fellow, Boehringer Ingelheim; Chair, IQ Consortium
Composed of members of the pharmaceutical and biotechnology industries, the International Consortium for Innovation and Quality in Pharmaceutical Development is a science-focused organization that enables companies to combine their experiences, expertise, and resources to collectively address the myriad scientific, technical, and regulatory challenges involved in the development of medicinal products.

By facilitating knowledge-sharing in nine major areas of pharmaceutical science, promoting best practices, publicizing pertinent findings, and engaging non-industry stakeholders such as academic centers, government agencies, and pharmacopeias, the Consortium aims to improve quality and decision-making, reduce product attrition and overall costs through innovation, and advance science-based and scientifically driven standards, guidance, and regulations.

Driving Innovation and Quality

Composed of members of the pharmaceutical and biotechnology industries, the International Consortium for Innovation and Quality in Pharmaceutical Development is a science-focused organization that enables companies to combine their experiences, expertise, and resources to collectively address the myriad scientific, technical, and regulatory challenges involved in the development of medicinal products.

By facilitating knowledge-sharing in nine major areas of pharmaceutical science, promoting best practices, publicizing pertinent findings, and engaging non-industry stakeholders such as academic centers, government agencies, and pharmacopeias, the Consortium aims to improve quality and decision-making, reduce product attrition and overall costs through innovation, and advance science-based and scientifically driven standards, guidance, and regulations.
A New Paradigm for Addressing Rare Diseases

The Progressive Multifocal Leukoencephalopathy (PML) Consortium is a collaborative multi-institution effort to enhance the understanding of and identify more effective methods for predicting, preventing, and treating PML, a rare but life-threatening disease associated with a variety of immunomodulatory and immunosuppressive treatments.

Through a wide variety of activities, including the development of a database of demographic information and clinical data, sample collection, and research conducted in collaboration with academia, health authorities, and other stakeholders, the Consortium aims to develop novel approaches for mitigating risk and achieving the best care and protection for patients.

www.pmlconsortium.org
Rx-360 brings together pharmaceutical and biotech companies, as well as suppliers to the industry, who have partnered to improve the quality, security, and integrity of the biopharmaceutical supply chain. The Consortium has developed two auditing programs that allow companies to share audit reports from audits that they have conducted on their suppliers and conduct joint Rx-360 sponsored audits of a supplier, with resulting audit reports available for purchase by non-sponsors or non-members.

Rx-360 produces up to the minute summaries, analyses, and reports on current and emerging regulation, legislation, and news affecting the biopharmaceutical supply chain, all made available to the public. The Consortium has also established an effort to collaboratively address with suppliers and regulators supply chain security challenges such as cargo theft, counterfeiting, and product diversion. In addition to its on-going efforts, Rx-360 regularly addresses emergent issues with significant impact on the industry such as natural disasters through ad hoc working groups.
The International Pharmaceutical Privacy Consortium (IPPC) is an association of research-based pharmaceutical companies that face worldwide responsibility for the protection of personal health information and other types of personal data. The IPPC provides a forum for industry dialogue and consensus-building on global privacy issues and engages government and stakeholders in a constructive dialogue about the need for personal data to support cutting edge biomedical research and other public health activities.

The Consortium’s areas of focus include the EU Data Privacy Directive and Member State implementing laws and enforcement initiatives; US federal and state data privacy and security requirements, applicable regulations, and regulatory guidance; and key privacy and security requirements in countries outside the US and EU. The IPPC analyzes the impact of these laws on clinical research, safety reporting, pharmaceutical sales and marketing, and human resource programs.

Ensuring Data Privacy Globally
The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) is a consortium of companies that develop, manufacture or market orally inhaled and nasal drug products (OINDPs) for treatment of respiratory and other diseases. The Consortium addresses chemistry, manufacturing, controls, delivery systems, and global regulatory issues. IPAC-RS develops best practices; publishes; meets with health authorities (US FDA, Health Canada, European Medicines Agency, Chinese FDA and others); and comments on regulatory guidances and standards proposed by the U.S. and European Pharmacopoeias, the International Standards Organization, and other authorities.

IPAC-RS also organizes conferences about directions and challenges in the development of OINDPs. Its most recent conference, Bringing Value to the Patient in a Changing World, incorporated the perspectives of patients, physicians, health insurers, industry, and regulators.

IPAC-RS has addressed other key topics, such as improved statistical tests for delivered dose uniformity, analytical and statistical aspects of dissolution testing of inhaled products, techniques and best practices for control of foreign particulates in OINDPs, efficient data analysis for cascade impaction measurements, analytical and safety thresholds for control of leachables and extractables, design and materials for OINDP devices, and Good Manufacturing Practices of the OINDP device components.

www.ipacrs.com
Additional Consortia at Drinker Biddle & Reath

**Alliance for Biosecurity**
The Alliance for Biosecurity promotes a stronger, more effective partnership between government, the biopharmaceutical industry, and other stakeholders in order to advance their shared goal of developing critically needed medical countermeasures. The Alliance also seeks to develop sound public policy proposals that could bolster national efforts to rapidly develop, produce, stockpile, and distribute medical countermeasures. Alliance members believe that innovations created in the biodefense space can inform and accelerate drug and vaccine development in many critical areas. The Alliance supports a long-term national security vision for achieving and sustaining defenses against a range of all infectious diseases that present national security challenges.

www.allianceforbiosecurity.org

**Extractables and Leachables Safety Information Exchange**
The Extractables And Leachables Safety Information Exchange (ELSIE) is developing a database of safety and chemistry information on chemical entities that are extracted from or can leach out of container closure systems and packaging materials used for pharmaceuticals, medical devices, and biologics. The database can be used by member companies to support regulatory filings, select appropriate materials, and conduct risk analysis.

www.elsiedata.org

**International Pharmaceutical Aerosol Consortium**
The International Pharmaceutical Aerosol Consortium (IPAC) represents leading manufacturers of metered-dose inhalers (MDIs) that contain chlorofluorocarbons (CFCs) and hydrofluorocarbons (HFCs) as propellants used to deliver medications to the respiratory system. IPAC addresses the interests of these manufacturers on issues under the Montreal Protocol on Substances that Deplete the Ozone Layer and the Kyoto Protocol to the UN Framework Convention on Climate Change.

www.ipacmdi.com

**Medical Device Privacy Consortium**
In light of the increasing compliance challenges for medical device companies in the area of data protection, the Medical Device Privacy Consortium was launched in January 2011. The mission of the Consortium is to facilitate medical device company efforts to understand how emerging data protection laws impact the industry, enable a coordinated industry response to legislative and regulatory initiatives that would impede critical data flows, and save resources through collaboration on common data privacy compliance tools.

www.deviceprivacy.org

**Nanomedicines Alliance**
The mission of the Nanomedicines Alliance is to promote and facilitate the scientific advancement, regulatory approval, and public appreciation of nanotechnology-based medicines world-wide for the diagnosis, treatment, and prevention of disease. The Alliance provides a sustained forum for exchange of ideas on nanomaterials and nanotechnologies; increased opportunities for collaborative research, industry surveys, and benchmarking exercises; and increases members’ presence in nanotechnology-related scientific, business, and regulatory communities.

www.nanomedicines-alliance.org

**Pharmaceutical Records and Information Management**
The Pharmaceutical Records and Information Management Organization (PRIMO) provides a forum for dialogue, benchmarking, consensus-building, and development of best practices, compliance strategies, training materials, and other practical tools for effective records and information management in the pharmaceutical industry. PRIMO aims to contribute to more effective regulations and standards by communicating consensus positions to US and international regulatory and standard-setting bodies.

www.pharma-rim.org
Our Team

Science Advisors and Policy Analysts

The Science Advisors and Policy Analysts on our team have expertise in scientific disciplines including chemistry, immunology, virology, physics, pharmaceutics, statistics, and others as well as regulatory policy. They are responsible for project management and providing scientific support for the consortia. In consultation with consortia leadership, they facilitate meetings and teleconferences; prepare presentations, agendas, and minutes; and implement plans of action. They frequently conduct technical research and analyses, prepare scientific papers, and coordinate interactions with regulators and other stakeholders.

Project Coordinators

Our project coordinators are responsible for scheduling, coordination, and communications. They have extensive background in organizational planning, meeting planning, administration and management, and project execution. They schedule teleconferences and meetings, maintain calendars of activities, administer websites and extranets, plan and organize conferences and symposia, and manage the financial affairs of the consortia.

Attorneys

Our attorneys provide legal counsel and strategic oversight, and are responsible for compliance with applicable laws and regulations including, in particular, the requirements of antitrust law. They also provide expertise in particular areas of law and regulation relevant to the biopharmaceutical and device industries, including regulatory affairs and government relations.

Our team of attorneys, science advisors, policy analysts, and project coordinators has over 20 years of experience working with pharmaceutical, biotechnology, and medical device consortia. At present, we represent 12 such organizations.

Clockwise from Top Left: Chihiro Ikegami, Ilse Peterson, Darle Godfrey, Maureen Hardwick, Jim Jamieson, Mary Devlin Capizzi, Kim Rouse, Kristin Colley, Lana Lyapustina, Maggie Liu, Maja Leah Marshall, Rebekah Grabowski, Lee Nagae, Debbie Armstrong

Inset Photos: Megan Cahill, Peter Blenkinsop, and Stan Crosley
Complete List of Consortia

Representative Consortia Members

- Alliance for Biosecurity
- Extractables and Leachables Safety Information Exchange
- International Consortium for Innovation and Quality in Pharmaceutical Development
- International Pharmaceutical Aerosol Consortium
- International Pharmaceutical Aerosol Consortium on Regulation and Science
- International Pharmaceutical Privacy Consortium
- Medical Device Privacy Consortium
- Nanomedicines Alliance
- Pharmaceutical Records and Information Management Organization
- Progressive Multifocal Leukoencephalopathy Consortium
- Rx-360

- 3M
- Abbott
- Amgen
- Astellas
- AstraZeneca
- BASF
- Bavarian Nordic
- Baxter
- Bayer
- Biogen Idec
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Chiesi Farmaceutici
- Elan Pharmaceuticals
- GE Healthcare
- Genentech
- GlaxoSmithKline
- Hospira
- Hovione
- Johnson & Johnson
- Merck & Co., Inc.
- Novartis
- Pfizer
- Roche
- sanofi
- Sigma Aldrich
- SHL Group
- Takeda
- Teva
- Rexam
- Watson
- Vectura

For further information on our practice and these consortia, please contact:

- Mary Devlin Capizzi
  Partner
  (202) 230-5101 phone
  Mary.DevlinCapizzi@dbr.com

- Maureen Donahue Hardwick
  Partner
  (202) 230-5133 phone
  Maureen.Hardwick@dbr.com

- Ballard (Jim) Jamieson, Jr.
  Partner
  (202) 230-5189 phone
  Ballard.Jamieson@dbr.com

By using sustainable printing methods including vegetable based inks and recycled paper, and partnering with an environmentally responsible printing facility Drinker Biddle saved the following resources:

- 17 pounds of solid waste not generated
- 27 gallons of wastewater flow saved
- 56,423 BTU's of energy not consumed