



Reflection on 2013 A Message from IQ's Chair, Lewis Kinter, Ph.D.

This past year has been one of reflection, ingenuity, and continued achievement for the IQ Consortium. In 2013 IQ expanded its membership to include 35 companies involved in pharmaceutical R&D. We concluded the year with our annual symposium "Pharma Landscape in 2020", which emphasized one of IQ's core initiatives - the necessity for innovation. During the symposium, we explored some of the future challenges our industry will face and collaborated to develop strategies to position IQ as a leader of innovation in the Pharma industry. We bring to 2014 fresh ideas, a clearer vision, and renewed determination.

Advancing Science and Best Practices

The thirty Working Groups formed and supported by IQ's Leadership Groups continue to advance IQ's mission through information sharing, joint research and publication. In 2013, IQ published papers on strategies and approaches to investigation of therapeutic protein drug-drug interaction, prediction of Cytochrome P450-mediated drug interaction, and important elements for an effective green chemistry program. Other Working Groups such as "Best Practices in Contract Manufacturing" and "Impact of Excipient Variation on Drug Product Performance" completed and shared comprehensive surveys within IQ member companies.

Proactively Building Consensus with Regulators

FDA's recognition of IQ as a leading industry organization for scientific and technical issues is evident, as IQ was invited by FDA to be the only industry partner for organizing the May 2013 Symposium on development of microphysiological systems for use as regulatory tools. Several IQ Leadership Groups also had constructive exchanges with various FDA offices in 2013. In June, the Clinical Pharmacology and Drug Metabolism Leadership Groups met with FDA's Office of Clinical Pharmacology to discuss model-based drug development. In July, the 3Rs Leadership Group held a workshop with FDA and CAAT (Center for Alternatives to Animal Testing) focusing on ways to enhance 3Rs in toxicology studies. These meetings have resulted in further exchange and collaborations between IQ and FDA, which will undoubtedly help shape industry practice and regulatory direction for those subjects.

External Collaborations

In 2013, IQ established important strategic partnerships with two organizations: National Center for Advancing Translational Science (NCATS) and International Pharmaceutical Excipients Council (IPEC). IQ and NCATS are collaborating on drug metabolism pharmacokinetics molecular model building, and exploring other projects such as

continuous manufacturing. With enthusiastic support and participation from IPEC, IQ is spearheading an initiative aiming to develop and secure support for a new regulatory framework that would simplify and expedite the approval of novel excipients. IQ has recently opened direct talks with the Pharmaceutical Research and Manufacturers Association (PhRMA) regarding collaboration on preclinical and CMC technological aspects of pharmaceutical development.

New Initiatives to Bring IQ to the Next Level

Building on IQ's record of achievement in 2011-2012, the Leadership Groups and Board of Directors brainstormed new plans with great potential and in 2013 gained approval to move forward with them. Importantly, the Board decided to establish a database framework for the Consortium, which will provide an unparalleled infrastructure for current and future data sharing initiatives. Other initiatives include the above-mentioned "Novel Excipients", collaborations with NCATS, and preclinical to clinical translation of safety data. IQ participants are also actively exploring several other topics and may bring them forward as additional "next-level" initiatives.

Communications and Outreach

The IQ Consortium has also increased its visibility amongst member companies and the pharmaceutical industry. Recently, IQ has launched a LinkedIn group, which shares many IQ accomplishments and increases the potential for collaboration. The website and member forum have also been updated this year. These platforms allow IQ to share their accomplishments with the broader community.

The Year Ahead

As Jim Collins points out in his books 'Good to Great', Good is the primary impediment to becoming/sustaining a Great organization. Great organizations have a clear and 'maniacal' focus upon their purpose, avoid distractions that would divert from that purpose, and in doing so generate 'brand momentum' that is discernible to both internal and external stakeholders, IQ is developing some of the characteristics that Jim Collins identifies with great organizations. During 2014, we will see more publications in leading journals, workshops and conferences, new webinars, and increased recognition of IQ as a leading organization, thanks to the commitment of IQ participants. It is with hope and excitement that I look forward to seeing IQ continued strides towards advancing pharmaceutical science and regulation.

Lewis Kinter, Ph.D.

Chairman of IQ Consortium, 2013-2014
Senior Director, Regulatory Toxicology
AstraZeneca Pharmaceuticals