



Reflection on 2014 A Message from IQ's Chair, Lewis Kinter, Ph.D.

I am elated by the enormous growth of IQ during my past two years as Chairman. IQ has continued to foster innovation across various Pharma disciplines by advancing science and best practices and by engaging regulators and other associations. This success was highlighted this October during IQ's annual Symposium, "Innovation through Precompetitive Collaboration". The event not only presented the hard work and achievements of IQ's Working groups, but also underlined the impact and value of IQ in the pharmaceutical industry. IQ continues to expand its membership, develop momentum for key initiatives, and increase awareness of the "IQ Brand" throughout the industry.

Advancing Science and Best Practices

The IQ Leadership and Working groups made outstanding contributions to the consortium's mission to advance science and best practices. In 2014, IQ published over 15 papers in 2014 on diverse topics ranging from CMC (e.g., API starting materials, applicability of design spaces, Process Analytical Technology, and Green Chemistry) to animal use for toxicology testing to pharmabiotech's approaches to 3Rs. Additionally, IQ hosted a number of workshops to engage relevant stakeholders, including academics and regulators besides the industry, in more informal and interactive dialog to facilitate perspective exchange and consensus building. These workshops, which covered topics such as the application of GMPs in early development, physiological-based pharmacokinetic modeling, best practices in 3Rs, and clinical pharmacology for pediatric drug development, generated outcomes that have either been published or are in preparation for publication.

Most recently, the IQ QTc Working Group, in collaboration with two other consortia, published a paper which summarized the results of a Phase 1 clinical trial and convincingly demonstrated alternatives to thorough QT studies in certain settings. This paper will help justify the industry using less resource-intensive approaches to assessing QT effects of new compounds while still ensuring patient safety. The results were presented and discussed in December at a workshop on FDA's White Oak campus.

To facilitate accomplishing its goal of developing positions and recommendations based on collective scientific data, IQ is both establishing a flexible database to collect and store voluntarily shared member company data and standardizing the data sharing processes. The new database and standardized processes will streamline the initiation and execution of data-sharing projects.

Proactively Building Consensus with Regulators

Throughout 2014, IQ has been very conscious of developing and strengthening relationship with regulators. The CMC Leadership Groups met with senior leaders of FDA's

Office of Pharmaceutical Quality, who expressed interest in being engaged in specific IQ projects. Additionally, the IQ Preclinical Safety Leadership Group (also known as "DruSafe") had a well-received one-day face-to-face meeting with FDA's Pharm/Tox supervisors and BioSafe Leadership to discuss topics including Adversity and the NOAEL in Toxicology Studies, Starting Dose for Phase 1 Clinical Studies, Non-Clinical Requirements to Support Orphan Drug Development, and New Pregnancy and Lactation Labeling. It is evident that the FDA recognizes IQ as a leading industry organization for scientific and technical issues, as IQ Preclinical Safety and Clinical Pharmacology Leadership Groups were invited by FDA to be the industry partner for organizing a workshop on best practices on dose finding of small molecule oncology drugs in Spring, 2015.

External Collaborations

IQ continued to strengthen and expand its efforts in collaborating with other organizations. For example, IQ has been actively collaborating with the International Pharmaceutical Excipient Councils (IPEC) on a new regulatory framework for the approval of novel excipients, and with the European Pediatric Formulation Initiative (EuPFI) on pediatric drug development. Most recently, IQ's Analytical and Statistical Leadership groups co-sponsored a workshop with the United States Pharmacopeia (USP) and the American Association of Pharmaceutical Scientists (AAPS) on Lifecycle Approach to Validation of Analytical Procedures with Related Statistical Tools. IQ will soon be sponsoring a session on Enabling Technologies to Continuous Manufacturing at IFPAC 2015 and co-sponsoring a session on Clinical Pharmacology for the Future with ASCPT in March 2015. IQ is also in the process of formalizing strategic partnerships with the Pharmaceutical Research and Manufacturers Association (PhRMA) and the Product Quality Research Institute (PQRI).

IQ has also continued to spearhead industry initiatives in the 3Rs. The 3Rs Leadership Group announced the creation of the IQ Consortium/Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International Partnership for Global 3Rs Award Program. The inaugural awards will be presented in 2015 to the scientists whose research has advanced the 3Rs and addressed an area of discovery, development, manufacture or testing for new medicines, vaccines, medical devices or healthcare products for humans or animals. This award will help continue to encourage the 3Rs in the industry throughout the world.

New Strategic Plan for 2015 – 2017

The IQ Board has developed a new strategic plan for 2015-2017. Consistent with the 2012-2014 strategic plan, the new plan reiterates the importance of proactively building consensus with regulators, sharing IQ's work products with the broader scientific and regulatory community, and ensuring the continued value of IQ through active leadership, focused priority-setting and efficient management. Additionally, the new strategic plan emphasizes the desire to create cross-functional data sets with greater scope and impact than possible by any member company alone, as well as the need to advance relationships with global professional organizations, other consortia, academics and government research institutes to ensure scientific excellence and harmonization.

Communications

IQ has worked to promote strong communication between Leadership groups, with prospective members, and with the broader scientific and regulatory community. This year we have had a number of new initiatives, such as the semi-annual update, the member recognition award program, and continued improvements to the IQ website. As IQ continues to grow, we recognize the need for more resources to help encourage participation and streamline the orientation process for new companies and participants. In order to do this, IQ will be introducing a short but comprehensive online orientation program. We look forward to releasing this resource in the coming days.

The Year Ahead

I would like to take this opportunity to let you know how much I have enjoyed my role as Chairman over these last two years. It has warmed my heart to see IQ grow with such determined and enthusiastic members. As James Collins says in his book, *Good to Great*, "Great vision without great people is irrelevant". With this in mind, I pass the mantle of leadership to Dr. Steve King, who I have no doubt will help IQ achieve a great many things. I thank you all for your effort and dedication to the IQ Consortium. It has been a sincere pleasure getting to know you at IQ events and meetings and it has been an honor to work with you. I look forward to watching IQ thrive and become an invaluable resource for innovation and quality in the pharmaceutical industry.

I wish everyone the very best for a healthy and prosperous New Year.

With warm regards,

A handwritten signature in black ink, appearing to read 'L. Kinter', with a horizontal line drawn across the middle of the signature.

Lewis Kinter, Ph.D.
Chairman of IQ Consortium, 2013-2014