



Semi-Annual Update

International Consortium on Innovation & Quality in Pharmaceutical Development

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IQ Consortium News

IQ 3Rs Leadership Group Announces 3Rs Award Program

The 3Rs Leadership Group is pleased to announce the creation of the IQ Consortium/Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) International Partnership for Global 3Rs Award Program. The inaugural awards, which will be presented in 2015, will be granted to the scientists whose research has advanced the 3Rs and addressed any area of discovery, development, manufacture or testing for new medicines, vaccines, medical devices or healthcare products for humans or animals. The awardees will be selected by an expert panel that is managed by AAALAC and uses criteria defined by the IQ Consortium. Up to four awards will be granted, for the areas of North America, Europa, Asia/Pacific Rim, and the Rest of World.

IQ Database Development Efforts Underway

IQ has recently begun developing a database framework to support data-sharing projects by IQ working groups. Prior to the last Board of Directors meeting, the database development project was officially kicked-off in a two day workshop. During this workshop, representatives from IQ met with IQ's database framework developer, Osthus Inc., to further define the technical specifications for this project. In conjunction with the development of this database, the IQ Board of Directors is initiating an effort to standardize IQ's data-sharing process. The new database and standardized process will make the initiation and execution of data-sharing projects more streamlined and user-friendly.

Quarterly IQ Member Recognition Awardees Announced

The IQ Board of Directors has developed the IQ Member Recognition Awards, to be presented on a quarterly basis to nominated individuals who have shown outstanding dedication to a Working Group or Leadership

Upcoming Events

Featured Event:

OCTOBER 9, 2014

[IQ Symposium "Pre-competitive Collaboration for Innovation"](#).

Alexandria, VA. Registration opening soon.

Keynote Speaker:

Dr. Bill Chin, PhRMA

JULY 30, 2014

PSLG Workshop with FDA and Biosafe

Q3 – Date TBD

[IQ Drug Metabolism PBPK Working Group Webinar](#)

DECEMBER 8-9, 2014

[2014 Lifecycle Approach to Validation of Analytical Procedures with Related Statistical Tools Workshop](#)

Q4 – Date TBD

[IQ Drug Metabolism PK/PD Working Group Webinar](#)

group's initiatives.

On behalf of the IQ Consortium Board of Directors, we proudly present the first winners of the IQ Member Recognition award, Drs. Dale Martin and Margaret Faul, due to their recent contributions and achievements. This award attests to their commitment, dedication, and efforts to the IQ Consortium and the scientific community. For more information about their achievements [click here](#).

If you would like to nominate a member of your leadership or working group for a future quarterly award, please [click here](#). These awards are open to all IQ participants. Nominees are evaluated on dedication, commitment, improvement, or valuable contribution in the past quarter.

New Initiatives at the IQ CMC Summit

On Wednesday, June 4, 2014, the IQ Consortium's Chemistry, Manufacturing, and Control (CMC) Leadership Groups held its annual Summit in Philadelphia, PA.

The CMC summit addresses continuing and upcoming joint initiatives of the API, Analytical, Drug Product, GMP QA, and Statistics Leadership and Working Groups. "This is an event where scientists from pharmaceutical companies meet to identify and discuss challenges and opportunities in drug discovery and development. One of the key objectives of this meeting is to list and prioritize topics of shared interest and importance. For example, we prioritized and are now taking action on having a CMC meeting with the FDA to discuss the new guidance on co-crystals and other CMC topics of mutual interest. I believe that the CMC summit played a critical role in facilitating progress on this important and potentially high-impact initiative", said John Orr, Eisai, Analytical LG Chair.

The CMC summit also provides a forum for discussing new and upcoming initiatives. Nick Thompson, Pfizer, Active Pharmaceutical Ingredient LG Chair commented, "I was most pleased about the opportunity to trigger a new exploratory working group on small molecule components of biologics. Pharmaceutical research and development is rapidly evolving to include an increasing array of targets and IQ is an excellent forum for precompetitive collaboration regarding the skills and development strategies we need to deliver future medicines. I see our new exploratory working group as a great opportunity to learn together."

IQ Consortium Achievements

Recent Publications

- Part 1 and 2 papers on Designation and Justification of API Starting Material (published May 05, 2014 in Organic Process Research and Development) [Read here](#)
- Process Analytical Technology: Tools and Applications in API Development -- **selected as an ACS Editors Choice article** (published May 02, 2014 in Organic Process Research & Development Industry Perspectives) [Read here](#)
- Process Chemistry: Recasting Regulatory Strategies to Enable Green Chemistry (published March 24, 2014 in C&EN) [Read here](#)

Green chemistry and engineering represent an important framework for the "design and application of chemical products and processes to reduce or to eliminate the use and generation of hazardous substances" that will help guide the development of such products and processes in a sustainable manner. An article by Stephen Ritter published in the March 24, 2014 edition of Chemical and Engineering News, "[Recasting Regulatory Strategies To Enable Green Chemistry](#)," has highlighted efforts by the IQ Green Chemistry Working Group to address perceived challenges to the integration of green chemistry and manufacturing in the pharmaceutical industry. The WG also sponsored a webinar, "Seven Important Elements of an Effective Green Chemistry Program", which was [featured on the ACS Nexus blog](#).

The IQ Green Chemistry WG is currently considering new initiatives and seeking new members. Contact In-grid.mergelsberg@merck.com for more information about this initiative or if you wish to join.

[Link to the Webinar](#)

[Link to the Article](#)

Recent IQ Events

- IQ DMLG Metabolites Webinar – June 2014
- CPLG Pediatrics Workshop – June 2014
- DMLG Manager’s Meeting – June 2014
- IQ CMC Summit – June 2014
- IQ Green Chemistry Webinar – April 2014
- Poster Presentation about the results of the IQ survey on “Current Industry Practices in the In Vivo Assessment of Human Drug Metabolism at ASCPT meeting – March 2014
- PSLG organized “Translational Safety” SOT session (most attended session of the conference) – March 2014
- PBPK WG held a workshop at the FDA – March 2014
- 3Rs Sharing Conference: Paving the Path to Regulatory Acceptance and Alternative Methods – February 2014
- GMPs in Early Development workshop – February 2014
- PAT WG Sponsored Session at IFPAC 2014 “Multivariate Model Validation in a Quality Environment”

If you would like to ask a question, make a comment or suggestion, or subscribe or unsubscribe from the newsletter, please contact the IQ Secretariat at: +1-202-230-5646 or info@iqconsortium.org.

For further information: <http://iqconsortium.org>

