DIVISION OF BIOCHEMICAL TECHNOLOGY OF THE AMERICAN CHEMICAL SOCIETY

BIOT

The Best of BIOT Awards: November 1, 2017

Date	Area	Time	Presenter	Institution
Wednesday, November 1st	Quality by Design	12.00 - 1.00 pm	**Brian Kelley**	Genentech
Perspectives on the impact of quality by design (after a decade in the making!)				

Webinar registration can be made at ACS BIOT WebEx Webinars

"Perspectives on the impact of quality by design (after a decade in the making!)"

Brian D. Kelley, Genentech, South San Francisco, CA (presently at VIR Biotechnology)

Quality by Design (QbD) is a global regulatory initiative that enhances pharmaceutical development through the design of the manufacturing process and controls to consistently deliver a product that performs as intended. The principles of pharmaceutical development relevant to QbD are described in the guidance documents ICHQ8-11. Roche/Genentech has licensed two therapeutic recombinant monoclonal antibodies, obinutuzumab (Gazyva®) and atezolizumab (Tencentriq®) in the U.S.; we believe these represent the first approvals for biologics that were comprehensively based on QbD information, including approved design space claims.

Roche/Genentech recently published seven articles in Biologicals describing the application of the principles of QbD for development and licensure of therapeutic antibodies. These articles present a self-consistent set of risk assessments and logical elements, based on refinement through the FDA and EMA pilot QbD programs and approvals of obinutuzumab and atezolizumab. They provide a standardized basis for the review of new product license applications, and establish transparent communication of the links between the manufacturing process and product storage, product quality and patient impact, the control strategy, and post-licensure change management.

These articles are an open-source sharing of the results of a decade-long investment. We hope that the tools will be used by other companies, which could advance the adoption of improved methodologies in support of license applications for products with enhanced product and process knowledge. This formalism will be used for all biologics in the Roche/Genentech pipeline, and, when combined with the use of process and product platform knowledge, should result

in significant efficiencies and resource savings. Although discussed in the context of antibodies, the tools should be applicable to other protein therapeutics, and perhaps to small molecules and other pharmaceutical modalities as well.

This presentation will briefly review the nature of this set of QbD tools and risk assessments, including examples of the elective trade-offs between the design space, product expiry, and the control strategy. Examples of the streamlining benefits will be shared, focusing on leveraging process and product platform knowledge. The future potential and applications for an approved design space will also be discussed.