

4<sup>th</sup> International Conference on

# DRUG DISCOVERY, DESIGNING CHEMISTRY AND PHARMACEUTICAL ANALYSIS

International Conference on

# BIOBETTERS AND REGULATORY AFFAIRS

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### Recent advances in analytical techniques for the implementation of quality by design in bio pharmaceuticals

**Statement of the Problem:** The complexities and subtle distinctions of biologics encounter challenges of implementing quality by design (QbD) concepts in the development and manufacture of biopharmaceuticals. A systematic approach of QbD is to design the product that meets patients' needs and then determine the quality target product profile (QTPP) and the critical quality attributes (CQAs) within an established design space. The development of appropriate analytical methods is, however, fundamental to establishing the product, process control, and the overall control strategy in a QbD development approach. Recent advances in analytical techniques have enabled the implementation of QbD in biopharmaceuticals. Many analytical techniques facilitate QbD early in molecular design and engineering, and during the manufacturing process via process analytical technology (PAT) to achieve real-time quality control and to ensure final product quality.

**Methodology:** Understanding structural and functional attributes of biopharmaceuticals is essential for the selection of desirable quality attributes during molecular design and engineering to ensure the proper bioactivities. The disulfide isoforms of IgG2 have been shown to have different agonistic bioactivities. Many advanced analytical techniques, such as HDX-mass spectrometry, RP-HPLC, and affinity chromatography have been used to characterize and purify these subtle structural isoforms for maximum clinical impact. Recently the multi-attribute method (MAM), a liquid chromatography-mass spectrometry (LC-MS) based method, has been developed and designed to specifically monitor and quantify molecular product quality attributes and product/process-related impurities. Although the online chromatographic/HPLC analysis has been one of the major obstacles for the implementation of PAT for biologics, the novel extra-fast HPLC and 2-dimensional HPLC approaches have demonstrated the feasibility to monitor CQAs in a real-time fashion.

**Conclusion:** The implementation of QbD concepts to biopharmaceutical development and manufacturing has been challenging compared to that of small molecules. The advances in various analytical technologies during the past decade give bright prospective on building "Quality" in biopharmaceuticals.

### Biography

Yite Robert Chou is the Head of High Throughput Analytical Core Facility and the Group Leader of Force Degradation and Impurity Profiling group in the Biologics and Vaccines Formulation at Merck & Co. Inc. Before joining Merck in 2015, he spent almost 10 years in the Process Development department at Amgen. He has over thirteen years of experience in discovering and developing biotherapeutic products from pre-IND to BLA/commercial stages. Dr. Chou received a B.Sc. degree in Applied Chemistry from Tamkang University, Taiwan, R.O.C., and Ph.D. degree in Biological Chemistry from University of Massachusetts, Amherst, USA.

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