

Spring 5-10-2016

Adjusting product quality attributes of a biosimilar using process levers

Brett Belogna

Momenta Pharmaceuticals, bbelongia@momentapharma.com

Follow this and additional works at: http://dc.engconfintl.org/cellculture_xv



Part of the [Biomedical Engineering and Bioengineering Commons](#)

Recommended Citation

Brett Belogna, "Adjusting product quality attributes of a biosimilar using process levers" in "Cell Culture Engineering XV", Robert Kiss, Genentech Sarah Harcum, Clemson University Jeff Chalmers, Ohio State University Eds, ECI Symposium Series, (2016). http://dc.engconfintl.org/cellculture_xv/100

This Abstract is brought to you for free and open access by the Proceedings at ECI Digital Archives. It has been accepted for inclusion in Cell Culture Engineering XV by an authorized administrator of ECI Digital Archives. For more information, please contact franco@bepress.com.

ADJUSTING PRODUCT QUALITY ATTRIBUTES OF A BIOSIMILAR USING PROCESS LEVERS

Brett M. Belongia, PhD
Momenta Pharmaceuticals
bbelongia@momentapharma.com

Key Words: biosimilars, product quality attributes

The development of a biosimilar introduces many unique challenges compared to that of a novel drug. The primary consideration in developing a biosimilar is that the product quality of the protein of interest be “highly similar” to that of the branded product. Product quality attributes are defined by the manufacturing cell line and the manufacturing process. The ability to manipulate the manufacturing process is key to obtaining a highly similar product. This poster will focus on the development of biosimilars and provide examples of how the product quality can be manipulated with process levers to achieve similarity with that of the branded product while maintaining cell culture productivity. Initial cell line screening to choose the “best” cell line will be addressed along with how process levers can be used to adjust the product quality attributes of these cell lines to make them “highly similar” to the desired branded product. Specific examples of the effects of DMSO on glycosylation, specifically on fucosylation and high mannose glycan species, will be discussed.