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This is a detailed case study to stimulate discussion around how the core principles contained in Q8(R2), Q9 and Q10 guidelines could be applied to product realisation programs for a biotechnology-derived monoclonal antibody.

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Product Development and Realisation Case Study A-Mab The CMC Biotech Working Group Page 5 of 278 4.6.2.5 Characterization Studies to Assess Impact to Product Quality

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The case study, which discusses a fictional monoclonal antibody product, referred to as " A-MAb, " was developed over the course of a year by participants of the working group representing Abbott, Amgen, Genentech, GlaxoSmithKline, Eli Lilly, MedImmune, and Pfizer.

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A case study is a detailed study of a specific subject, such as a person, group, place, event, organization, or phenomenon. Case studies are commonly used in social, educational, clinical, and business research. A case study research design usually involves qualitative methods, but quantitative methods are sometimes also used.

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Case Study 4 – Biosimilar MAb Showed Significant Conformational Differences: Several biosimilar MAb molecules we have tested fall into this category. In one instance, the biosimilar developer noticed changes in MAb stability. Bioassay testing showed that the biosimilar MAb lost potency in an ELISA-based binding assay; however, no analytical testing used could detect structural changes.

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In addition to highlighting the case study here on our web site, we have plans to use it extensively around the world in discussions with industry and regulators throughout 2010 and beyond. Look for sessions in the programs of the CMC Forum Europe (April 2010) and CMC Strategy Forum (July 2010) as well other workshops to be announced focusing on the A-Mab Case Study.

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30 October 2009: A – Mab: A Case Study in Bioprocess Development, CMC Biotech Working Group, version 2.1 This is a detailed case study to stimulate discussion around how the core principles contained in Q8(R2), Q9 and Q10 guidelines could be applied to product realisation programs for a biotechnology-derived monoclonal antibody.

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Product Development and Realisation Case Study A-Mab CMC Biotech Working Group Page 25 of 278 2 Design of Molecule and Quality Attributes Assessment A-Mab is a humanized IgG1 monoclonal antibody that was designed to maximize clinical performance and minimize potential impact from undesirable product quality attributes.

[QbD Model Case Study of MONOCLONAL ANTIBODY – A-Mab](#)

This study aims to elucidate the formation of various kinds of aggregates as outcomes of a variety of mechanical, chemical, and thermal stresses applied to a monoclonal antibody therapeutic. The extent of aggregation, nature of aggregates, and impact of aggregates on biological activity and potency, all depend on the source of aggregate formation.

[Impact of mAb Aggregation on Its Biological Activity ...](#)

Case Study: Robustness Study for Virus Filtration of mAb Processes Peter Kosiol; Anika Manzke Sartorius Stedim Biotech GmbH, August-Spindler-Str. 11, D-37079 Goettingen, Germany 1. Introduction All biopharmaceutical products derived from human or animal origins must have a proven virus safety concept to ensure

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The A-Mab case study discusses the development of a monoclonal antibody and incorporates many advanced and aspirational QbD concepts.

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