
A Mab A Case Study In Bioprocess Development

Case Study 1 — MAB Strategic Marketing Group

Quality by Design A-MAb Case Study Challenges Conventional ...

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Characterization Studies to Assess Impact to Product QualityCMC Biotech Working

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Case Study Objectives
The case study does: The case study does not:
Demonstrate implementation of the principles of Quality By Design Present a prescriptive approach Leverage the significant knowledge base of both commercial and investigative monoclonal antibodies Follow a traditional approach Show application to both drug substance and ... QbD Model Case Study of MONOCLONAL ANTIBODY : A-Mab. MAB Facility Management Case Study.

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 we tested, one was made
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 Quantitative measure for
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safety and efficacy. Using
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Case Study 6 — Biosimilar MAb Produced from Plant Cells: Among the many

biosimilar MABs we tested, one was made using plant cells (data not shown). We found significant conformational differences to be present for the biosimilar molecule, with many regions showing >1% new-epitope exposure.

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