EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guideline on Similar biological medicinal products containing biotechnologically-derived proteins as active substances: **quality issues**

Session 2
Panel discussion

moderated by: Niklas Ekman

QTPP in biosimilar development
1/4

What is the specific purpose of QTPP in biosimilar development?

QTPP in biosimilar development
2/4

How to handle drifts in the quality profile of the reference medicinal product?

QTPP in biosimilar development
3/4

Are expectations on the target acceptance ranges (to be used as part of the QTPP and in the side-by-side comparability exercise) sufficiently clear in the guideline?

The use of different/novel expression systems as compared to the originator

What are the Benefits?

What are the drawbacks?

QTPP in biosimilar development
4/4

Which differences are still acceptable while maintaining the demand of being similar?