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# **Global Development for Biosimilar Medicines**

## **In the Light of US and International Developments**

**EMA-EGA Info Day, 10 November 2010**

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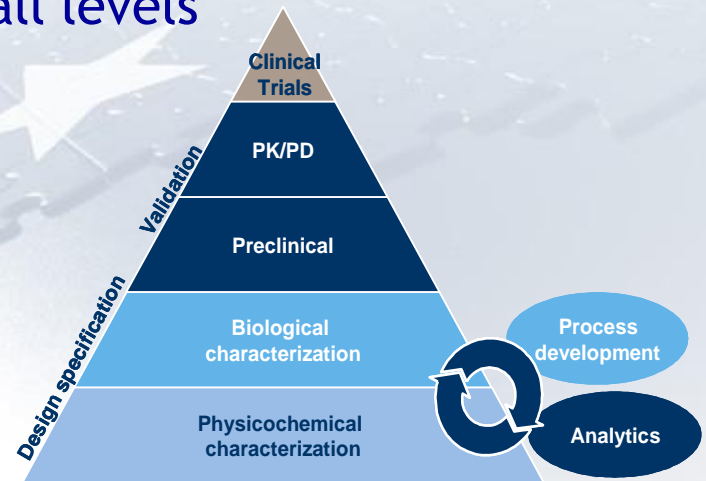
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# Setting the Scene: The “Real” Biosimilar Development

- Development of a biosimilar product requires - on top of an independent product and process development - a thorough **comparison to a reference product at all levels**
- Reference product chosen has to be used for all parts of this comparability exercise and needs to be authorised in a **highly regulated market (ICH standards) e.g. EU, US, JP, CAN**
- Biosimilar development and the comparability exercise have to be performed according to the stringent requirements laid down in a highly regulated market
- The term ‘biosimilar’ should only be applied to biopharmaceuticals that have been approved on the basis of a rigorous and extensive comparability exercise at quality, non-clinical and clinical level according to ICH standards against an ICH standard reference product





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# Need for Global Biosimilar Development: The Issue

- Reference products are **often the same** or highly similar in different countries, even though licensed under different jurisdictions, and are thus, **legally ‘different’ products despite being the same with regard to quality, safety and efficacy**
  - Often, **documentation** is available in the public domain, confirming that the products are the same
  - **Comparability** of reference products of one original manufacturer from different highly regulated countries (US, EU) can be clearly established by stringent analytical and functional studies
- Many countries have recently established legal frameworks and regulatory pathways for biosimilars and most **require** that the comparison occurs against „their“ **national reference product** or are silent about this issue
- This would mandate the performance of **separate, full development programs for each country**
- This is **unnecessary, potentially unethical** (duplication of preclinical and clinical studies), **uneconomical and to be avoided**



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# Often Same Global Reference Product

Batches  
for EU



Batches  
for US



**Objective:**

to be able to use batches of the US reference products for the comparability exercise and vice versa, if the same/highly similar reference product is authorised in the EU and the USA

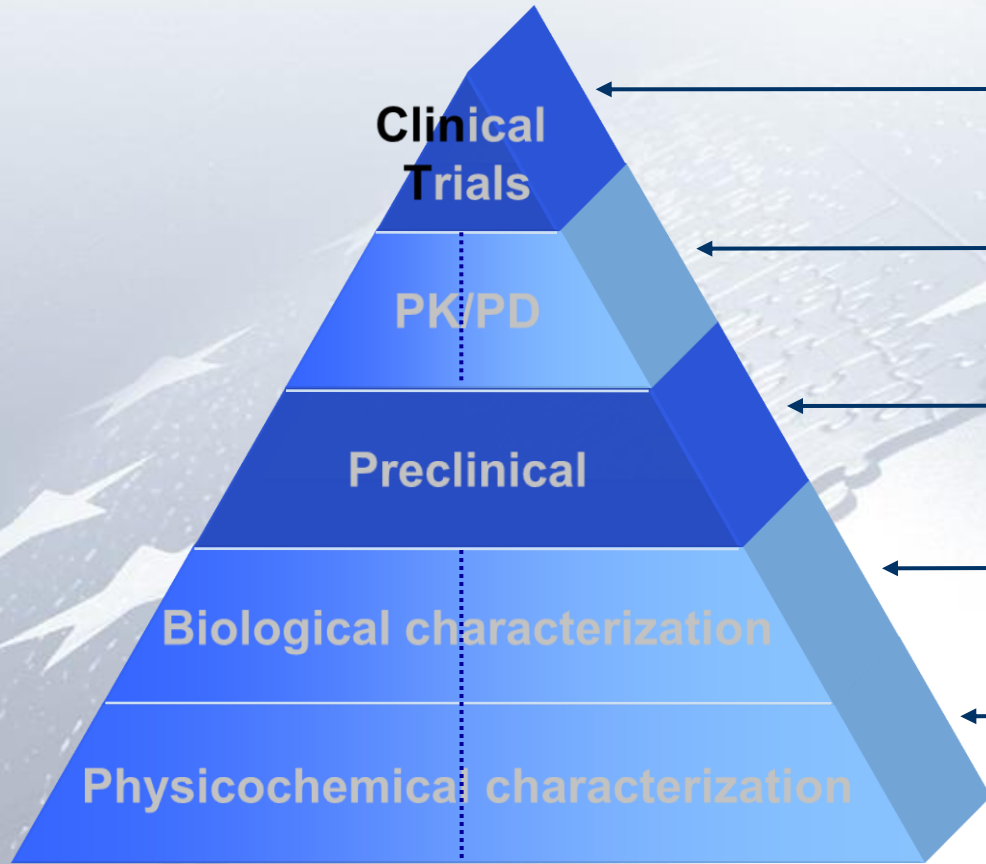


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# Further Considerations

- Directive 2001/83/EC as amended does no longer stipulate that the reference product has to be marketed in the Community
    - *'.....reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or the Community'*
  - SmPC is not part of the *definition of a medicinal product*
    - see article 1 point 2 of Directive 2001/83/EC as amended
  - ISO Identification of Medicinal Products (IDMP) standards (context of ICH M5): ideal tool to identify reference products in the future
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# The Global Biosimilar Development: The Proposal



Clinical phase III with reference product from one region

Case by case -> Rigorous PK&PD comparison

No additional preclinical studies

Physicochemical and biological comparison of reference product and biosimilar

Biosimilar product as developed for approval in an ICH jurisdiction

Bridging studies to a reference product from a different ICH jurisdiction

# EU-FDA Transatlantic Administrative Simplification Action Plan

- Under the TAS Action Plan we fully support
  - the collaboration of EU/EMA/FDA on product specific Risk Management initiatives
  - further convergence of Risk Management formats and
  - the FDA/EMA collaboration on biosimilars



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**Global development is the key to remain competitive and financially viable**

**It is the only way to improve worldwide availability, affordability and access to high quality biopharmaceuticals**

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**Thank you**

