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Cell line development for the production of biosimilar monoclonal antibodies with high target bioactivity and high productivity

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The cell line development group at NeuClone generates high quality cell lines for the production of biosimilar monoclonal antibodies (mAbs). Two characteristics are required to ensure the successful generation of a biosimilar production cell line – (1) the recombinant molecule must be expressed in sufficient quantity to ensure the project is economically viable, and (2) the molecule expressed must be highly similar in structure and activity to the originator molecule. Traditionally the selection of cell lines expressing antibodies has been based on the selection of high producing mini-pools of cells that are subsequently further enriched for production by either limiting dilution cloning, clone-picking in semi-solid medium or by single-cell fluorescence-activated cell sorting. Clones are then expanded and evaluated in laboratory scale bioreactors to determine the best process development parameters prior to production scale up that will generate purified material for further product characterisation. The biological activity of a biosimilar mAb should mimic the originator in all aspects in order to achieve biosimilarity, including target binding and various effector functions such as signalling, cell death, proliferation, etc. We have designed a strategy that concurrently screens mini-pools and clones at an early stage for productivity as well as biosimilarity. This novel quality by design approach aims to minimise the risk of isolating high producing clones with insufficient biosimilarity early on– thus reducing the time in identifying clones with high productivity and with the right biosimilar attributes.

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Key regulatory and legal developments for biosimilars in the EU

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The EU operates a well-established biosimilars review process that has more than a decade of experience. Almost all biosimilar applications are reviewed by the EMA, which has issued extensive guidance that covers general principles for review of biosimilars and also addresses specific aspects for various active ingredients. The practices and guidelines are also regularly updated in light of regulatory experience and international developments.

Key areas of attention now are:

(i) What role should the EMA play with regard to switching and interchangeability? This must be assessed also against the background of the separation of EU and national powers under the EU treaties, which provide, for instance, that the Member States have responsibility for "the organisation and delivery of health services and medical care."

(ii) What role could the EMA play in the context of HTA? Should this focus on relative efficacy or relative effectiveness and would this have an impact on biosimilars?

(iii) What role can big data play for biosimilars?

The regulatory approval system must also be seen in the broader context, which can have a significant impact on real use of biosimilars. This includes the INN policies of the WHO and the role of public procurement and its practical implications for switching. The talk will focus on these elements and also provide a general update on the regulatory situation in the EU. Recently, for instance, some applications for non-biotech biosimilars were made at the national level and add a new dimension to the picture.

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