

The Science and Business of Biologics *and Biosimilars*

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Abstract:

Biologics are much larger in size and are more complex than Small Molecule drugs – and, present major bioprocessing challenges during their development and commercial production. In spite of that, biologics are at the leading edge of therapeutic intervention modalities because of their exquisite specificity and manageable safety profile. Biologics have been particularly useful in the treatment of serious disorders such as cancer, inflammation and autoimmune diseases. Biologics include a diverse group of products that range from recombinant proteins, monoclonal antibodies (mAbs) to virus like particles. Of those, mAbs are the preferred treatment modality for many diseases. The early mAbs are approaching the end of their patent life – thereby presenting the opportunity for the development of “biosimilars”. Pfizer intends to leverage its legacy of biologic products to broaden patient access to high quality therapies across the spectrum of innovative biologics and biosimilar products. Skillsets needed to successfully develop biologics – including bioprocessing, formulation development and analytical characterization – will be described. The demand on analytical testing is particularly high for biosimilars in order to demonstrate similarity in quality attributes between the biosimilar and its reference innovative product. Leveraging external innovation and internal expertise will be key to successfully developing a diverse array of biological products in the future.