BIOPROCESSING 101:
CELLS TO PROTEINS, OPERATIONS TO PROCESSES, CONTROL TO QUALITY

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This presentation will provide an initial introduction for delegates attending the pre-conference workshop on Basics of Biotechnology [1, 2]. It is designed primarily for those from physical science and traditional engineering backgrounds wishing to gain a rapid overview of biological products and methods for their manufacture. It will also be useful for life scientists wanting to gain insights into the design, monitoring and control of bioprocess unit operations and whole process sequences. This information will be presented in the context of the required product quality characteristics and their relationship to regulatory requirements.

The first part of the presentation will focus on different types of protein-based products, e.g. therapeutic enzymes, vaccines and antibodies, their basic structure and analytical techniques for their characterization. It will then discuss the features of different expression systems, such as microbial and mammalian cells, their growth requirements and suitability for producing different types of protein product.

Fermentation or cell culture is at the heart of any biomanufacturing processes. This part of the talk will give an overview of fermentation and cell culture process development focusing initially on growth media design and optimization. It will then discuss key features of traditional stirred bioreactors and how their operation impacts on cell growth and product formation. Bioreactor monitoring and control will also be addressed with particular emphasis on the types of probe conventionally used for monitoring culture conditions such as pH, temperature and dissolved gasses (O_2 and CO_2).

The final part of the presentation will give an overview of the different stages of downstream processing from primary product recovery to purification. It will outline the key unit operations used at each stage (centrifugation, filtration, chromatography) and their role in removing key product and process related impurities and contaminants. It will also address the synthesis of typical downstream process sequences in relation to meeting economic and regulatory requirements such as cost and purity.

This presentation is designed to lay the foundations for the following talks focused on the manufacture of antibody and cell therapy products. These will address the specific features and therapeutic applications of these key product classes and their industrial manufacture. These subsequent talks will also address the drivers and challenges associated with the introduction of single-use bioprocess technologies for their manufacture.

[1] Ratledge, C. and Kristiansen, B. (2006) *Basic Biotechnology*, 3rd Edition, Cambridge University Press.
[2] Doran, P.M. (2012) *Bioprocess Engineering Principles*, 2nd Edition, Academic Press.