



# Pre-Conference Workshops and Symposia

Sunday 26th June | 10:30-12:00

**ADVANCED INSTRUMENTS LLC SPONSORED SYMPOSIUM**

**Auditorium III & IV**



## **Section 1: KEY CONSIDERATIONS FOR MANUFACTURING IN CELL AND GENE THERAPY**

*Speaker:* Marta Rucka, PhD, Global Product Manager

Cell and gene therapy (CGT) is one of the most promising and faster growing sectors in biopharmaceutical industry. With the increasing popularity of gene editing and reprogramming of human cells, it is crucial to understand and recognise the differences between steps involved in process development (PD) and commercial manufacturing. The clinical manufacture of a CGT product is governed by stricter requirements vs PD and regulations as per Good Manufacturing Practices (GMP). However, as the cell line development (CLD) technologies continue to rapidly evolve, GMP regulations need to adopt accordingly to meet the demand and reflect the clinical risk profile of these innovative solutions. Importantly, the transfer of practices from PD to GMP-friendly settings can pose several challenges, which with the right planning can be easily avoided. A detailed analysis of the CLD workflow from single cell seeding, through the use of clinical grade reagents to risk and data management, can be extremely helpful in establishing a GMP-compliant manufacturing process early on. During this session we will discuss the following the key considerations for manufacturing of CGT including:

- Best strategies for single cell isolation and homogenous MCB generation
- Improving CLD efficiency using the right instrumentation and clinical-grade reagents
- Controlling osmolality to enhance yield, purity and efficiency of AAV Manufacture

Key words: Cell line development, single cell seeding, clonal outgrowth, data management, GMP, viral vector production, cell and gene therapy, bioproduction, data management

## **Section 2: STREAMLINING THE FED-BATCH CLD PROCESS FOR EARLIER SELECTION OF CLONES VIA ICON TITER AND VCD ANALYSER AND INSTISHAKE CELL GROWTH SUPPLEMENTS**

*Speaker:* Paul Butler, Senior Global Product Manager

The trend in Cell Line Development (CLD) is to screen and select clones earlier and with more confidence. At the fed batch stage of the CLD process, particularly in DW 96, 48 and 24 well plates, limited sample availability precludes some measurements from being taken (VCD and titer for example). The low speed of currently available cell counting technologies means that the time taken to analyse, outweighs the benefit of the data. In this talk we introduce the ICON analyser which rapidly measures small volume samples for titer and VCD and combines with confluence and clonality results within the STUDIUS data management platform to make secure, early decisions on best performing clones. Also, we will discuss how our InstiSHAKE supplements for the shaking cell culture and fed- batch stage, improve the outcomes for cell lines to ensure all candidates are considered in the search for best performers.

Key words: Cell line development, data management, shaking fed-batch, Deep Well plate, titer, VCD