

## **INTEGRATING ANALYSIS WITH PROCESS CONTROL FOR CONTINUOUS BIOPROCESSING: EXTENDING THE LIFECYCLE CONCEPT TO PROCESS ANALYTICAL TECHNOLOGIES.**

Francisca F. Gouveia, 4Tune Engineering Ltd  
Pedro M. Felizardo, 4Tune Engineering Ltd  
José C. Menezes, 4Tune Engineering Ltd

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The most notable trends in the use of PAT tools in bioprocessing nowadays are: (1) the combined use of multiple tools to a product & process and (2) that information fusion provides a better process estimation and product quality knowledge foundation than the use classical use of one analytical method

The lifecycle management aspects of validation launched by FDA in its 2011 Validation Guidance, arrived - through ICH Q11 (2012) and the forth coming ICH Q12 (2017), to all aspects of development, qualification and commercial manufacturing of large molecule drug substances. For continuous bioprocessing that challenges are significantly different and more complex than for batch processing of small molecules.

The homeostasis state that are targeted for most continuous bioprocesses, puts specific requirements in each individual PAT tool chosen and in their combined use over lifecycle. Here, using case-studies, a discussion is done of specific challenges at each of the three stages of lifecycle, about how and when the shift is made from understanding (acquiring data & information) to enhanced bioprocess control (knowledge-based decisions) to realize product quality by design (predictive product quality).

Finally, we show how platform knowledge can be managed across multiple products for a company's own portfolio benefit, through aggregation and high-level visualization of multiple PAT projects.