REGULATORY ASPECTS OF CONTINUOUS DOWNSTREAM PROCESSING

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Over the past few years, various technologies have been developed to enable a partially or fully integrated continuous bioprocessing platform. Many companies have explored the potentials of these innovative production systems and a lot of data has been published that support the technical viability of integrated continuous bioprocessing.

The regulatory agencies, such as the FDA, have repeatedly expressed their support for these developments as they recognize the potentials for enhanced process and product quality control. In addition to this, continuous bioprocessing may allow the industry to move towards a more agile state that would allow biopharmaceutical products to become available to a wider audience at lower costs.

Even though the regulators are supportive, no guidance was provided in terms of the regulators' for submissions and how the guidelines as summarized in ICH Q8 and Q9 can be applied in continuous bioprocessing.

Many different companies working towards integrated continuous bioprocessing platforms, all of which are relying on a combination of innovative and existing technologies. In order to facilitate and harmonize the interactions with the regulatory bodies, we have developed strategies and approaches that would cover the typical regulatory aspects of integrated continuous manufacturing platforms, covering both upstream and downstream processing.

In this presentation, we will present and discuss regulatory strategies for integrated continuous bioprocessing. This will cover critical quality attributes, bioburden control and virus safety strategies for continuous bioprocessing platforms. In addition to this, some aspects of traceability, lot definitions and deviation management will be addressed.