GMP DESIGN OF A SINGLE-USE INTEGRATED CONTINUOUS BIOMANUFACTURING SYSTEM

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This presentation will show design work by Pfizer and Boehringer Ingelheim on a single-use integrated continuous system for GMP Biomanufacturing including consideration of scale, facility-fit, automation, single-use devices, hardware, and process control and monitoring. The scale of the system needs to be appropriate for the expected quantities of drug substance needed and needs to fit within the constraints of the GMP facility, including physical size and interaction with other facility systems. The system automation needs to control and monitor the entire process, since the upstream and downstream are integrated and the downstream operates semi-continuously. This presentation will discuss the challenges of designing an automation scheme capable of controlling an integrated upstream and downstream process along with the unique features that proved enabling to the integrated system. The single use devices and instruments in the system, including those made with additive manufacturing, are the process contact surfaces, so they need to be compatible with all the process fluids, perform consistently over process cycling and be constructed with sanitary design appropriate for GMP biomanufacturing. The system hardware provides the interface between the automation and the single-use devices controlling operations and the single-use instruments monitoring in-line process data. The design also needs to consider on-line instrument needs and off-line sampling analysis for a continuous flowing process stream.