A Culture of Excellence

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Prior to 2010, Pfizer Health AB produced its legacy products Genotropin® and Somavert® in separate facilities. Somavert was sourced from a contract manufacturer, while Gentropin was manufactured at a Pfizer facility in Strängnäs, Sweden.

The two drugs have opposite effects on the human physiology — Genotropin is used to treat growth hormone deficiency and Somavert is a growth hormone antagonist — but the proteins used in each are very similar. Pfizer's development scientists saw an opportunity to exploit this similarity to develop almost identical unit operations that could be used for both products within the same facility.

The project — dubbed Project Pegasus — had two fundamental ground rules: The new Bio 7 facility would not require an increased head count and a two-shift pattern would be sufficient to produce two batches per week. To achieve this, the project team went back to the drawing board and re-evaluated a number of steps in the manufacturing process, including some thought to be standard in pharmaceutical processing.

Today, the Bio 7 facility is able to produce the two products much more efficiently — exceeding the goal of two batches per week with three-and-a-half batches per week — and is recognized in this year's Facility of the Year Awards (FOYA) as the winner of the Operational Excellence category. Here's how Pfizer made it happen.

Time Is Money

The FOYA judging panel recognized the effort that Pfizer put into reducing equipment turnaround times. A major focus of the de-bottlenecking projects was to optimize the clean-in-place (CIP) and steam-in-place (SIP) procedures.

Four CIP skids are used to provide dedicated cleaning functions to the various

processing areas. Skids one, two and three are used to clean equipment, vessels and lines that have been exposed to proteinaceous material, and require both chemical make-up and water rinse tanks. The cool water pre-rinse is executed at the same time as the hot chemical solution is prepared, creating a seamless CIP sequence.

CIP time is further reduced by eliminating the purified water pre-rinse compressed air blowdown sequence. Inline conductivity measurements conducted at the facility showed that air blowdown was not required to remove residual pre-rinse water from the object prior to preparing the cleaning solution.

Further tests found that the manual removal and reinstallation of vent filters before and after vessel CIP was unnecessary. As a result, the vent filter housings at the Bio 7 facility are designed so that the vent line can be cleaned without removing the filter element or housing. This also eliminated delays and potential accidents caused by fittings that are not secured properly.

SIP Realities

Conventional wisdom suggests that SIP functionality should be allowed for in downstream processing areas. SIP was included in the original downstream design specifications, but the functionality was removed when the project team determined that materials with the highest risk of retaining contaminating microbes cannot be steamed-in-place — chromatography gels and some TFF membranes, for example.

The Project Pegasus team found that the added value from SIPing vessels and lines was questionable, and in some instances, may in fact hide a cleaning problem. The decision to eliminate downstream SIP made a significant contribution to the reduction in equipment turnaround times and increased facility capacity.

Pharmaceutical Counterculture

The ability to improve efficiency by questioning and changing processes that many think are standard in biopharmaceutical processing requires an environment in which operational improvements and innovation are encouraged and applied.

“Every voice and idea counts no matter where it comes from. Everyone on the team is continuously encouraged to contribute ideas,” explains Kim Sandell, receiving project manager for the Bio 7 facility and Pfizer Health AB’s director of Operational Excellence.

“We also communicated that not everything could be implemented directly, but we track proposals so that we can pick them up as the facility evolution continues. I like to think of a process and a facility as a journey, and that by finalizing the project, we have just left the station; we need to improve and get better as we move along over the years,” adds Sandell.

Risk-based approaches helped Sandell’s team challenge common practice with scientifically sound arguments.

“We used risk-assessment technologies, such as failure mode and effects analysis (FMEA), to ensure that we focused on the important stuff.”

And what is Sandell most proud of?

“We built Bio 7 in a platform technology — I like to compare it to the car industry’s way of building many different models on one common platform. This makes it simpler to introduce new processes in the future.”

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