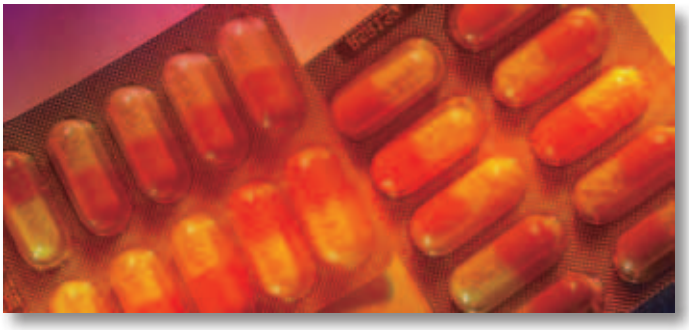
Exceeding European Pharmaceutical Requirements

Although Sanford, N.C.—almost halfway between Greensboro and Fayetteville, and just southwest of Raleigh/Durham—has been called the “Brick Capital of the U.S.”, the city is also home to a biotech industry giant. What used to be the Wyeth plant in Sanford is now part of Pfizer, the world’s largest pharmaceutical company. Pfizer acquired Wyeth in October 2009.

The pharmaceutical industry is one of the most highly regulated fields in manufacturing. In addition to U.S. Food and Drug Administration requirements, pharmaceutical companies that seek to provide products to other countries must meet their regulations as well. For example, both the EN 285 and the HTM 2010 standards require dryness values of at least 0.95 for the pure steam used in pharmaceutical processes. Based on the U.K. health document HTM 2010, the EN 285 is the European standard for steam sterilization and is regarded as the definitive reference on steam quality testing. Both documents are titled “Sterilization—Steam Sterilizers—Large Sterilizers.”

Simply stated, if a pharmaceutical facility can’t pass EN 285, it can’t ship its product to Europe. This was the case at the plant in Sanford. Consequently, production was halted until the issues preventing the facility from complying with the standard were corrected.

The management at the Sanford plant turned to Spirax Sarco, Blythewood, S.C., for help, requesting an evaluation of the entire pure steam system. The company’s primary goal was to be able to comply with EN 285 so that production could resume and its pharmaceutical products could be shipped to Europe.



PURE STEAM SYSTEM AUDIT TO THE RESCUE

Bryan Johnson, district manager responsible for the North Carolina area, and Glenn Hahn, national government account manager spent two days at the facility performing a pure steam system audit. Their goals going into the audit included:

- Evaluating the existing pure steam distribution system within the Bio Vaccine Development (BVD) and Isolated Pilot Plant (IPP) areas
- Evaluating, testing, and creating an inventory of the existing steam traps for the pure steam generators and pure steam distribution system
- Reporting the audit’s findings, making recommendations, and suggesting action items.

The pure steam distribution system for the BVD and IPP areas starts at the pure steam generators, sending steam through distribution lines to points-of-use, which includes heat exchangers that heat water for production processes, fermentors, and autoclaves. Johnson and Hahn conducted the audit focusing on ways to improve pure steam quality—or dryness—at all points of use, thereby improving operations.

AUDIT IDENTIFIES CHALLENGES—AND OPPORTUNITIES

In order to find problems, one must look for them. However, if properly executed, an audit does more than just expose problems; it seeks to identify areas in a steam system where improvements can be made in reliability, performance, and cost-effectiveness. In the Wyeth/Pfizer plant's situation, Johnson and Hahn discovered several conditions that prevented the company's existing pure steam system from meeting EN 285 requirements.

In general, the two issues that prevented the facility from achieving EN 285 compliance were pure steam quality and conditions associated with pure steam operations. The term "steam quality" refers to the "dryness" of the steam. EN 285 requires steam dryness greater than 0.9 for porous loads and greater than 0.95 for metal loads.

Condensate backing up in the pure steam distribution system and the lack of a means to remove moisture and non-condensables were the main culprits affecting the facility's pure steam dryness. Johnson and Hahn found that:

- There were 30 low points in the pure steam distribution system with no pure steam trap stations
- There were no inline pure steam separators to the autoclaves
- There were nine failed steam traps.

Other than steam dryness, the situations affecting pure steam operations included:

- Signs of "rouging," or carbon contamination (rouging indicates iron oxide that forms on surfaces in high-temperature steam systems)
- No standardization among steam traps—traps were misapplied, nonexistent, or had failed
- No way to measure steam flow for validation purposes
- No steam dryness test points for validation purposes
- No steam trap management program, which would improve maintenance efforts and ensure pure steam system reliability.

Condensate backing up in a pure steam distribution system presents a serious situation in a pharmaceutical manufacturing facility. Forget about using return pumps because condensate must not be returned in a pure steam system. "We opened the steam line and condensate came out," said Johnson. "From the boiler on down, condensate wasn't being removed from the headers."

A drip station is a trap that comes off the steam header to remove condensate from it. "They didn't have drip stations," Johnson said. "All they had was a steam header, but they've never had a steam trap on there. When steam condenses into condensate, you have to remove it; otherwise, it will back up in your system."

Johnson and Hahn also noted that there were no steam separators in the steam lines that fed four of the facility's autoclaves. They emphasized that without pure steam separators, achieving steam dryness values that could satisfy EN 285 requirements was highly unlikely. Even in the best-designed pure steam system, entrained moisture can still occur, resulting in an unacceptably low dryness fraction, non-compliance, of critical sterilization standards, damage to control valves and/or instrumentation, and low system efficiency. A separator installed in the steam line is designed to remove moisture droplets entrained in the steam flow, and as well as any condensate that has gravitated to the bottom of the pipe.

Typically, steam separators use baffles to remove entrained condensate and noncondensables. Steam is forced to change directions several times as it flows through the body of the separator. The baffles create an obstacle for the heavier water droplets, while the lighter dry steam is allowed to flow freely through the separator. The moisture droplets run down the baffles and drain through the bottom connection of the separator to a steam trap.

FROM IDENTIFICATION TO RECOMMENDATION

To correct the situations that were preventing the Wyeth/Pfizer facility from meeting EN 285 requirements and to improve the operation of the company's pure steam system, Johnson and Hahn made several recommendations, a summary of which follows:

- Install pure steam separators on four autoclaves to ensure steam dryness and improve autoclave performance
- Add pure steam traps and steam trap stations to equipment drop-down legs, heat exchangers, fermentors, and pure steam feed lines to remove condensate from the pure steam system
- Replace non-approved pure steam traps and piping components with pure steam system components
- Replace failed steam traps on the pure steam distribution lines
- Standardize steam traps on both the pure steam and plant steam systems
- Implement a steam trap management program
- Institute periodic steam distribution system audits.

Not only did the pharmaceutical plant's management agree to all of recommendations that Johnson and Hahn made, they asked the Spirax Sarco experts to design, install, and validate the company's pure steam improvement project.

What started as a steam system audit to correct process and regulation compliance issues turned into a turnkey solution that enabled the Wyeth/Pfizer facility to exceed EN 285 requirements, resume production activities, ship products to Europe, and improve its pure steam system.

Although regulations can be extremely challenging, Spirax Sarco's pure steam solutions help pharmaceutical industry manufacturers exceed regulatory requirements.

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