HYDE CORE LAB

LEGACY CLEANING PROCESS OPTIMIZATION

Ireland - MSD Swords Manufacturing Facility

United States - Hyde CORE Laboratory

PROJECT DESCRIPTION

A legacy cleaning process for the removal of a product residue containing significant amounts of the Active Pharmaceutical Ingredients (API) residue was identified by the engineering team as both a potential safety hazard and a known bottleneck in the manufacturing process.

The cleaning process could take up to five (5) working days for Cleaning in Place (CIP) operations. The long duration of the cleaning process was due to an inconsistent cleaning cycle that did not completely remove the hormonally bases oral solid dose residue from the process equipment. Due to the inconsistent nature of the residue removal, the process routinely required manual intervention, including confined space entry resulting in a breach of the room integrity. As the product residue represents the highest danger at a Level-5 on the Occupational Exposure Band (OEB), manual cleaning was not desirable.

MECHANICAL SERVICES

- **GREATER CLEANING EFFICIENCY**
  Replaced existing spray balls with new Toftjorg spray ball design
- **COMPLETE SPRAY COVERAGE**
  New pipe work & spray ball locations in Bolz vessel based on computer imaging
- **INCREASED THERMAL MASS**
  New 6kW Air Heater (Increased thermal mass)
- **CONTINUITY OF AIR SUPPLY**
  New Air supply header
- **GUARANTEE HOMOGENUITY of CIP SOLUTION**
  New Conductivity probe
- **OBVIATES AIR LOCKS & PRIMING ISSUES**
  New detergent pumps & set-up

SCALE UP OF DEVELOPMENT & PILOT CIP PROCESS

- New designed recipe, developed at Hyde CORE lab introduced to production scale
- Successful Riboflavin & "Edge of Failure" performed
- Installation, Operation, & Performance Qualification (IQ/OQ/PQ) as well as Commissioning Validation (CV) successfully complete on schedule/budget

AUTOMATION SERVICES

- A new recipe designed from 1st principles to clean and dry
- New intelligent detergent dosing program incorporated

Hyde ENGINEERING +CONSULTING