

Validation of GMP Critical Processes

Validation is fundamental in processes with a large number of variables that are not directly interrelated. It is a task that requires different sorts of skills, from engineering to production, from R&D to quality control

Thanks to their multidisciplinary teams of engineers, chemists, physicists and microbiologists, Eurofins can prepare custom-designed validation protocols. Moreover, Eurofins technicians guarantee that these studies will be done quickly and efficiently

Validation services cover the following GMP critical processes:

- Cleaning validation:
- Development and validation of analytical methods for cleaning validation. (HPLC, TOC, etc)
- Microbiological control of surfaces, air, water, etc,
- Cleaning validation protocol execution (sampling and analytical control)
- Aseptic filling validation (media fills).
- Sterilization process validation (steam, ETO, radiation) and depyrogenation.
- Bioburden studies and testing.
- Sterility testing.
- Calculation of radiation dose.
- Determination of contaminants residues and degradation products
- Packaging qualification studies
- Validation of the sterilizing filtration process
- Customized validation protocols for cleaning and disinfection procedures

In addition to the analytical services during process validation and process monitoring, Eurofins experts support the manufacturer during process risk analysis, protocols and SOPs definition, interpretation of results and preventive and corrective actions definition

Process validation services are complementary to our infrastructure qualification services: clean rooms and water facilities validation and monitoring, GMP critical equipment qualification, etc.