



Clean Room Qualification and Monitoring

Clean room qualification and monitoring are critical activities in order to minimize and manage the risk of contamination of the manufactured product.

Eurofins provides analytical control, including sampling services, for hygiene and clean rooms conditions monitoring and qualification. Sampling is performed at the customer site by highly efficient technicians that are specifically qualified for pharmaceutical facilities and GMP procedures.

The service includes:

- Sampling and microbiological controls of air and surfaces.
- Particle counts.
- Microbial identifications.
- Determination of chemical contaminants.
- Qualification of disinfectants used for clean room.
- Validation of cleaning and sanitization procedures

Eurofins' experts give support to the manufacturer from an external and independent point of view in all the critical phases of commissioning, validation and monitoring of the production areas which are subjected to qualification and control:

- Validation protocols based on risk analysis
- Assessment and definition of material and personnel flows
- Training and qualification of the personnel that operate in the controlled areas
- Assessment and definition of environmental monitoring SOPs
- Environmental and process control planning
- Trend analysis and interpretation of microbial identifications

