# Facility Monitoring and Support

Eurofins BioPharma Product Testing offers a comprehensive range of microbiology and chemistry capabilities in support of your facility monitoring and process validation projects—all performed in strict adherence to cGMP requirements. We have completed more than 250 facility validation projects for pharmaceutical manufacturers, biopharmaceutical companies, pilot plants, API manufacturers and tissue processors. Our experts are well versed in fulfilling validation needs with the flexibility to handle the unique specifications of any project.

## Why Choose Eurofins BioPharma Product Testing?

Our Facility Validation team is the largest in the industry, and with unmatched laboratory capacity, we are capable of handling multi- and large-volume projects while consistently meeting your needs for rapid turnaround time and results.

We offer outstanding service and flexible options in sample collection with daily sample courier service in the U.S. and pickup and analysis of samples on weekends (with advance arrangements by the client).

We can provide sample collection containers for your Process Water Testing and Environmental Monitoring.

### **Testing Available**

#### Process Water Testing (Ph. Eur./USP/ JP/BP)

- On-Site Sample Collection
- Total Aerobic Microbial Count (membrane filtration or pour plate)
- Endotoxin Testing
- Total Organic Carbon Testing

- Conductivity Testing
- Nitrate Testing
- Heavy Metals Testing
- EU Directive Testing on Drinking Water
- Total Coliform/Fecal Coliform Testing (source water)

#### **Environmental Monitoring**

- On-site Sample Collection
- Incubation of Samples
- Viable Air Sampling
- Non-viable Air Sampling
- Compressed Gas Sampling
- Process Water Sampling
- Clean Steam Sampling
- Surface Sampling

#### **Process and Facility Validation**

- Cleaning Validation & Consulting studies designed to quantify the elimination of bacteria and virus during the cleaning procedures utilized at your manufacturing facility
- Disinfectant Efficacy Testing
- Biological Indicator Incubation & Enumeration
- Endotoxin Indicator Preparation & Testing

#### Instrumentation

- Applied Biosystems Genetic Analyzer
- MALDI-TOF (Bruker)
- 9,000-square-foot, limited-access-controlled microbiology laboratories include HEPA filtration and validated cleaning, disinfection & monitoring programs
- High Volume SAS 100/180 (Surface Air System)
- Lasair III Non-viable Air Sampler
- HPLC, GC, TOC, ICP-OES, NVR for testing swab & rinse samples for residual product, raw material or cleaning agents

Fee For Service (FFS)