

Support for Pharmaceutical/ Biopharmaceutical Facility and Process Validation

Lancaster Laboratories offer a comprehensive range of capabilities in support of facility and process validation projects—all performed in strict adherence to current GMP requirements. Using client-designed sampling protocols we can provide the following analytical services:



- Analysis of process water-purified, DI, WFI, and clean steam systems:
 - USP chemistry (TOC, conductivity).
 - Microbiology.
 - Endotoxin.
- Trace metals analysis on water samples.
- Analysis of surface and air environmental monitoring samples, including contact plates, RCS strips, slit-to-agar plates, and swabs. We can also provide study design and sampling protocol support for environmental monitoring projects.
- Identification of environmental isolates and testing of organisms to genus and species using a GC-based microbial identification system or a DuPont Qualicon Riboprinter®.
- On-site sample collection services.
- Analytical support for cleaning validation, including residual analysis on a variety of samples, such as rinse waters and swabs from equipment.
- Microbiological support for cleaning validation, including consulting, testing, sample collection, and training.
- Preparation and analysis of endotoxin indicators for validation of depyrogenation cycles.
- Analysis of biological indicators, including incubation and enumeration.

Lancaster Laboratories also offers a number of services that are particularly helpful with regard to facility and process validation:

- Sample containers at no charge, which can be pre-labeled with the client's designation or sampling sites.
- Daily sample courier service in most parts of central and eastern Pennsylvania, Delaware, Maryland, New Jersey, and northern Virginia.
- Pick-up and analysis of samples on weekends and, with advance arrangements by the client, the capability to accommodate weekend sample collection.
- Laboratory capacity and multiple shifts of experienced analysts to handle large quantities of samples.
- Rapid and flexible turnaround-time results to meet your requirements—available by phone, fax or e-mail.

For more information on our process validation testing capabilities or any of our pharmaceutical capabilities, please contact your project manager or Pharmaceutical Business Development at 717-656-2300.



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