

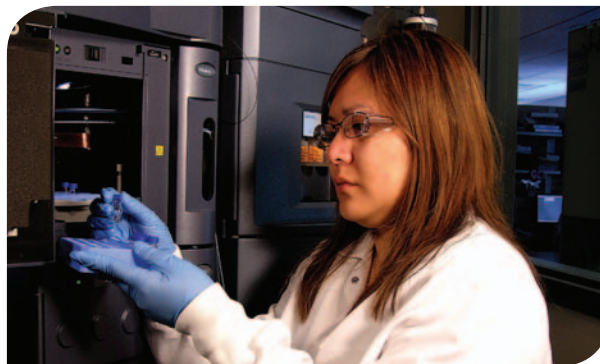


## Method Development and Validation

Whether you need expert testing consultation, method development or validation protocol design, Lancaster Laboratories offers you the widest range of laboratory techniques in the industry. We are also the only laboratory capable of providing method development for Comparator Product Testing. We support customers at various stages of the development/validation process and have a proven track record of success on full development and validation studies, optimization of existing research methods and transfer of previously validated methods.

### Why Choose Lancaster Laboratories?

- We collaborate with you by thoroughly understanding your testing requirements, resulting in a method that meets your specifications, is validated for its intended use and is developed in the most efficient manner to maximize your research budget.
- We offer phase appropriate method validation, or when needed, we can perform your work under full cGMP compliance.
- We have the most experienced staff, performing more than 200 validation, verification and transfer protocols for our customers in 2011.
- We place an emphasis on building relationships and rapport with our clients. Thanks to our extraordinary rate of employee retention, you can be confident that you will have the same management team for the duration of your project, as well as for any future work you may do with us.
- For additional services you may need, our Method Development and Validation Team works hand-in-hand with our other departments to ensure a smooth transfer.



### Method Development & Validation for

#### Chemistry/Biochemistry

- Assay/Potency, Purity/Impurity/Dissolution
- Cleaning Validation Analysis (Specific and Non-specific Analysis)
- Assay and Dissolution Methods for Comparator Products
- Residual/Impurities Testing
- Extractables and Leachables
- Excipients

#### Microbiology

- Bacteriostasis/Fungistasis for Sterility
- Inhibition/Enhancement Screening for Endotoxin
- AET and Microbial Limit

#### Molecular and Cell Biology

- Cell-based Assays
- ELISA
- qPCR

#### Protocol Writing for

- Method Validation
- Method Transfer
- Stability Protocol

Discover our solutions at: [LancasterLabsPharm.com](http://LancasterLabsPharm.com)

#### Global Services:

Biochemistry  
Cell Bank Manufacturing  
Facility & Process Validation  
Method Development & Validation  
Microbiology  
Molecular & Cell Biology

Mycoplasma Services  
Raw Materials Testing  
Release Testing  
Residuals & Impurities Testing  
Stability Testing & Storage  
Viral Clearance & Viral Safety

#### Facilities:

USA  
Lancaster, PA | 717-656-2300  
Portage, MI | 269-323-3366

Ireland  
Dungarvan Co. Waterford | 00 353 (0) 58 48300