



Pharmaceutical Services

Chemistry/Biochemistry

Method Development & Validation

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

Release Testing

- HPLC, GC, IC and GPC Analysis
- Stability & Release Testing
- Dissolution Testing
- Physical Testing
- Cleaning Validation
- LC/MS/MS Analysis
- GC/MS Analysis
- Moisture Analysis
- Container/Closure Testing
- EU Batch Release

Raw Materials

- Complete Compendial Analysis (USP, EP, JP, BP, ACS, FCC)
- TOC Analysis
- GC, HPLC & IC Analysis
- USP <467>
- UV Spectroscopy
- Pharmaceutical Water Testing (USP, EP, BP, JP)
- Fourier Transform-Infrared Spectroscopy
- Elemental Analysis (AA, GFAA, ICP/MS, ICP)
- Container/Closure Testing (USP, EP)
- Arsenic
- Heavy Metals
- Karl Fischer
- Differential Scanning Calorimetry
- Thermogravimetric Analysis
- CHN Analysis

Stability Testing & Storage

- Marketed & Clinical Release Testing
- Marketed & R&D Stability Testing
- Method Validation
- Stability Storage
- Comparator Product Testing
- Protocol Writing

Consulting Services

- Protocol Development and Writing for Method Validation, Method Transfer & Stability Protocol

All services above are also applicable for API/Reference Standard Release/Stability/Re-Certification Programs.

Microbiology

Method Development & Validation

- Bacteriostasis/fungistasis (to support sterility testing)
- Inhibition/Enhancement (to support endotoxin testing)
- AET & Microbial Limit Validation

Organism Identification

- Fatty Acids Analysis (FAME)
- Mold Identification
- Sequence Analysis (MicroSeq®)
- Ribotyping

Sterile Products

- Sterility
- Endotoxin
- Particulate Matter
- Microbial Immersion Studies
- H₂O₂ D-value Studies
- AAMI Sterilization Validation
- Media Fills

Non-Sterile Products

- Microbial Limits
- Antimicrobial Preservative Effectiveness
- Bioburden Studies
- Water Activity

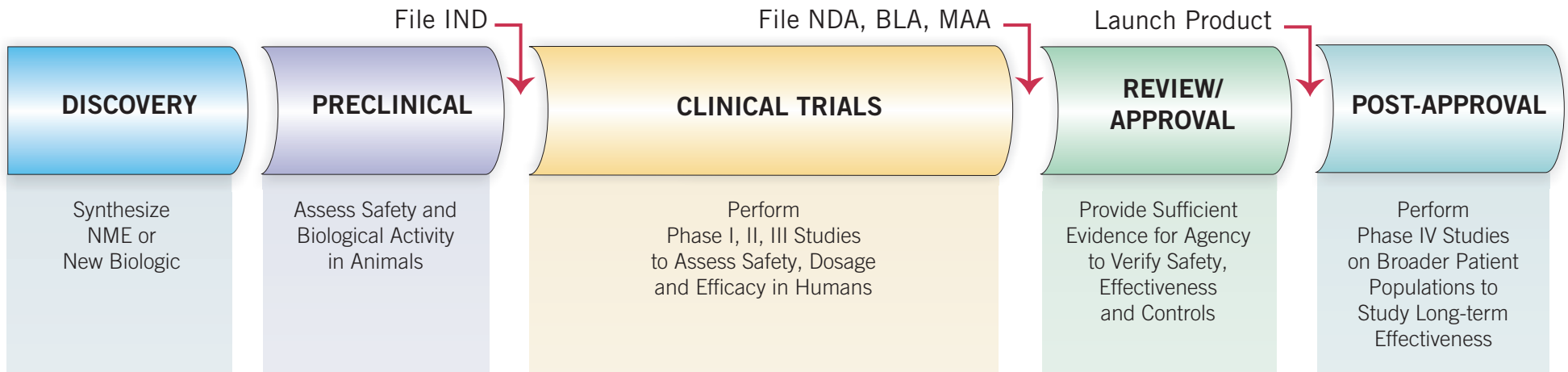
Facility Validation Support

- Process Water Testing
- Environmental Monitoring
- On-site Sample Collection
- Cleaning Validation & Consulting
- Biological Indicator
- Enumeration/Incubation
- Endotoxin Indicator
- Preparation/Testing

Container Closure Integrity

- Dye Ingress
- Microbial Immersion

Pharmaceutical Drug Development Process - "The Pipeline"



How Lancaster Laboratories Helps You Advance Your Development Candidate

