



## Biopharmaceutical Services

### Biospectroscopy • Biochromatography • Mass Spectrometry

#### Method Development & Validation

- Purity, Concentration, Identity, Impurities, Characterization
- Cleaning Validation Analysis (Specific & Non-specific Analysis)
- Residual Impurities Testing
- Extractables & Leachables

#### Characterization

- Post-Translational Modifications
- Peptide Mapping
- Amino Acid Analysis
- Charge Isoforms
- N- and O-Glycan Profiling
- Molecular Weight Determinations (Exact Mass)
- Aggregates
- Secondary Structure

#### Residual Impurity Testing

- DNA, HCP, Protein A
- Antibiotics
- Surfactants, Antifoams
- Residual Solvents
- Extractables & Leachables
- Metals/Ions
- Process-Enhancing Agents

#### Lot Release Testing

- Purity/Impurities
- Product Characterization
- Activity
- Identity
- Contaminants

#### Stability

- Stability Testing
- Stability Storage
- Method Validation
- Protocol Development

#### Consulting Services

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

### Biosafety Testing • Cell Bank Manufacturing

#### Molecular & Cell Biology

- Optimization & Validation of Cell-Based & Non-Cell-Based Potency Assays
- qPCR Assays for Residual DNA, Viruses, Mycoplasma
- USP Cytotoxicity Testing
- Host Cell Protein Analysis
- ELISA Assays

#### Microbiology

- Sterile Products
- Non-Sterile Products
- Facility Validation Support
- Organism Identification
- Sterility Testing
- Mycoplasma Testing

#### Viral Safety

- Adventitious Virus Assays
- Retrovirus Assays
- Bovine & Porcine Viral Screens
- Infectivity Assays
- Full Master, Working & End-of-Production Cell Bank Characterization

#### Viral Clearance

- Dedicated Clearance Suites
- Validated Virus Stocks
- AKTA Chromatography Systems
- Validated Virus Titer Methods

#### Cell Bank Manufacturing

- Manufacturing of Master & Working Cell Banks
- Dedicated ISO 7 Cleanrooms
- Validated Manufacturing Processes

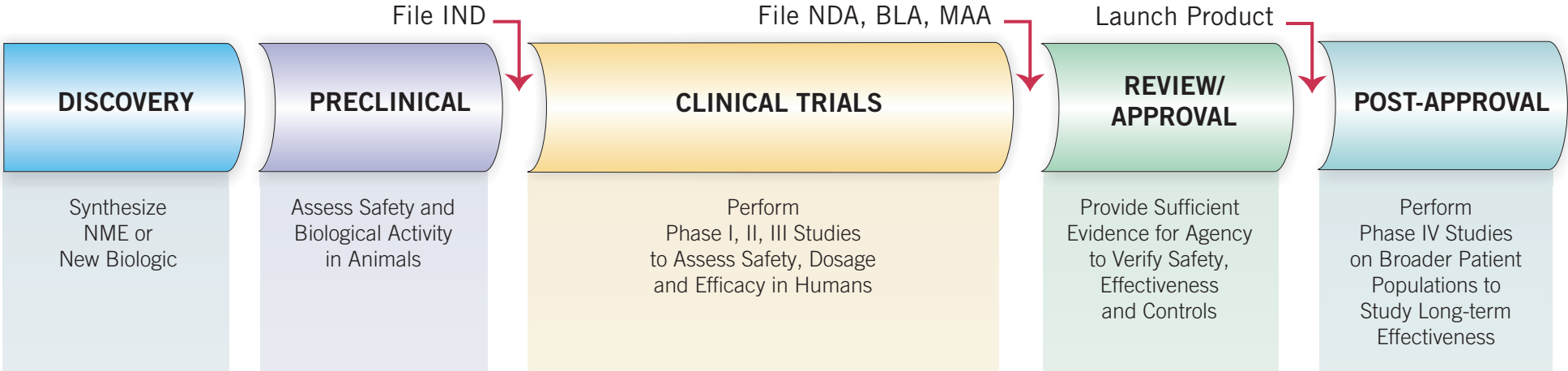
#### Facility Validation Support

- Cleaning Validations (viral, mycoplasma, microbial organisms)
- Disinfectant Efficacy Studies (viral, mycoplasma, microbial organisms)

### Comprehensive Testing Services

Raw Materials/Excipients, Culture Media, Cell Banks, Bioprocess Intermediates, Drug Substances, Drug Products

# Biopharmaceutical Drug Development Process - "The Pipeline"



## How Lancaster Laboratories Helps You Advance Your Development Candidate

