eurofins | BioPharma Product Testing

Pharmaceutical Services

Chemistry

Raw Materials

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

Consulting Services

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

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
- Trace Metals

Release Testing

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

Stability Testing & Storage

- Marketed, Registration & Clinical Stability & Release Testing
- Critical Reagent and Reference Standard Storage and Qualification
- Method Validation
- Stability Storage
- Comparator Product Testing
- Forced Degradation Studies
- In-use and Shipping Studies
- Protocol Writing

Microbiology

Method Development & Validation

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

Organism Identification

- MALDI-TOF (Bruker)
- Sequencing
- Mulitlocus Comparative Sequencing (MLSA)
- Molecular Typing

Sterile Products

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

Non-Sterile Products

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

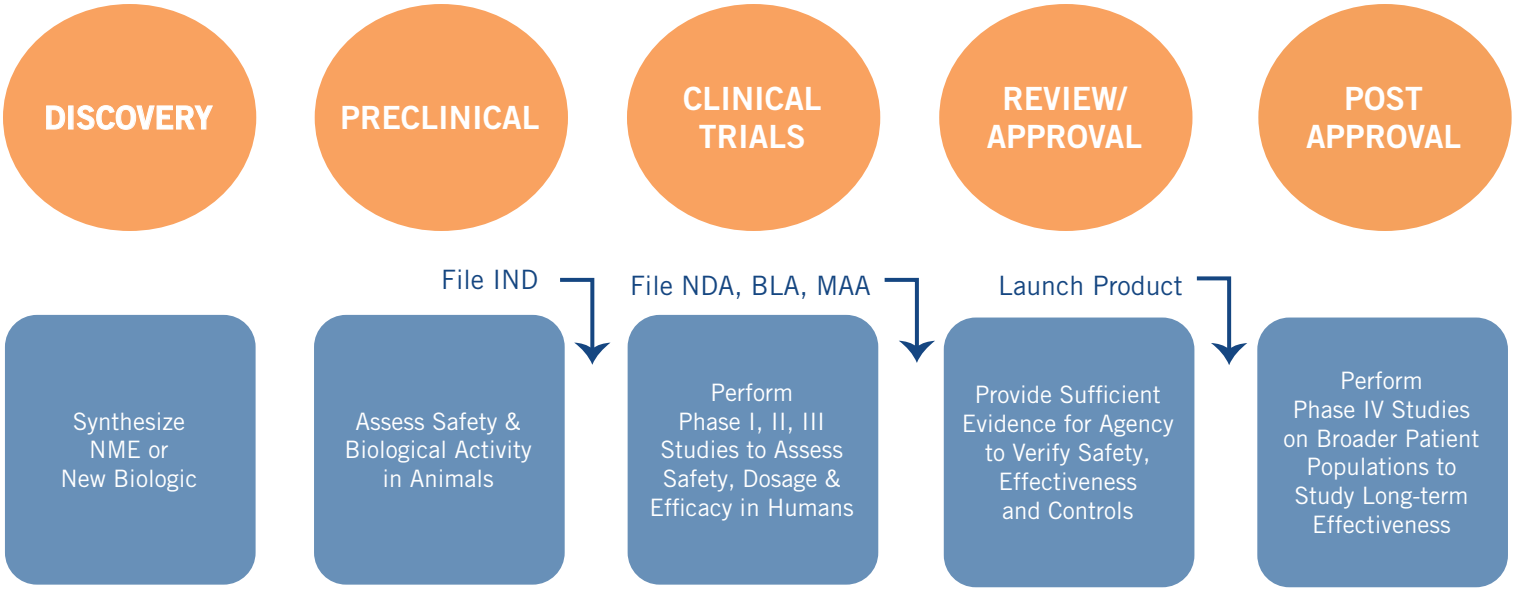
Facility Validation Support

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

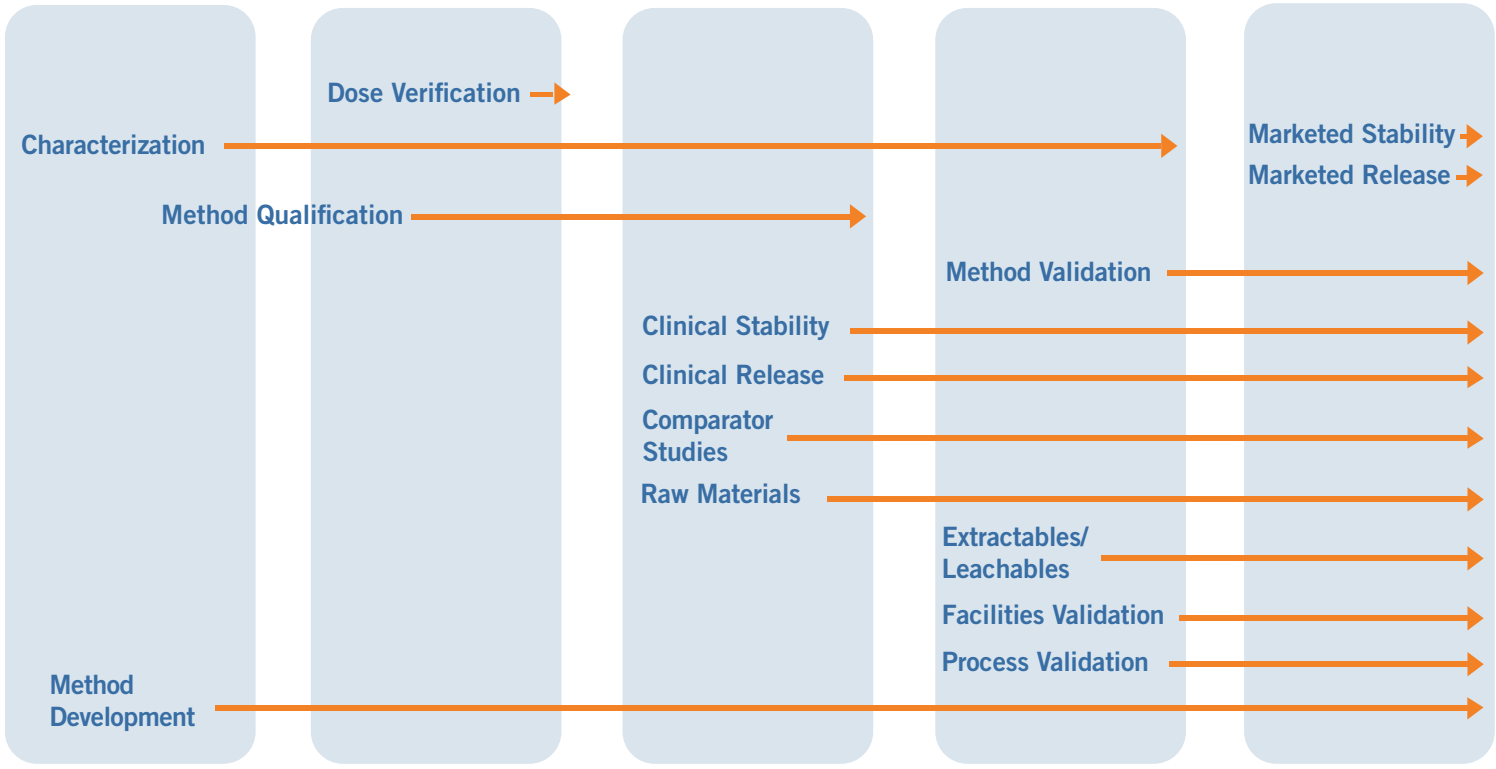
Container Closure Integrity

- Dye Ingress
- Microbial Immersion

Pharmaceutical Drug Development Process
"The Pipeline"



How We Help You Advance Your Development Candidate



Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

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