Eurofins Biopharma Product Testing
Congrès Proteinov 2016

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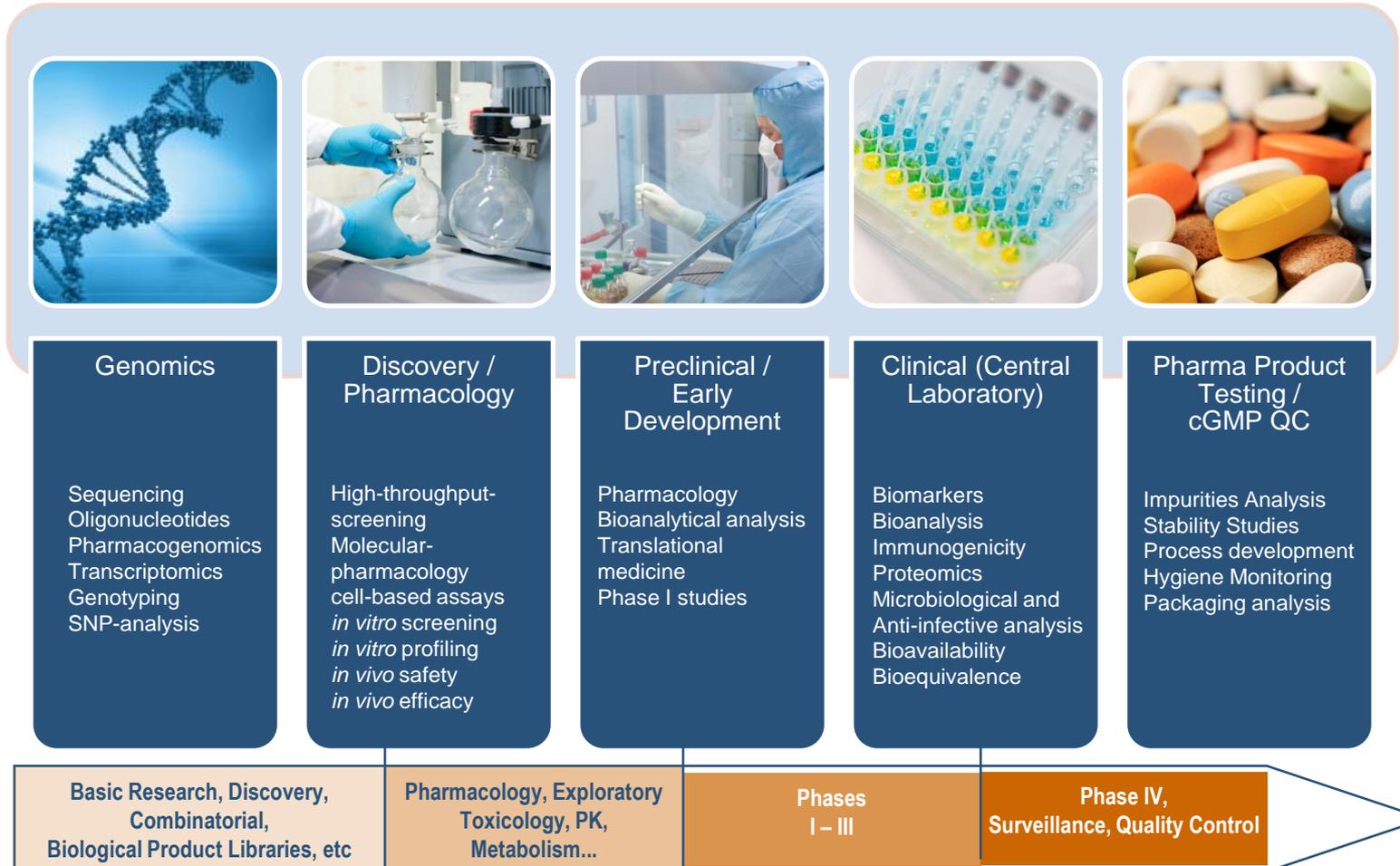
Eurofins Bio/Pharma Services

Spanning the entire drug development cycle

Genomics

Sequencing
Oligonucleotides
Pharmacogenomics
Transcriptomics
Genotyping
SNP-analysis

Discovery / Pharmacology

High-throughput-screening
Molecular-pharmacology
cell-based assays
in vitro screening
in vitro profiling
in vivo safety
in vivo efficacy

Preclinical / Early Development

Pharmacology
Bioanalytical analysis
Translational medicine
Phase I studies

Clinical (Central Laboratory)

Biomarkers
Bioanalysis
Immunogenicity
Proteomics
Microbiological and Anti-infective analysis
Bioavailability
Bioequivalence

Pharma Product Testing / cGMP QC

Impurities Analysis
Stability Studies
Process development
Hygiene Monitoring
Packaging analysis

Basic Research, Discovery, Combinatorial, Biological Product Libraries, etc	Pharmacology, Exploratory Toxicology, PK, Metabolism...	Phases I – III	Phase IV, Surveillance, Quality Control

eurofins | BioPharma Product Testing

Our Global Capabilities in GMP Testing

Small Molecules

- Raw Materials
- Residuals/Impurities
- Comparator Product Testing
- Extractables & Leachables
- Aerosol Product Testing

- Sterile Products Testing (isolator technology)
- Non-sterile products
- Endotoxin
- Environmental Monitoring
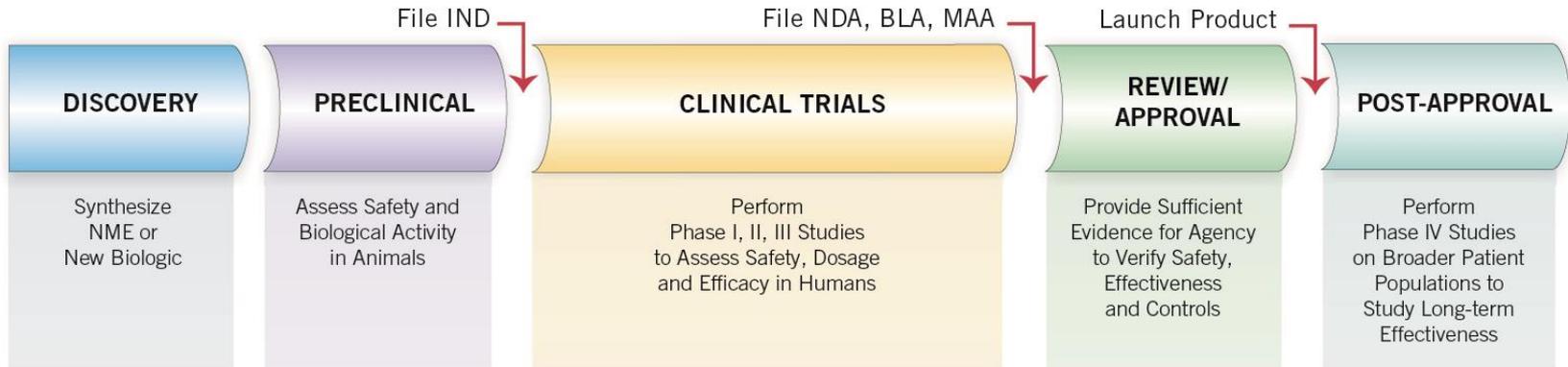- Organism Identification

Large Molecules

- Cell Bank Manufacturing & Storage
- Cell Bank Characterization
- Viral Clearance
- Biochemistry Protein Characterization
- Residual Impurity Testing
- Molecular & Cell Biology (PCR)
- Microbiology & Mycoplasma

- Method Development & Validation
- Facility & Process Validation
- Environmental Monitoring
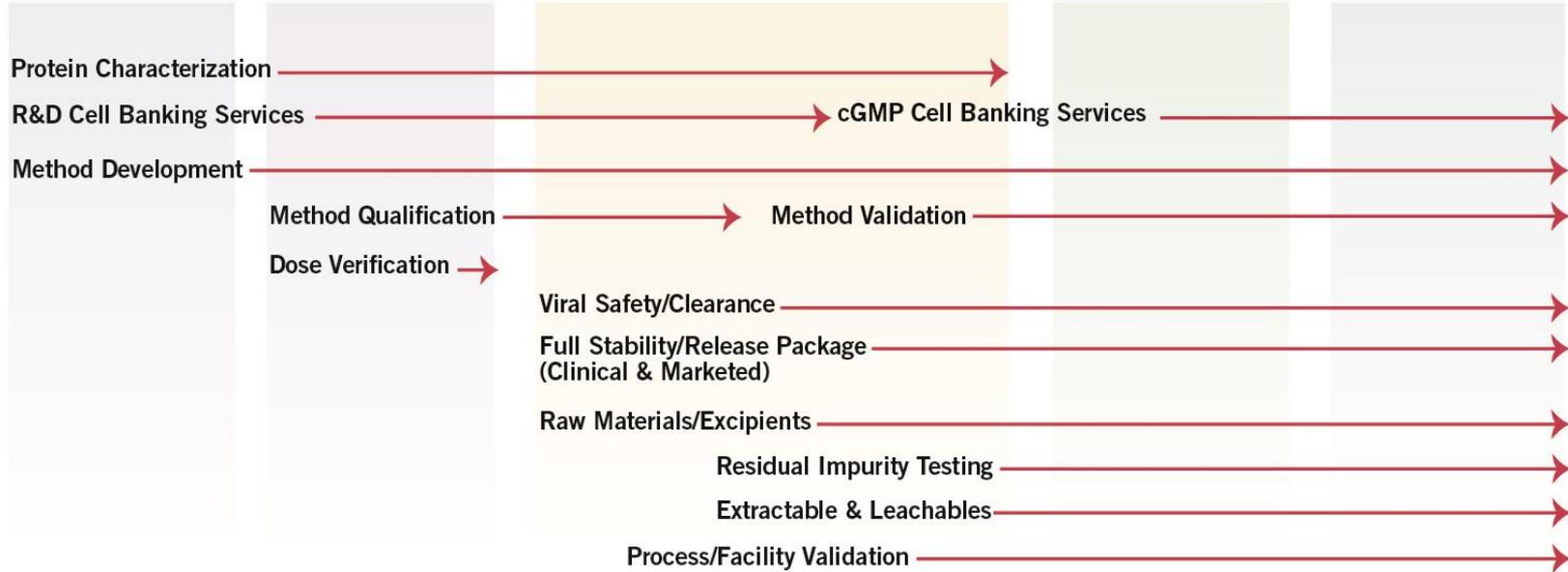- Product Release & Stability Testing

- **Fee-for-Service**
- **FTEs (full time employees) - working exclusively for one client**
- **PSS (Professional Scientific Services) - Client's facility, equipment, procedures, and quality systems**

Note: Largest Clients Use Multiple Tiers

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BioPharma
Product Testing

Biopharma Drug Development Process

DISCOVERY	PRECLINICAL	CLINICAL TRIALS	REVIEW/ APPROVAL	POST-APPROVAL
Synthesize NME or New Biologic	Assess Safety and Biological Activity in Animals	Perform Phase I, II, III Studies to Assess Safety, Dosage and Efficacy in Humans	Provide Sufficient Evidence for Agency to Verify Safety, Effectiveness and Controls	Perform Phase IV Studies on Broader Patient Populations to Study Long-term Effectiveness

File IND — File NDA, BLA, MAA — Launch Product —

How we help you advance your development Candidate

Protein Characterization →

R&D Cell Banking Services → cGMP Cell Banking Services →

Method Development →

Method Qualification → Method Validation →

Dose Verification →

Viral Safety/Clearance →

Full Stability/Release Package (Clinical & Marketed) →

Raw Materials/Excipients →

Residual Impurity Testing →

Extractable & Leachables →

Process/Facility Validation →

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BioPharma Product Testing

Outsourcing & Insourcing Locations

The Largest Network of Harmonized Bio/Pharmaceutical GMP Product Testing Laboratories Worldwide

- **13 Countries**
- **24 Laboratory Locations**
- **> 65,000 m^2 / 700,000 ft^2**
- **> 65 PSS sites**
- **> 3,000 Employees**

- Professional Scientific Services
- Biopharma Product Testing

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EU Centers of Excellence

**Leiden,
Netherlands**
Biologics/
Biochemistry,
Biosafety,
Manufacturing
(Aseptic F&F)

**OSS,
Netherlands**
GMP NMR/XRD

**Dungarvan,
Ireland**
Biologics/
Biochemistry

**Lyon,
France**
Micro ID
& typing

**Munich,
Germany**
Biologics/
Bioassays

**Paris,
France**
Raw Materials,
Stability Studies

**Milan,
Italy**
Extractables &
Leachables

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Thank you