

SOUTHERN RESEARCH

**Conducting basic, translational, and
contract research for pharmaceutical and
biotechnology companies**

Life Sciences

Located in Alabama and Maryland

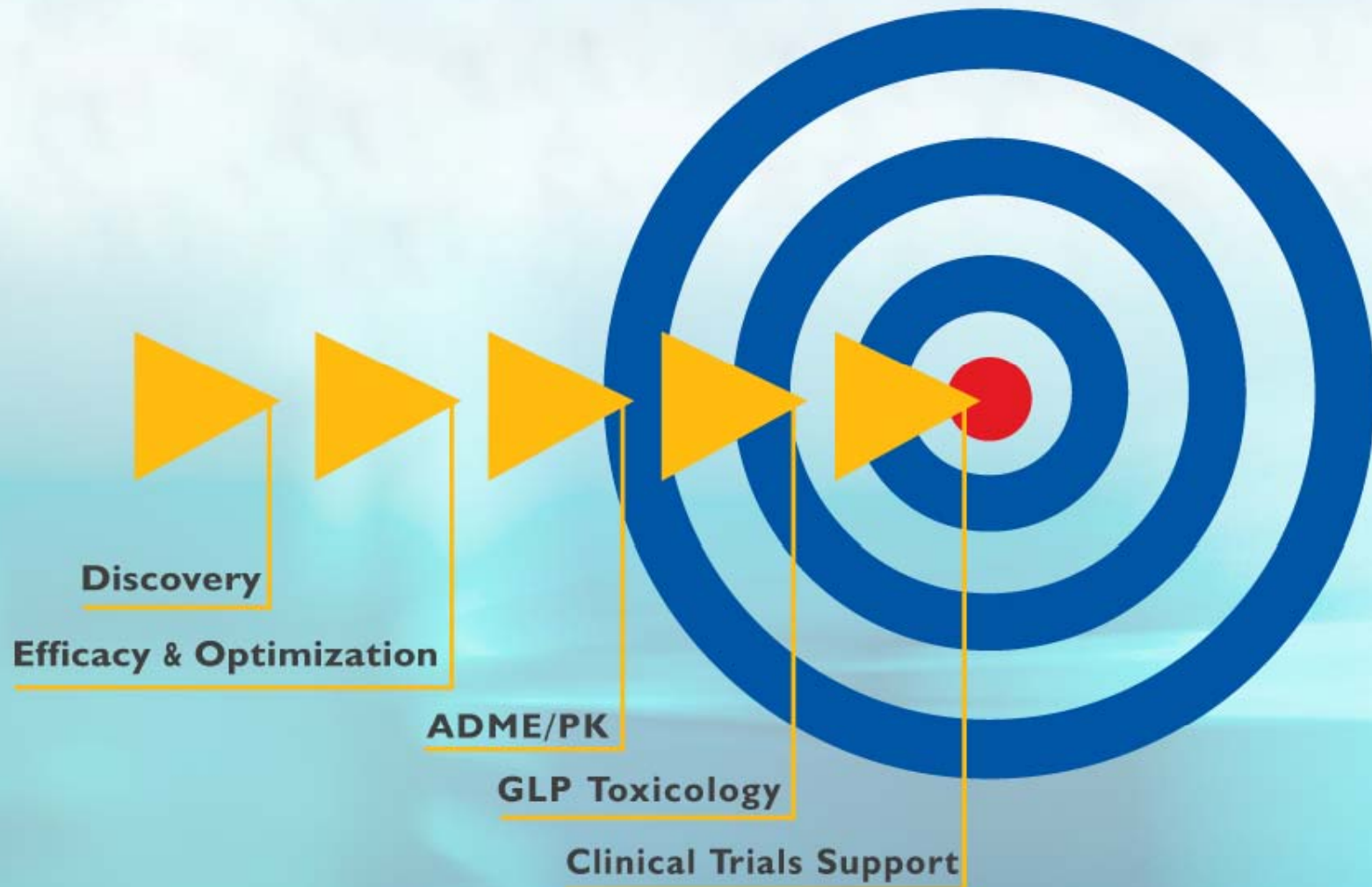


**Birmingham, AL
Main Campus**



Frederick, MD

Partnering with Clients to Move Drugs Through the Pipeline



Drug Discovery and Development Accomplishments

Southern Research discovered seven of the anticancer drugs that are currently being marketed for patients.

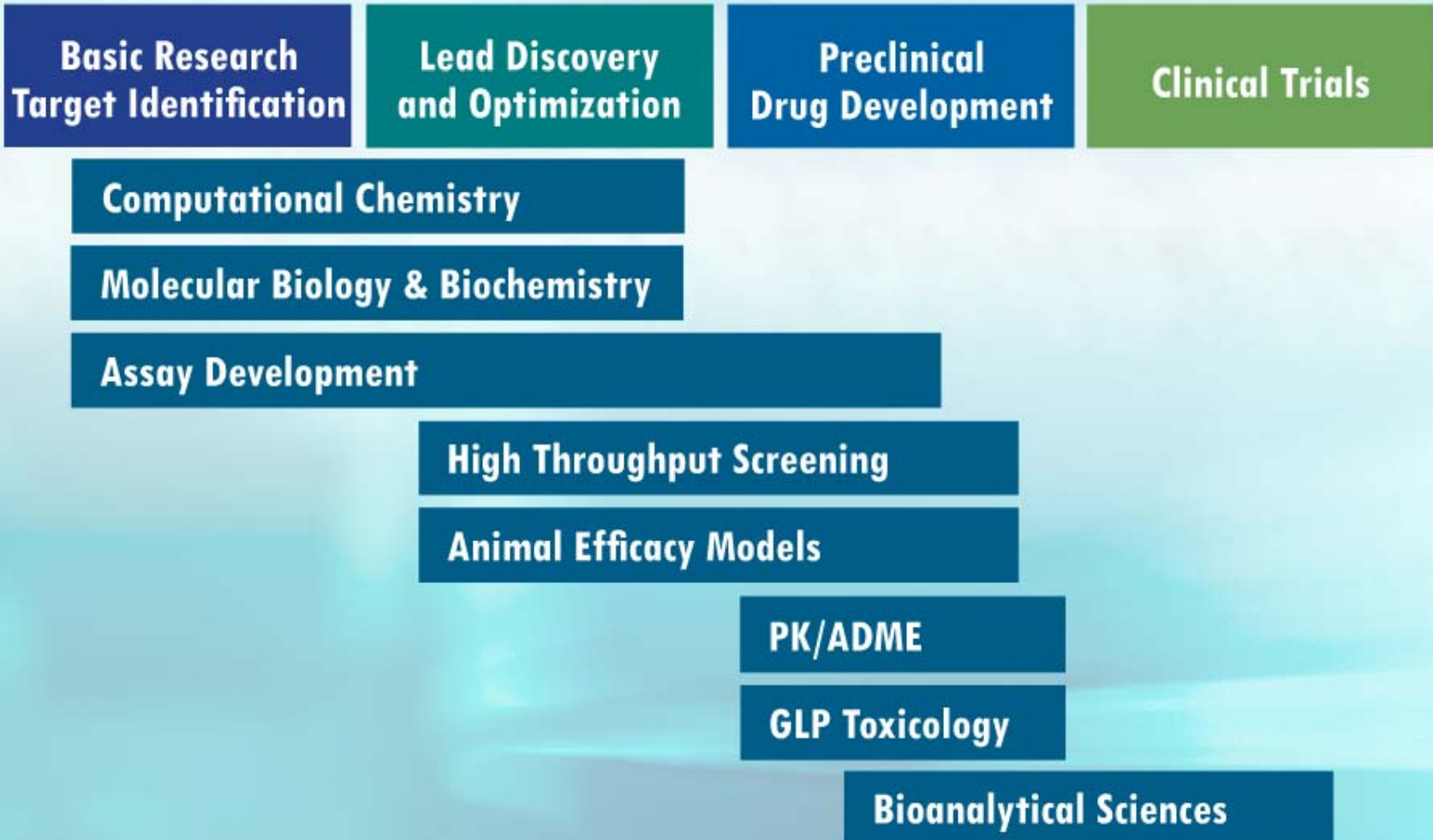
Twenty drugs discovered at Southern Research have entered clinical trials.

Over half of the FDA-approved anticancer drugs were evaluated at Southern Research.

Drug Pipeline

DRUG PROGRAM	THERAPEUTIC USE	PRECLINICAL	IND SUBMISSION	PHASE I	PHASE II	PHASE III	NDA SUBMISSION	APPROVED	MARKETED BY	TRADE NAME
AMIFOSTINE	A chemotherapy and radiotherapy protective agent								MedImmune	Ethyol®
FLUDARABINE	Adult leukemias and lymphomas								Sanofi-Aventis	Fludara®
DACARBAZINE	Melanoma, Hodgkin's disease, and soft tissue sarcoma								Merck	DTIC-Dome®
LOMUSTINE	Brain tumors								Bristol-Myers Squibb	CeeNU®
CARMUSTINE	Brain tumors, multiple myelomas, and Hodgkin's Disease								Bristol-Myers Squibb	BiCNU®
CLOFARABINE	Leukemias, solid tumors, and autoimmune diseases				In trials for adult cancers	Approved for pediatric ALL			Genzyme	Evoltra® Clolar®
PRALATREXATE (PDX)	Lymphomas and solid tumors			In trials for other indications	Approved for T-cell lymphoma				Allos Therapeutics, Inc.	FOLOTYN™
PALIFOSFAMIDE	Advanced sarcoma								DEKK-Tec ZIOPHARM	
THIARABINE	Leukemias and autoimmune diseases								Access Pharmaceuticals	
DMPEN	Metastatic breast cancer and brain tumors								Antisoma	Clomet™
PNP	Gene therapy treatment of solid tumors								PNP Therapeutics	
BITHIONOL	Solid tumors								Champions Biotechnology, Inc.	
ISOPHOSPHORAMIDE MUSTARD ANALOGS	Late stage cancers								ZIOPHARM	
4'-THIOIDU	Pox viruses								Southern Research / UAB	

Full Range of Discovery and Preclinical Development Series



Chemistry



Drug design, synthesis & route selection for scale-up

Medicinal chemistry, SAR & lead optimization

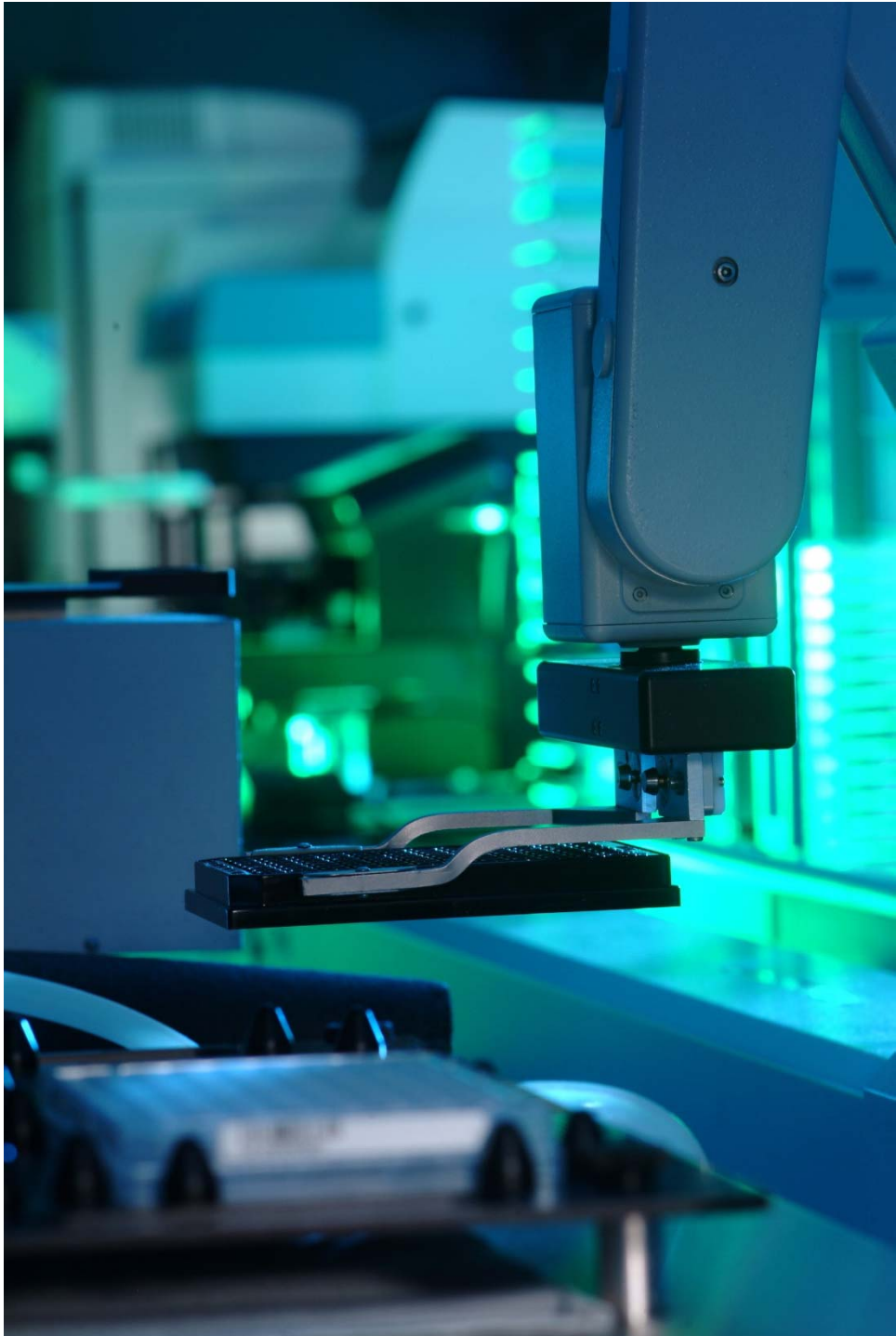
Library design & combinatorial chemistry

In silico screening

Molecular modeling

Structural biology/protein crystallography

Cheminformatics, repository & database services



Discovery Biology

Assay development & validation

High throughput screening

Mechanism of action

Target discovery and validation

Genomics

Proteomics

Cell biology

Immunology

Cancer Therapeutics Evaluation & Testing

In Vitro capabilities

Over 200 human tumor cell lines

60 cell-line panel testing

Cytotoxicity/anti-proliferative assays

Mechanism of action (apoptosis, cell cycle, cell differentiation)

Combination and/or sequencing studies including irradiation

Custom cell-based assay development



Cancer Therapeutics Evaluation & Testing

In Vivo capabilities

Over 80 human tumor xenograft models

Extensive clinical drug efficacy database

Numerous murine tumor models

In vivo imaging with IVIS Lumina

Combination therapy with clinically useful agents or irradiation

Automated data acquisition



Immunology

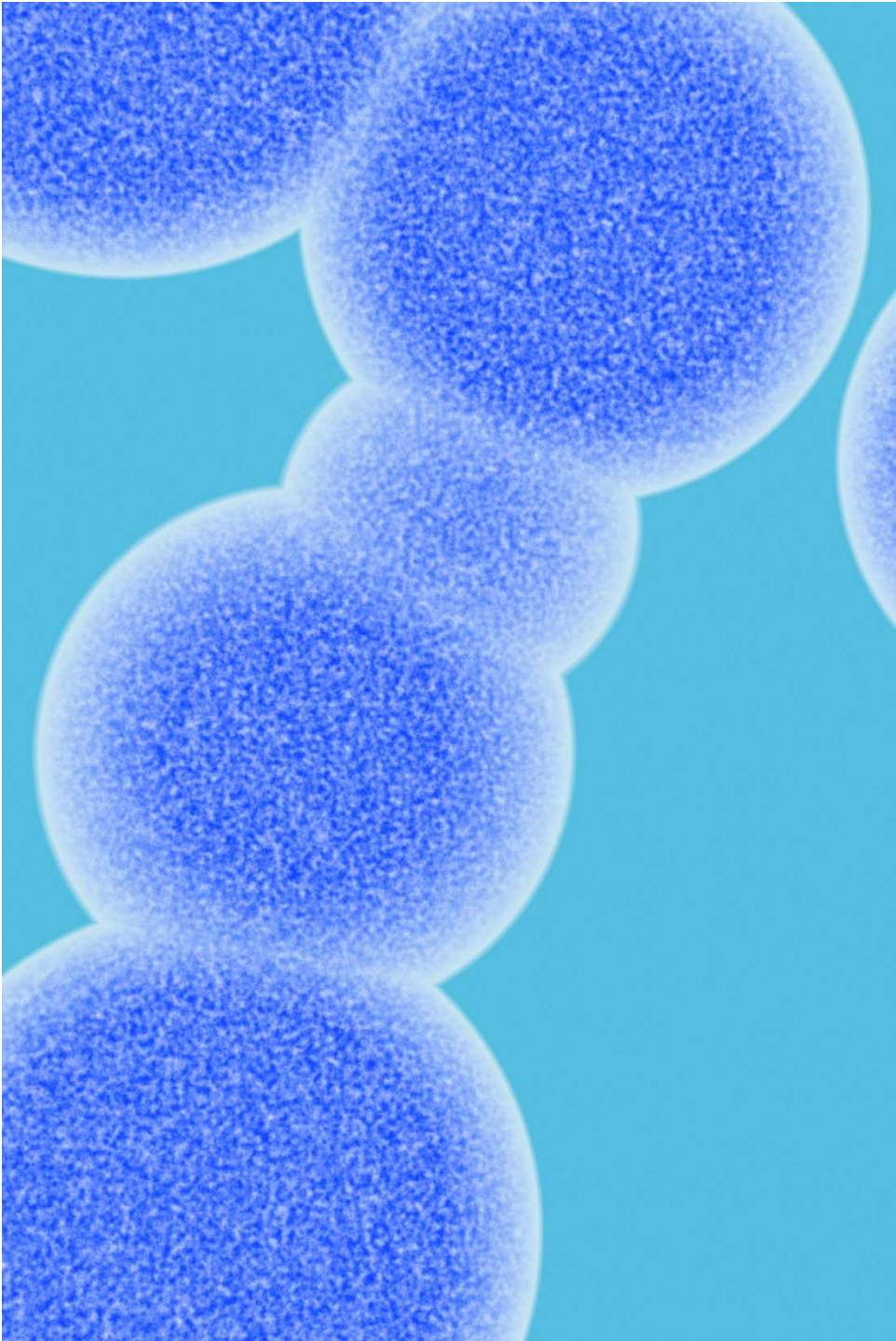
Immunoassays (e.g., ELISAs)

Immune function testing

Custom assay development

Flow cytometry

Immunohistochemistry



Infectious Disease Therapeutics Evaluation and Testing - Types

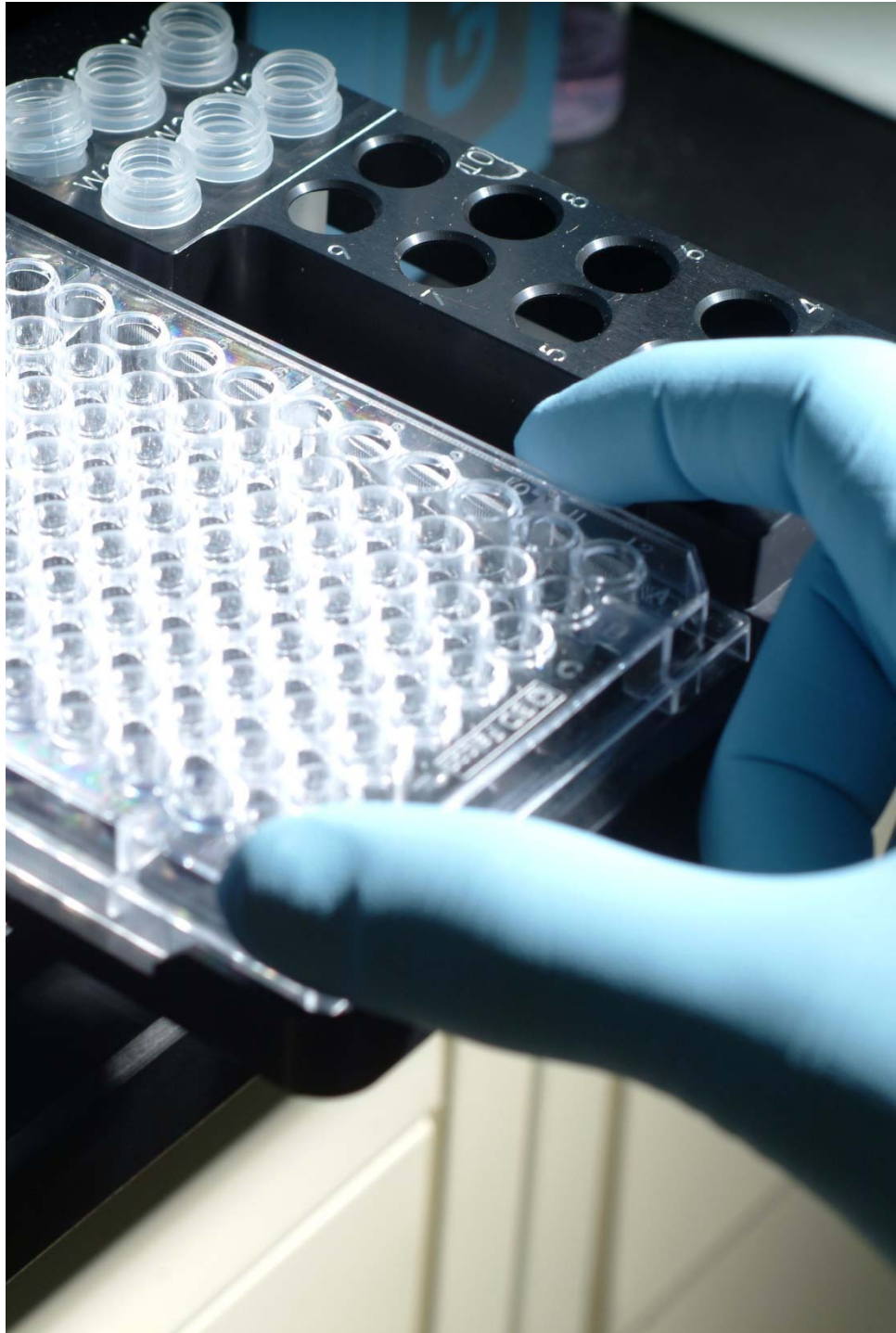
Antibiotics

Antivirals

Antifungals

Vaccines

Topical Microbicides



Infectious Disease Therapeutics Evaluation and Testing Capabilities

Custom assay development

Wide variety of pathogenic bacteria

In vitro models

In vivo evaluation of drugs and
vaccines

BSL-3/ABSL-3 for select agents

BSL-3 aerobiology

Immunologic assays



Infectious Disease Therapeutics Evaluation and Testing Agents

Influenza viruses

(including H1N1 and HPAI)

TB (including multi-drug resistant)

Pox viruses

SARS-CoV

Hantavirus

HIV

Anthrax

RSV

Tularemia

Herpes viruses

Plague

Hepatitis B & C

MRSA

ADME/PK

Single and multidose

Absolute and relative
bioavailability

Proportionality and linearity of
absorption

PK species-to-species
extrapolations

Toxicokinetic support

Protein binding

In vitro metabolic profiling

Pathway definition



Pharmacodynamics

Target- or organ-specific enzyme activity

CBC alterations

Proteomic and genomic changes

Tumor growth

Cell permeability

Modulation of cell-cycle pathways

Bioanalytical Chemistry

Method development and Validation (GLP)

LC-MS/MS

LC/MS

HPLC with UV-VIS

GC with FID and ECD detectors

GC/MS with PCI, NCI, and EI ionization sources

Plasma and tissue drug-level determinations




PCR Laboratory

TaqMan® and Molecular Beacons™ assays

Isolation and purification of DNA and RNA

Quantitation using PicoGreen/RiboGreen

Biodistribution and gene expression



**GLP Toxicology Studies
and
Preclinical Safety Assessment Evaluations**



Toxicology Test Articles

Small molecules

Biologics

Nutraceuticals

Botanical Extracts

Vaccines

Gene therapy vectors

Toxicology Test Species



Mice

Rats

Dogs

Nonhuman primates

Mini-pigs

Rabbits

Guinea pigs

Hamsters

Ferrets

Toxicology Routes of Administration

Oral Gavage/Capsule

Dietary admixture

Drinking water

Dermal

Injection

Infusion

Intranasal

Ocular

Rectal

Surgical implant

Intracranial



Clinical Pathology

GLP-compliant

BSL-1 - BSL-3

25 years experience

ASCP certified

CAP proficiency testing

Clinical Pathology - Analyzers

ADVIA® 120 Hematology

ACL™ Elite Pro Hemostasis

COBAS® 6000 Clinical Chemistry

Clinitek 500 Urine Chemistry

Anatomic Pathology

ACVP board-certified pathologists

Histopathologic examinations

Consultations

Peer review

Digital photography

Necropsy

Histology and histopathology



Quality Assurance - GLP Personnel

Registered Quality Assurance Professionals (RQAP-GLP)

More than 85 years collective experience

Hosted 20 regulatory inspections without an FDA Form 483

Quality Assurance - GLP Program

**Audits/inspections conducted in accordance with US FDA, US EPA,
OECD, MOHW, UK Compliance Programme**

More than 60 internal audits/inspections conducted biennially

18 internal facility inspections conducted annually

Vendor/Supplier audits conducted biennially

GLP training annually and as needed

Proven Science.

Experienced People.

Trusted Results.

Since 1941.