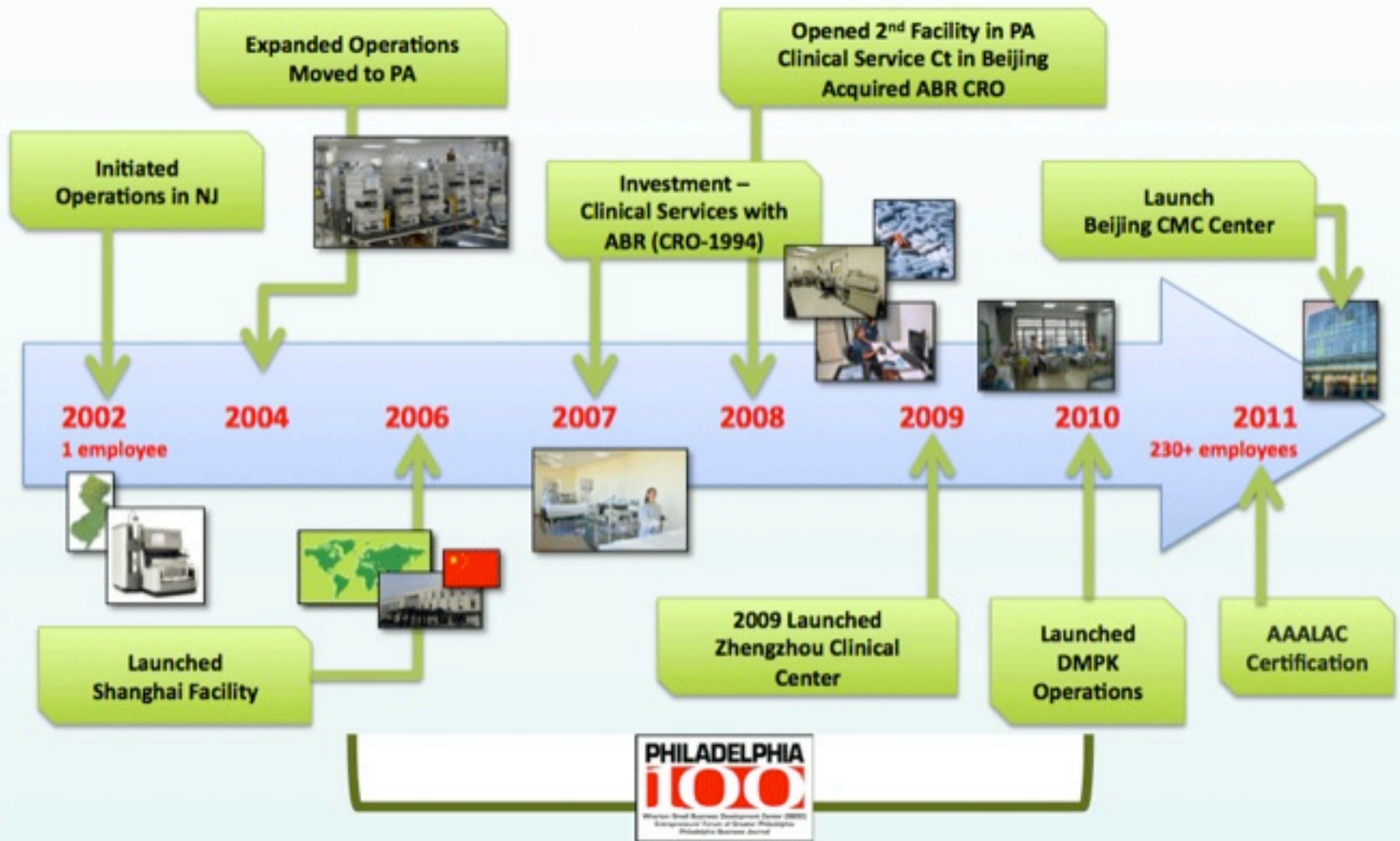




CORPORATE OVERVIEW

FRONTAGE LAB MILESTONES



A FULLY INTEGRATED GLOBAL CRO

ACCOMPLISH MORE WITH ONE SERVICE SUPPLIER

CMC

API / Organic Synthesis
Pharmaceutical Analysis
Formulation Development
Clinical Manufacturing
GMP & CMC Consulting

GMP

Preclinical/Bioanalytical

Bioanalytical
DMPK
Biological / Immuno Assays
Biomarker Assays

GLP

Clinical

Clinical Studies Phase I/IIA
Data Analysis
Regulatory Affairs
Oncology Studies (China)

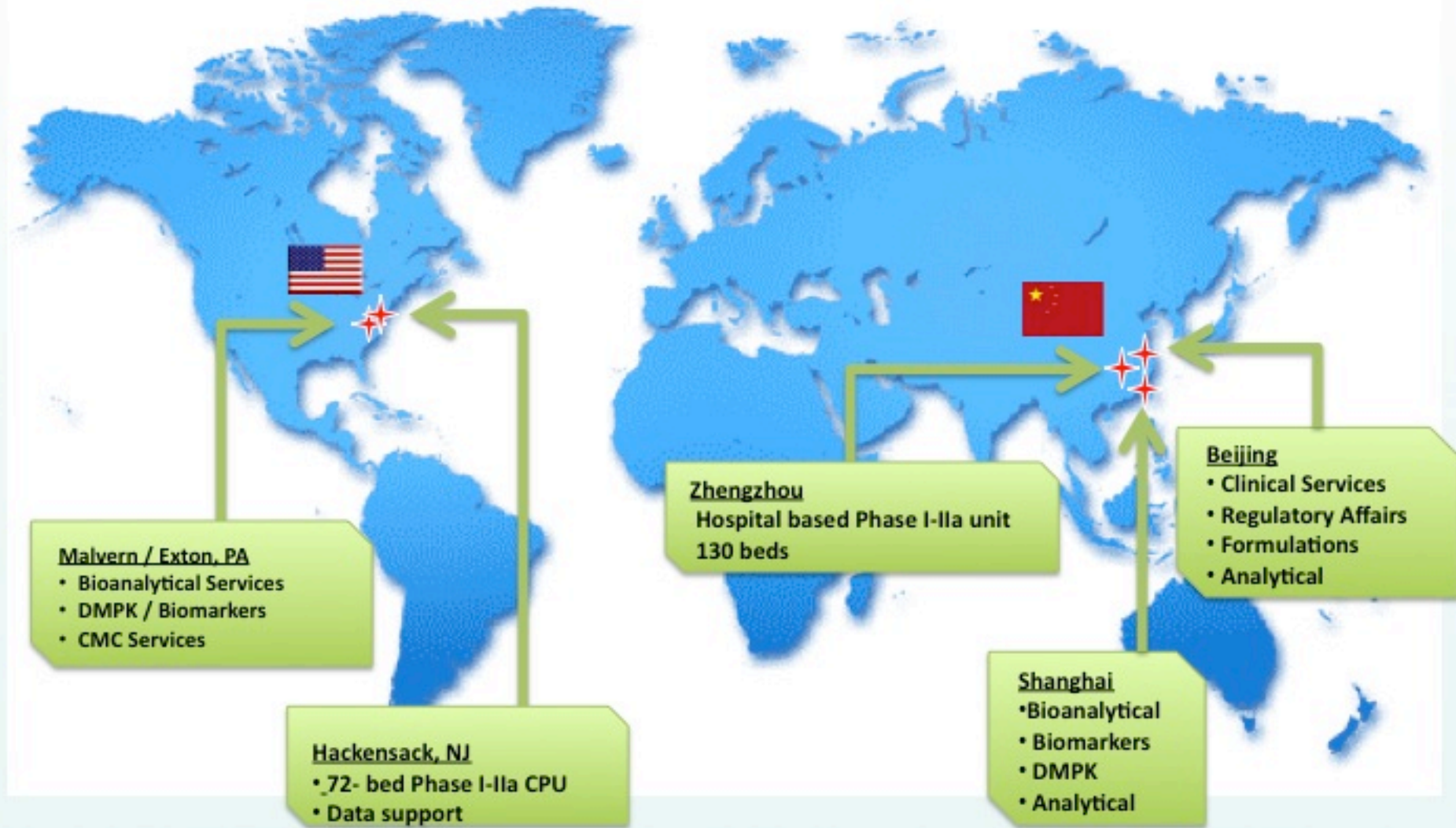
GCP



Multiple Successful (10+) FDA Inspections

- Helping US, EU and Chinese companies to introduce new products to the US marketplace, from IND submissions to NDA / ANDA filings
- Helping US and EU companies to introduce products to China

OUR LOCATIONS



API SYNTHESIS AND RESEARCH CHEMISTRY

- **GMP Synthesis of Small Molecules**
- **Reference Standard Synthesis**
- **Metabolite ID and Synthesis**
- **Impurity Identification and Purification Projects**
- **Process Development & Optimization**
- **Sourcing & Scale-up to Commercial**



GMP CONTRACT MANUFACTURING - CLINICAL TRIAL MATERIALS

- **Oral Solid Dosage Forms**
 - Neat API fill in Capsules & Vials: >5 mg using automated dosing system
 - Immediate and controlled release: tablets and capsules
 - Tablet-in-Tablet
 - Liquid-filled Capsules
- **Sterile Dosage Forms**
 - Aseptically-filled vials using disposable mixing and filling technology
 - Nasal, Injectables, and Ophthalmic Solutions
- **Topical Dosage Forms**
 - Gels and Ointments
- **API's via chemical synthesis**
 - Quantos – Neat API fill & liquid compounding

Pre-formulation Characterization and Screening

- **Physicochemical Evaluations**
 - pH/temperature Degradation Rate Profiles
 - pKa determinations
 - pH/Solubility Profiles
- **Excipient Compatibility Studies**

- **Immediate and Controlled Release Development Expertise**
 - Oral Solid Dosage Forms
 - Sterile – Parenteral, Lyophilized, & Ophthalmic Forms
 - Creams, Ointments and Gels
 - Nasal Sprays (including characterization – droplet size, geometry)
 - High Potency Suites

GMP Analytical Services

- **> 200 Method Development/Validation since 2008**
 - Assay / Cleaning Methods
 - Impurities
 - Content Uniformity
 - Dissolution
 - Misc (Enzymatic Methods, AA, Wet Chemistry)
- **Impurity Identification and Characterization**
 - 10-12 ID projects (LC/MS and NMR)/yr
 - Use various concentration techniques such as SPE, liquid/liquid extractions/precipitations and fraction collection

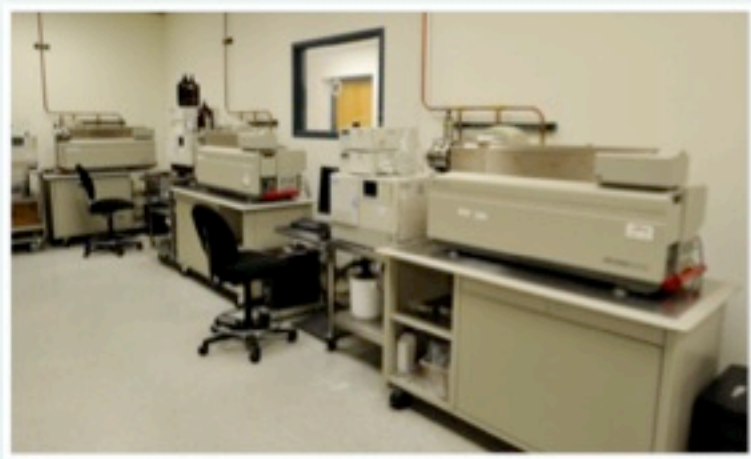
BIOANALYTICAL SERVICES

One of the largest laboratories in the East Coast, USA and China

- 26 LC/MS/MS Bioanalytical systems linked to Watson LIMS system
- Industry-leading staff with 18 Ph.D.'s (6 posters presented ASMS 2010)

In 2010

- Over 90,000 Samples Analyzed (GLP/Regulated)
- Over 80 Methods Developed (GLP/non-GLP in 2010)
- 80% Repeat Customers

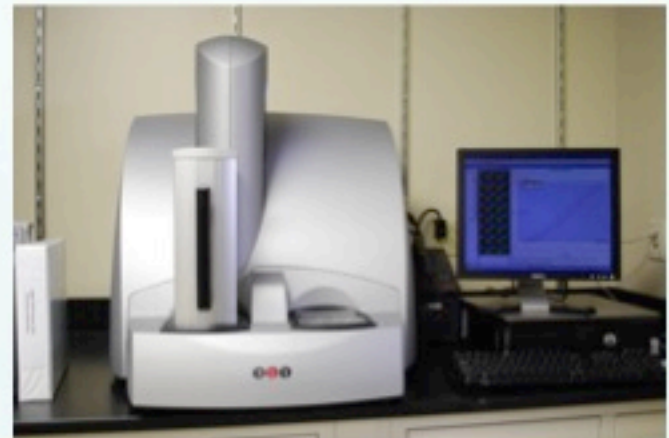


Method Development/Validation and Sample Analysis in Compliance with FDA and GLP Guidance.

- Track record of developing and validating difficult, high sensitive methods CC/MS/MS methods
- Development of stabilizing procedures for analyte with stability issues for sample collection
- Fast turnaround for preclinical and clinical sample analysis for TK, PK and BE studies
- Biomarker and immunogenicity method development/validations, PK, TK, PD sample analysis
- Integrated Services Between our Phase I Clinic and Bioanalytical labs

BIOLOGY SERVICES _ Large Molecules

- **GLP Labs**
- **Assay Development / Transfer / Validation**
- **Clinical / Pre-clinical Sample Testing**
- **Variety of Assay platforms**
- **Automation**
- **Statistician on Staff**
- **ADA – Anti Drug Antibody Assays (Immunogenicity)**
- **pK/tK – Pharmacokinetics Assays**
- **NAB – Neutralizing Antibody Assays**
- **Cell Based Assays**
- **Biomarker Assays**



DMPK SERVICES

IN VITRO STUDIES

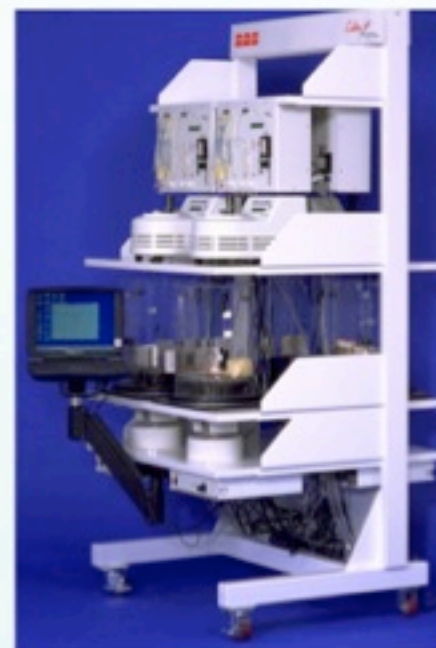
- **Metabolic Stability, Protein Binding, MDCK, CYP inhibition etc**

IN VIVO STUDIES (RATS AND MICE) – *FAST PK*

- **In-life + Bioanalytical Support + PK Report Using WinNonLin) with a Turnaround time of 5 days after receipt of compound.**

MASS BALANCE STUDIES

- **(C14 and tritium)**

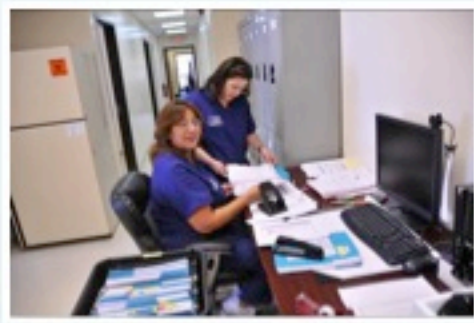


Overview

- 15 years of operational experience
- Dedicated 72-bed Research Facility in Hackensack, NJ
- Dedicated 120 bed in-hospital unit located in Zhengzhou, China
- Full-time Principle Investigator with Emergency Medicine background
- BLS and ACLS trained staff
- Close proximity to major medical center

Types of studies

- First in Human
Single & multiple ascending dose
- Absolute and Relative BA, fed /fasted BE, food effect, PK/PD studies
- Drug / drug interaction (DDI) and drug / alcohol interaction studies
- Thorough QT (TQT) and other cardiovascular evaluations (Holter Gateway, etc)



- Study Protocol Design
- Project Management
- Clinical Data Management (Oracle Clinical)
- Biostatistical & Pharmacokinetic Analysis
- SAS Programming
- Medical Writing
- Regulatory submissions
 - Clinical Study Reports
 - PK Summaries
 - IND, IDE, NDA (505b1 and b2), PMA, ANDA



KEY ADVANTAGES

PRIORITY & FLEXIBILITY

Our size allows us to treat each project with priority and troubleshoot quickly



FULL INTEGRATION

Allow for streamlined processes reducing time and operational risk

EXPERIENCED LEADERSHIP

Each Project Manager has a more than 15 years experience



FAST RESPONSIVENESS

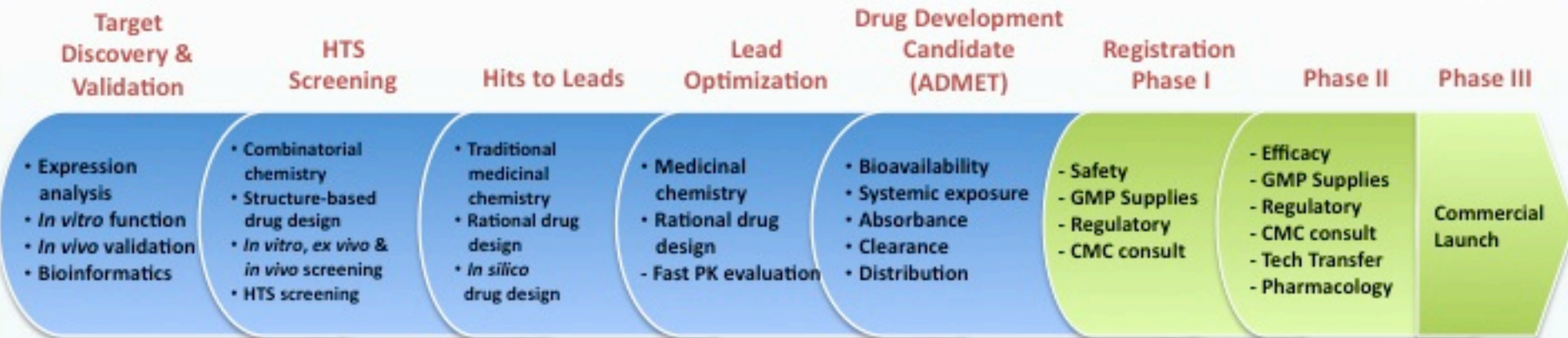
Communication is regularly coordinated between each team



STRATEGIC LOCATIONS

Close proximity contributes to ease of oversight and monitoring

FULLY INTEGRATED GLOBAL CRO



EARLY PHASE & BEYOND

Accomplish more with one service supplier

- API Synthesis
- Preclinical / DMPK Services
- Dosage Form Development
- GMP Manufacturing
- Clinical Study Execution via 72-bed CRU
- Bioanalysis & Biomarker / Immunology
- Regulatory filing, GMP Consulting and Support



Thank you!