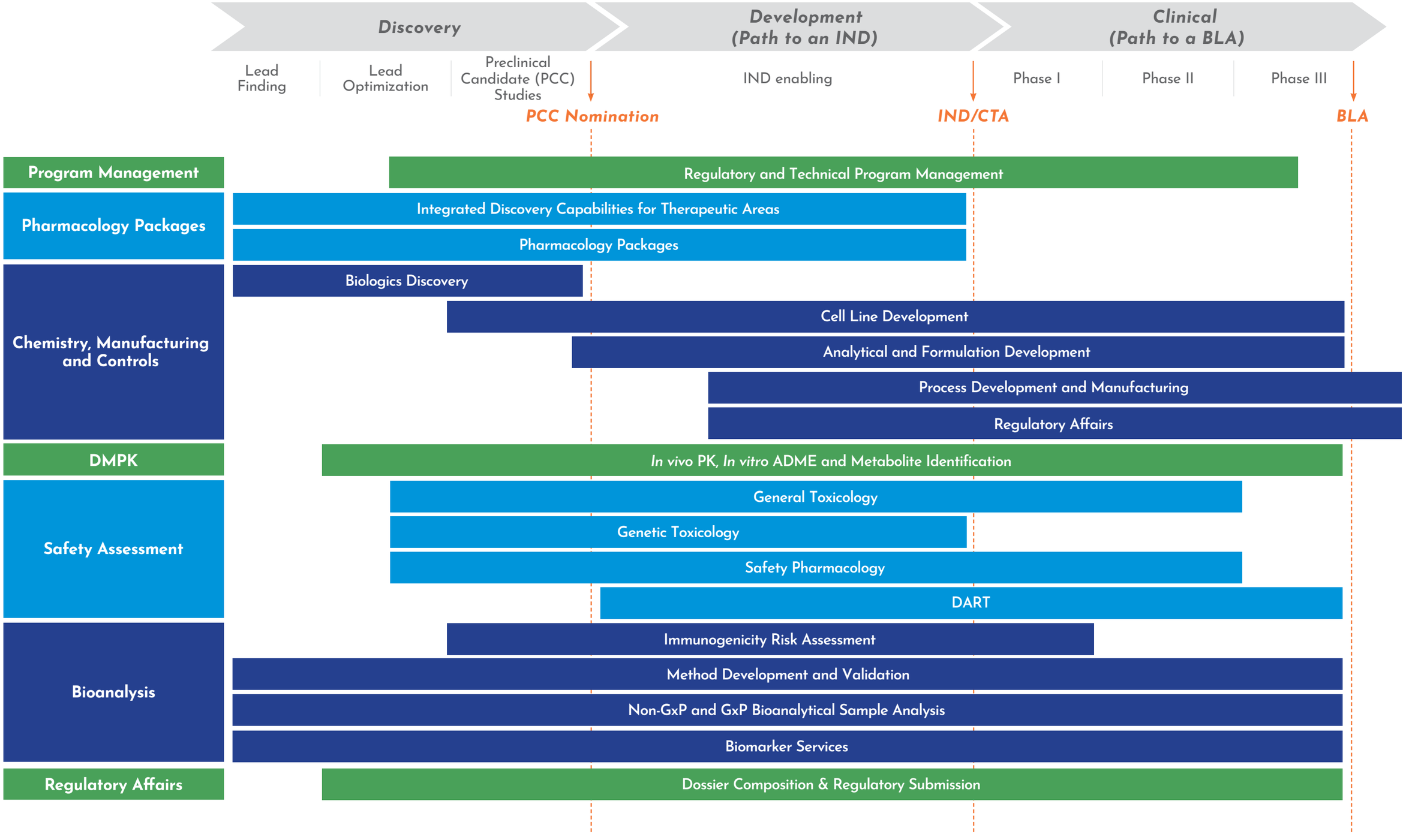
WuXi AppTec's Integrated Drug Development Services

Large Molecule Development

WuXi AppTec

Drug Development Process



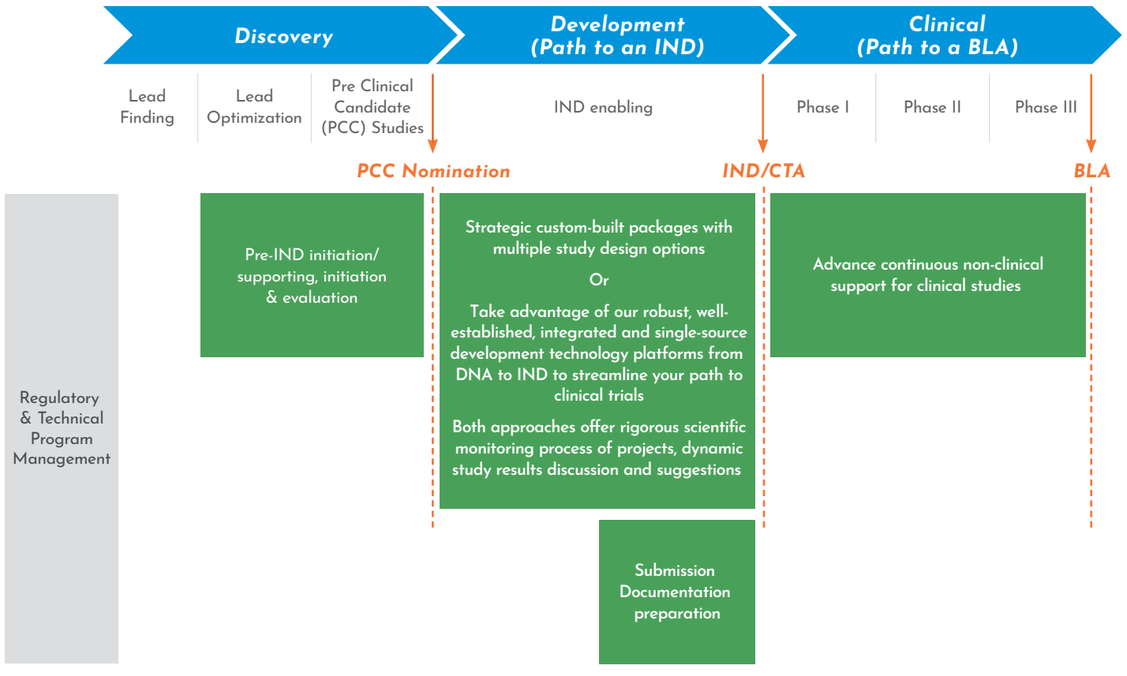
Program Management

WuXi AppTec's program management (PM) team provides support for IND program design, study execution to dossier preparation and submission. The PM team provides information and consultation during the initial project discussion with our Business Development team.

Accelerated Timeline	Dual Filing	Truly Integrated Platform	Flexible Collaboration	High Quality
to expedite your molecule to IND	in U.S. and China to increase asset value	consolidating everything done within one organization	ranging from a la carte to IND package	experienced expertise and state-of-the-art facility to ensure standard with global regulatory compliance

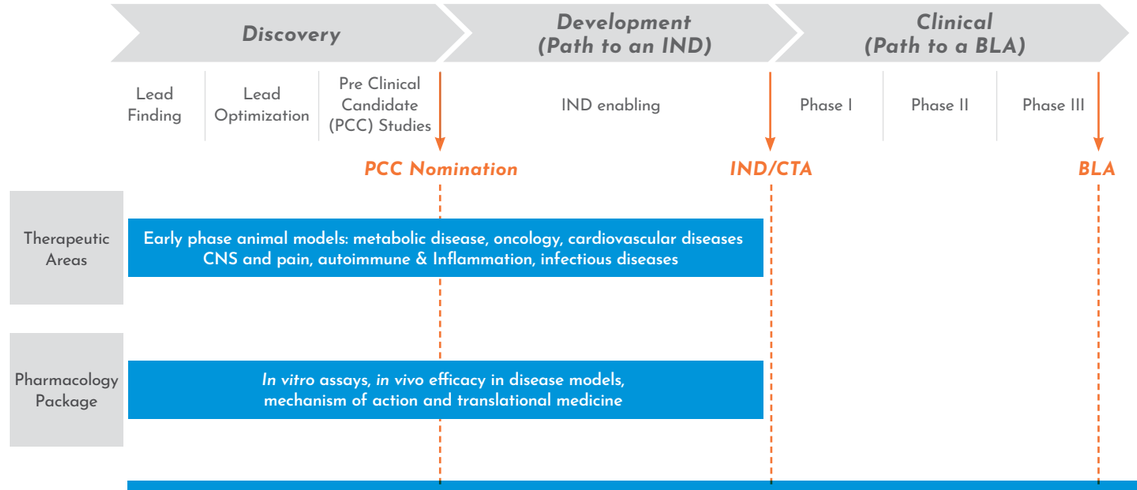
Cross Functional Program Management

Our PM team will help you design programs based on global submission requirements. They establish project timelines for initiation and completion of required studies and help track the progress of your ongoing activities. They coordinate with technical groups and scientific experts to help resolve any issues that may occur during ongoing studies. Along with the regulatory affairs group, the PMs will help you prepare the dossier and design your submission plan.



Pharmacology

WuXi AppTec's full-service pharmacology department provides validated discovery assays, including *in vitro* assays (HTS, SAR screening support, compound selectivity and early safety profiling, and cancer cell panel profiling) and *in vivo* disease models in cardiovascular, CNS, respiratory, and metabolic and infectious diseases. Founded in 2008, we have multiple function teams of ~400 scientist, including 11% PhD, 55% MSc, and we are led by 10 seasoned scientific leaders with an average of 15 years of R&D experience in the US, Canada, and the UK.



Capabilities at a Glance:

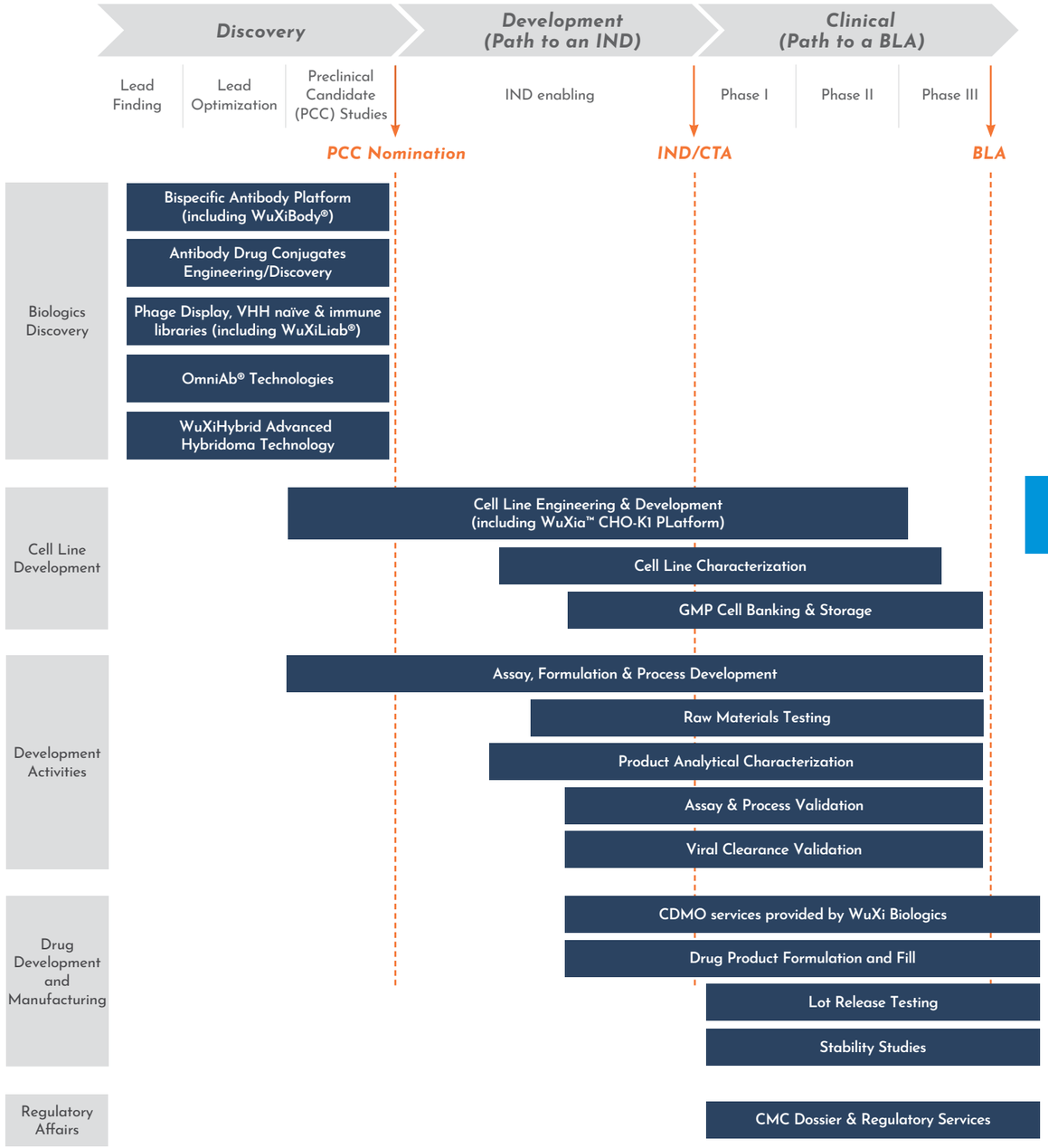
- More than **340 global collaborators** including 14 partners from the top 20 pharmaceutical companies
- **4 locations**, including **360 scientists** working on *in vitro* and *in vivo* biology in Shanghai, **9 scientists** on assay development/transfer, SAR screening support and HTS in Plainsboro, New Jersey, **19 scientists** in our pharmacology team in Suzhou, and 40 scientists in Qidong.
- **CAP-certified FACS**, as well as pathology services and a molecular testing laboratory for clinical virology
- A total of **~400 biologists**, offering plate-based screening, and pharmacology services under FTE or FFS models
- **More than 30 PhD.**, trained in US & Canada, 10 with >15 years R&D experience
- **43,000 ft²** of Biology labs and AAALAC-accredited animal facility
- **50,000+ ft²** of new small animal facility is under construction at Qidong, Jiangsu

Chemistry, Manufacturing, and Controls (CMC)

WuXi Biologics provides end-to-end solutions to healthcare organizations seeking to discover, develop and manufacture biopharmaceuticals and vaccines. Our full spectrum of discovery services for the generation, characterization and selection of high-potency novel antibody therapeutics seamlessly integrates with our single-source development technology platforms to help take your product for discovery to IND. With world-class quality systems and state-of-the-art facilities, WuXi Biologics offers non-GMP/GMP pilot, clinical and commercial drug substance and drug product manufacturing for biologics produced from mammalian cell culture and microbial fermentation.

Capabilities at a Glance:

- Project Management
- Six Antibody Discovery Technology Platforms
- R&D-Grade Protein Generation and Research Materials Generation
- Lead Drug Candidate Developability Assessment
- Cell Line Engineering/Development
- GMP Cell Banking and Characterization/ Testing
- Assay Transfer or Development and Qualification/Validation
- Drug Substance Manufacturing Process Development (Upstream and Downstream)
- Non-GMP/Pilot Manufacturing up to 500 L Scale
- cGMP Manufacturing at 500, 1,000, 2,000 or 4,000 L Scale (currently over 60,000 L capacity steadily increasing to over 300,000 L in 2023)
- Drug Substance QC Release and Stability Studies
- Drug Product (DP) Formulation and Manufacturing Process Development
- Viral Clearance Validation Studies
- cGMP DP Manufacturing
- Drug Product QC Release and Stability Studies



CDMO services provided by WuXi Biologics

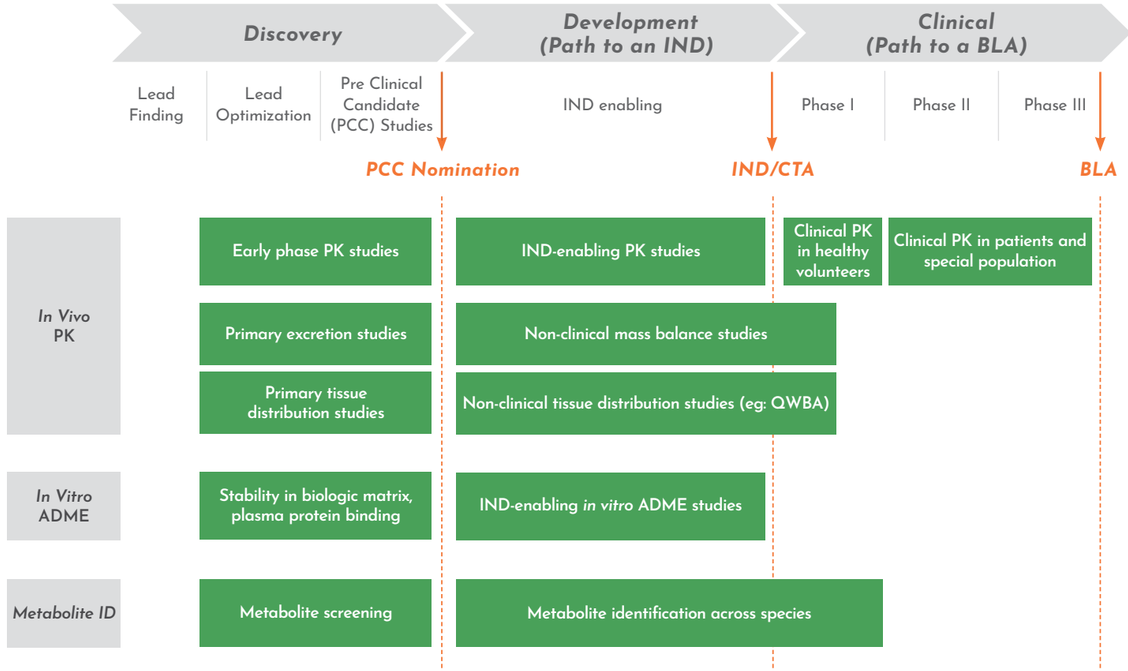
DMPK

WuXi AppTec offers a true end-to-end platform of discovery through clinical Drug Metabolism and Pharmacokinetic (DMPK) services that provide comprehensive *in vitro* and *in vivo* Absorption, Distribution, Metabolism and Excretion (ADME) solutions that are needed during the drug development journey.

The DMPK team has secured a diverse client base comprising nearly all big pharma companies, and over 800 small to mid-sized biopharma, virtual pharma, nonprofit organizations and academic institutions around the world by producing industry-leading turnaround times and acceleration discovery and development efforts.

Capabilities at a Glance:

- *In Vivo* PK
- *In Vivo* Tissue Distribution
- *In Vivo* Mass Balance
- *In Vitro* ADME
- Metabolite Identification and Quantification



Safety Assessment

WuXi AppTec's full-service toxicology department adheres to the highest quality standards and will accelerate your program to the next level of development.

Our team of experts have performed more than 11,000 safety assessment studies and completed over 700 IND and NDA packages in our expanded facility of 1,000,000 ft^2 with 500+ animal rooms.

Capabilities at a Glance:

General Toxicity

- Acute toxicity study
- Repeat dose toxicity study at – 7-day, 14-day, 28-day, 13-week, 26-week, and 39-week
- Species: Mouse, rat, dog, monkey, rabbit,and mini-pig
- Administration route: oral, injection (iv, ip, sc), dermal, ocular, etc.

Developmental and Reproductive Toxicology (DART)

- Seg I fertility and early embryonic development to implantation (mouse and rat)
- Seg II embryo-fetal development (rat and rabbit)
- Seg III pre-and postnatal development (mouse and rat)
- Juvenile toxicity study (mouse and rat)

Special Toxicity

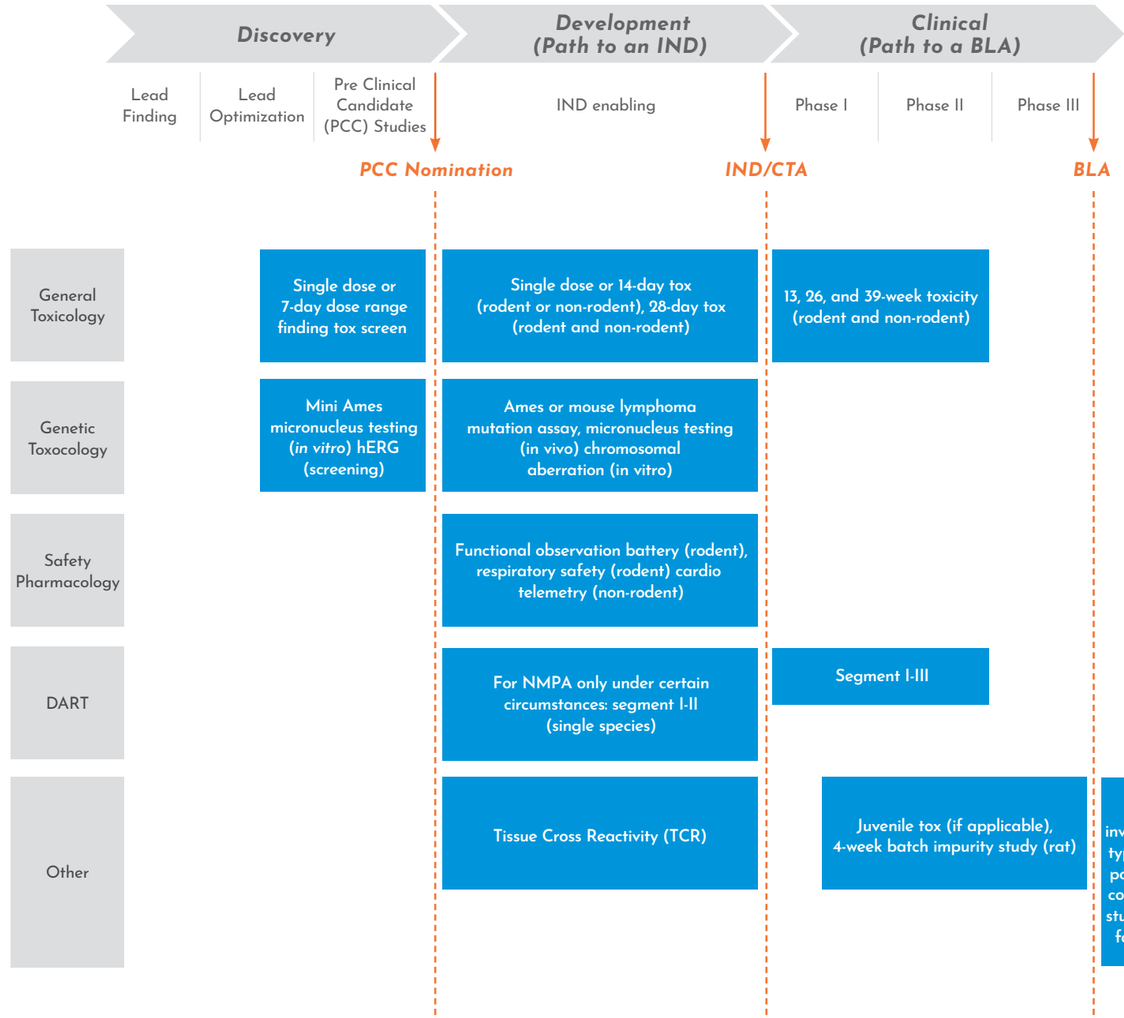
- Local irritation (skin, vessel, and eyes)
- Sensitization (ASA and PCA)
- Hemolysis (*in vitro*)
- *In vitro* phototoxicity study
- Ocular toxicity study
- Tissue Cross Reactivity (TCR)

Safety pharmacology

- Central nervous system (mouse and rat)
- Respiratory (mouse, rat, dog, and monkey)
- Cardiovascular (dog and monkey)
- hERG (*in vitro*)

Genetic Toxicity

- Ames (*in vitro*)
- Micronucleus (*in vitro* or *in vivo*)
- Chromosome abbreviation (*in vitro*)
- Mouse lymphoma assay (*in vitro*)
- Comet assay (*in vitro*)



Bioanalysis

WuXi AppTec's bioanalytical team works closely with you to design a fit-for-purpose solution to accelerate your program. Our diverse range of bioanalytical services support discovery, preclinical and clinical phases of development. The bioanalytical strategies are designed to establish and execute the right assays for successful regulatory submission - Investigational New Drug (IND), New Drug Application (NDA) or Abbreviated New Drug Application (ANDA)

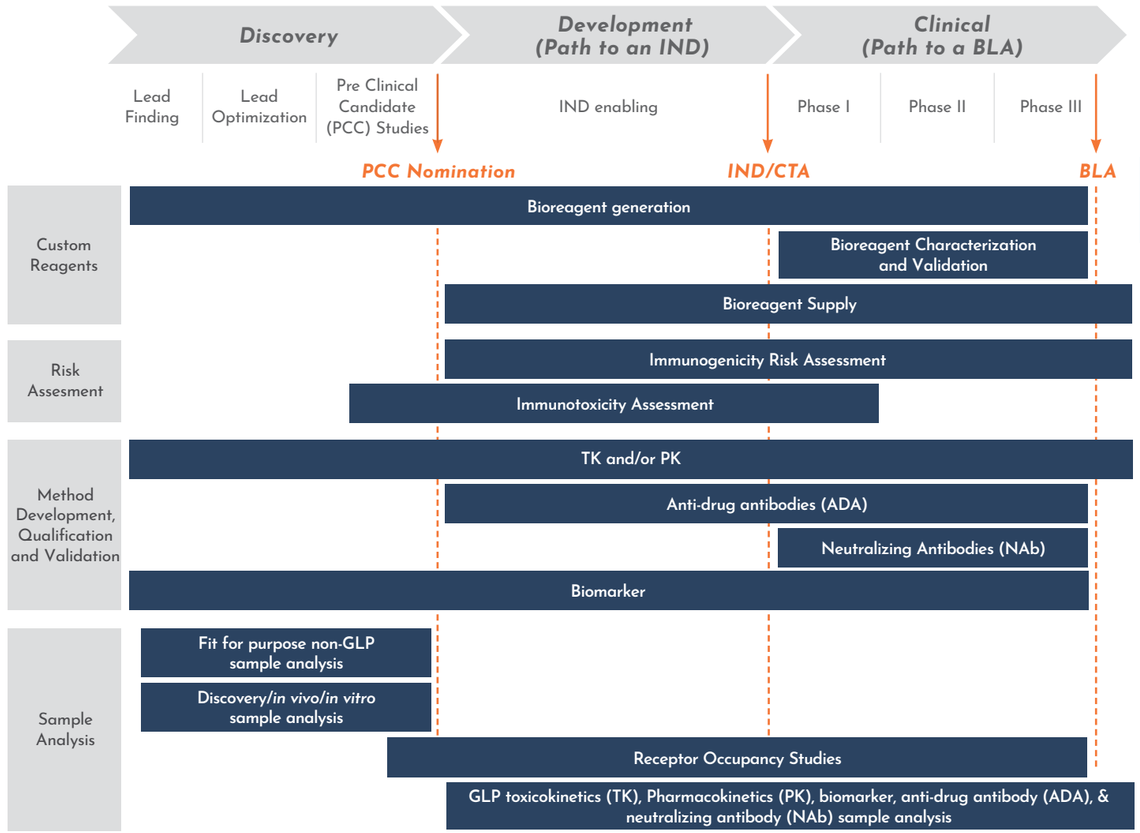
Capabilities at a Glance:

Key Highlights

- World-wide first-in-class drugs clinical program experience
- 15+ years GCLP bioanalytical experience
- 60,000+ sample analysis/month
- One-stop service: From reagent customization to sample analysis
- 190+ analytical team members

State-of-the-Art Instrumentation to Rapidly Deliver High-Quality Results

- 10+ ELISA Plate readers
- 7 MSD multiplex assay platform
- 5 Flow Cytometry units
- qPCR and Thermocyclers
- Advanced automation systems
  - 3 Tecan workstations
  - 2 Hamilton Liquid Handling
  - 9 Cybi-Selma semi-automation platforms

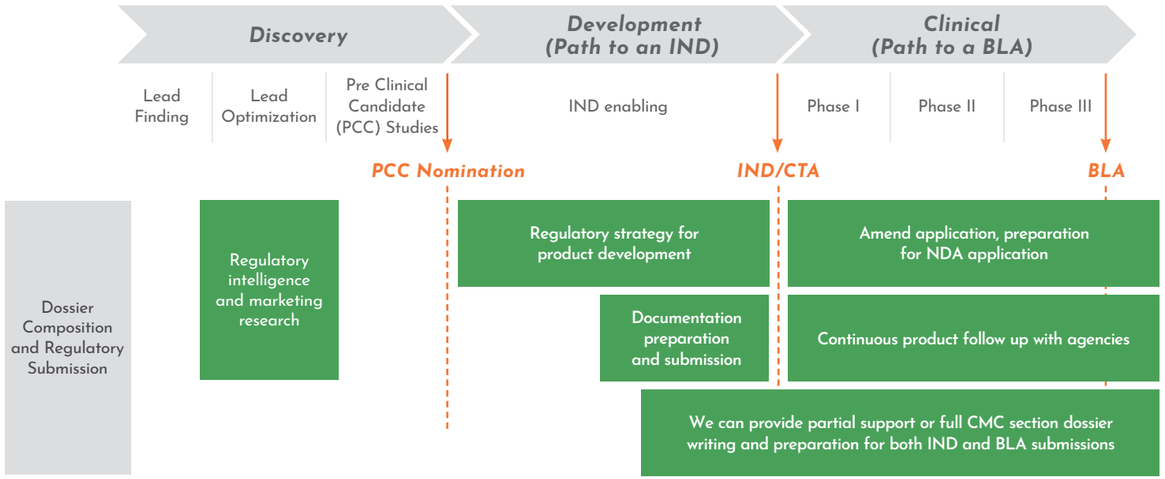


Regulatory Affairs

WuXi AppTec's regulatory affairs team provides you a complete package of services to support global regulatory submission by incorporating internal expertise and partnering with external consultation networks. Our one-stop service can make your global filling convenient, efficient and cost-effective across U.S. Food and Drug Administration (FDA), National Medical Products Administration (NMPA) and European Medicines Agency (EMA). The global quality systems and facilities have been audited and approved by regulatory agencies worldwide.

Capabilities at a Glance:

- Regulatory consultation, project feasibility assessment, product registration strategy, and planning
- Gap analysis based on available dossier information
- Dossier composition
- Communication meetings with different regulatory agencies
- Electronic Common Technical Document (eCTD) submission
- Coordination of on-site inspection
- National Institute for Food and Drug Control (NIFDC) testing progress follow-ups in China
- Annual reports and subsequent supplement submissions
- Other assistance in product registration



Contact Us to Learn More

labtesting.wuxiapptec.com