

PHARMADIRECTIONS

Structured for Science. Built for Speed.



PharmaDirections is a unique best-of-breed solution whose scientific caliber and track record are unequaled in traditional outsourcing organizations.



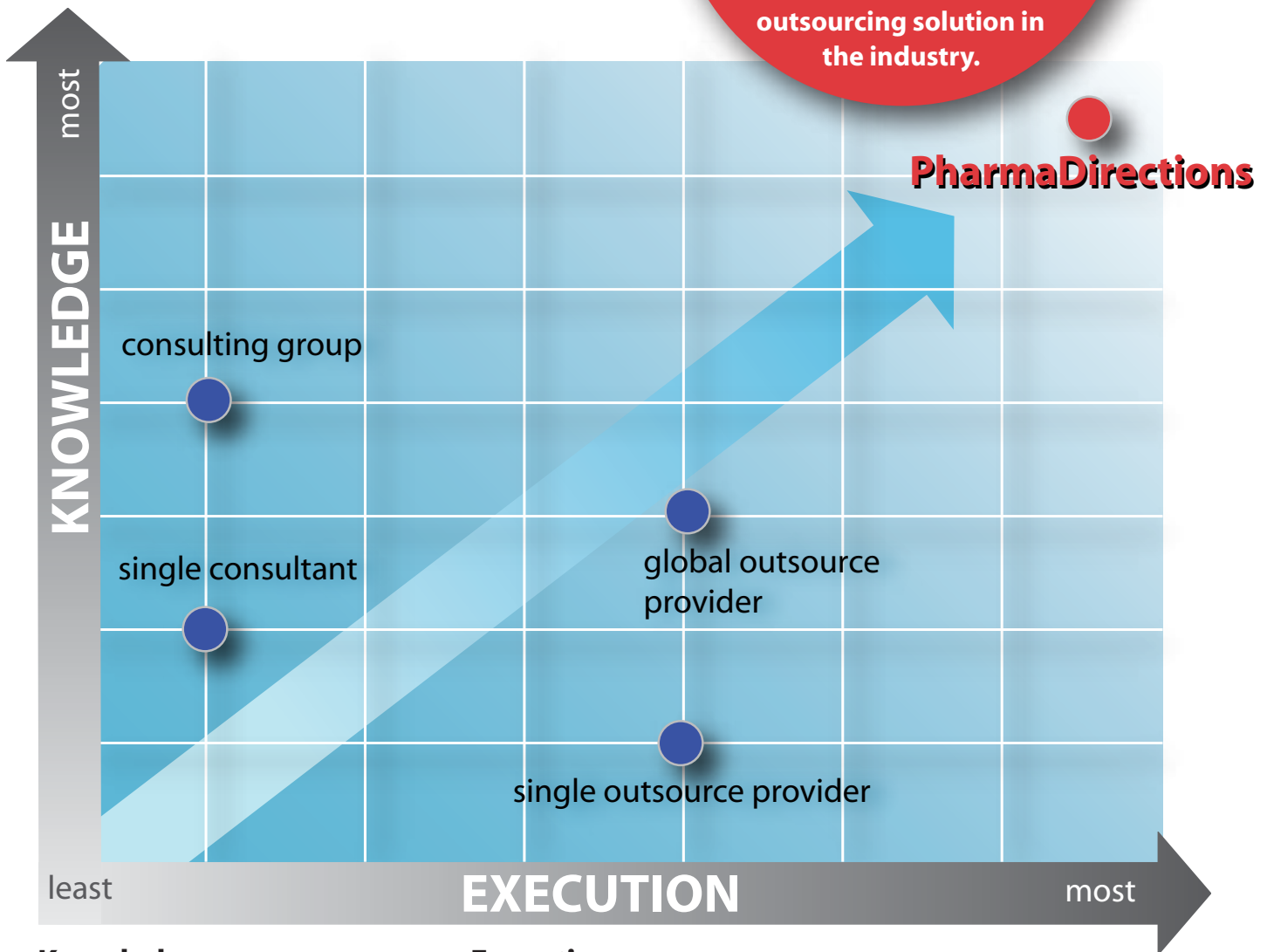
We are a drug development management company organized specifically for the complex and competitive demands in the current pharmaceutical environment. We are different

from the traditional outsourcing options to which everyone is accustomed. Like anything new, this paradigm requires some explanation. Please let us answer your questions:

Discover a new paradigm in drug development management.

► How is PharmaDirections different from traditional solutions?

From Preclinical Pharmacology to the IND and the Chemistry, Manufacturing and Controls (CMC) critical path, PharmaDirections offers the deepest assembly of proven scientific knowledge and the broadest, most flexible outsourcing solution in the industry.



Knowledge

The level of technical expertise and understanding in scientific and regulatory aspects of drug development.

Execution

Meeting milestones with time, cost and quality under control

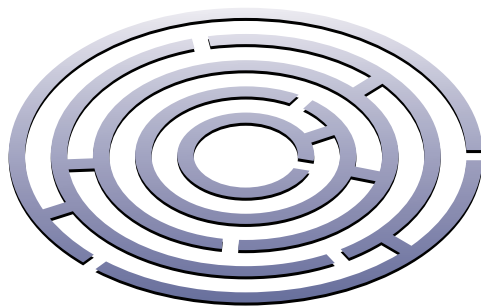


► Why do we need a new paradigm?



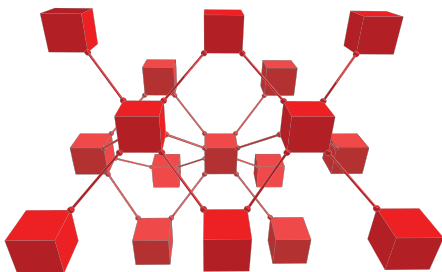
► Acquiring Access to Serious Science

Pharmaceutical development is complex, requiring multidisciplinary resources that can be quickly accessed when needed. Current outsourcing options often fail to provide experienced science when it is needed, especially when unanticipated product development challenges arise.



► Navigating the Complex World of Contract Outsourcing

Finding, contracting and integrating flexible project management, quality management, regulatory compliance oversight, communication of critical data and coordinating resolutions to unanticipated challenges remains a major hurdle to any company attempting to manage outsourced execution.



► Getting Just What You Need When You Need It

Fierce pressure to maximize investment in your development critical path forces the need for access to broad multidisciplinary expertise and resources while stretching funds to your next valuation point. On the one hand, building and controlling in-house scientific and technical resources contributes to excess cost. On the other hand, an underdeveloped infrastructure leaves you without the resources and capacity that you can confidently access to mitigate your critical path risk.



Traditional Consultant

PharmaDirections

▶ **Do you need access to science?**



Deep in one area of expertise



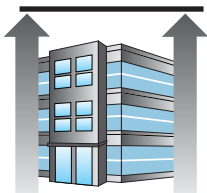
Broad and deep in all drug development areas

We have structured our company around the critical scientific and technical expertise required to plan and execute your product development program. We are staffed with Practice Heads and technical experts to lead your projects, who are augmented with a vast assembly of deeply experienced scientists, regulatory experts and project managers in our associate network, PharmaDirectNet™. We have the industry's leading cadre of industry proven, experienced development experts available to support you by the hour, day, week or for the full duration of your program.

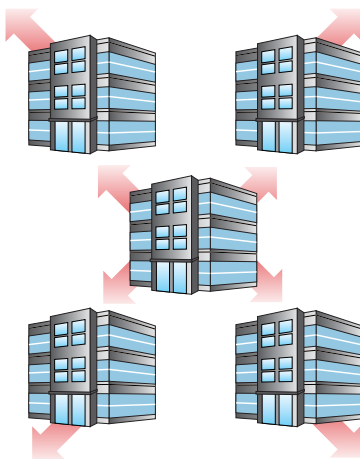
Traditional Outsourcing

PharmaDirections

▶ **Do you need outsourced resources?**



Limited by their resources



Expandable resources

We have an extensive alliance network of pre-qualified, audited and contracted resources that is not limited by one set of bricks and mortar facilities. With PharmaDirectNet™ we can rapidly execute your product development program using our flexible, extendible and proven resource infrastructure. With the confidence that resources in PharmaDirectNet™ represent the best quality, experience, and assured regulatory compliance, we reduce project execution risk for our customers.



Flexible resources allocated appropriately over project timeline

▶ **What is PharmaDirections new paradigm?**

PharmaDirections offers the right resources at the right time with the capability to meet your program's precise scientific requirements and with the flexibility to deploy the essential resources only when they are needed. We carefully match the expertise within our network to the particular needs, tasks and timelines for each individual project. The results are custom fit resources with unprecedented scientific oversight that leads you in the right direction faster, while conserving capital and increasing assurance that your critical path will not be at risk.



▶ What are PharmaDirections' services?



Expert Consulting

PharmaDirections provides scientific, regulatory and project management expertise on an as-needed basis. With access to our multidisciplinary pool of experts, you are sure to acquire the right resource at the right time.

- Preclinical Pharmacology
- Toxicology
- Synthesis Chemistry
- Pharmacokinetics
- Drug Product Formulation
- Analytical Chemistry
- Clinical Trial Material Manufacturing
- Global Regulatory Support
- cGMP, cGLP, Quality Management
- Supply Chain Expertise
- Strategic Development Planning
- Scientific Due Diligence
- Intellectual Property Assessment

Project Management and Execution of Your Development Plan

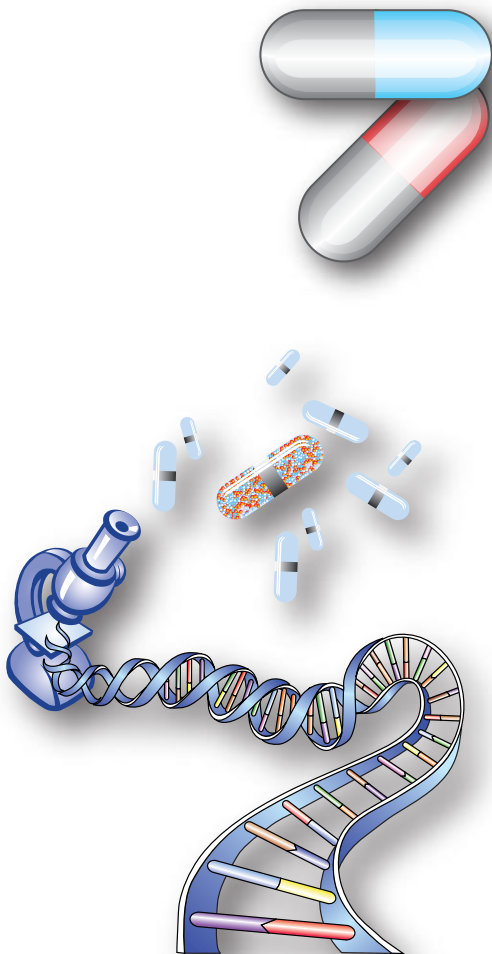
PharmaDirections manages full execution or assigned program sections, filling gaps with people and resources specifically matched to your program needs. Hands-on project teams are appointed to develop scientific strategies, create schedules that meet milestones, engage and manage service providers, resolve IP issues, keep budget within constraints and ultimately execute the project deliverables to a standard beyond what can be reached with traditional outsourcing options.

- Preclinical Pharmacology
- IND Filing and Regulatory Support
- Critical Path to IND
- Formulation of Drug Product for CTM
- Vendor Contracting and Oversight
- Project Scheduling and Management

Complete Turn-Key Outsourcing

PharmaDirections can provide all of the requirements to take you from preclinical pharmacology to an IND and the Chemistry, Manufacture and Controls (CMC) critical path of your clinical development program. We will coordinate the planning, staffing, and outsourcing, then execute with sharp scientific oversight to drive to your success.

- Preclinical Pharmacology to IND
- CMC critical path to the NDA and launch



► What drug development services does PharmaDirections offer?

Strategic Planning

- Pre-IND Pharmacology to IND to CMC critical path
- Preclinical program design
- CMC program design
- Vendor Selection

IND Candidate Selection

- Pivotal animal studies
- Receptor binding
- In vitro* ADME
- High dose pharmacology (safety pharmacology)

Preclinical Development

- Safety pharmacology
- Toxicology
- Genetic Toxicology
- Reproductive Toxicology
- Drug/drug interaction studies
- ADME
- Pharmacokinetics
- Tissue Distribution
- Bioanalytical method development and testing

Clinical Pharmacology and Pharmacokinetics

- In Silico* Formulation Development and Optimization
- Clinical Study Design
- Pharmacokinetic Modeling and Data Analysis
- Clinical Pharmacology Study Management

IND Enabling CMC

- API Development and Pre-clinical batches
- Investigation of synthetic routes
- Drug substance for Preclinical, tox, and pharmaceutical studies
- Preparation and Characterization of Analytical reference standards
- Analytical Method development for Drug Substance

Formulation development (dosage form)

- Route of administration and dosage form selection
- Excipient compatibility
- Preformulation and characterization
- Prototype formulations and selection
- Final formulation development for Phase 1, 2 or 3 studies
- Packaging and Labeling Selection
- Identification of stability indicating analytical methods
- Development and validation of analytical methods – suitable for clinical stage
- Stability program design

Drug Substance (API) Manufacturing

- Vendor selection & qualification
- Project management
- Process design and equipment selection
- Source intermediates and starting materials
- Quality oversight and document review
- Specification development
- Method development and validation
- Process scale-up & manufacturing
- Process validation and stability
- Oversight of amendments to Drug Master File

Drug Product Manufacturing

- Development of commercialization strategy
- Project management
- CMO selection and qualification
- API and Excipient sourcing and qualification
- API method transfer/development and validation
- Specification generation
- Design, selection and qualification of primary packaging components
- Process Design
- Experimental/Lab batch design and oversight
- Preliminary stability data review
- Process/Product optimization
- cGMPPHase I & II CTM manufacturing
- Post clinical FDA meeting guidance
- cGMP Phase III CTM/Registration batch manufacturing
- FDA Submission document generation
- Full scale process validation
- PAI preparation

Regulatory / Quality Assurance

- IND Regulatory Support
- NDA Regulatory Support
- Coordination with Federal Agencies
- Vendor Qualification
- Quality Agreement
- GMP Documentation Management

Project Management

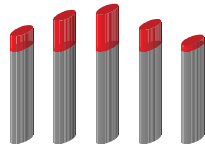
- Project planning and Gantt charts
- Resource allocation
- Budget management
- Vendor coordination
- Contracts and quotes
- Document control



▶ How can we work together?

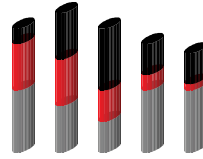
Customer Relationship Options

- PharmaDirectNet Vendors
- PharmaDirectNet Experts
- Client Resources



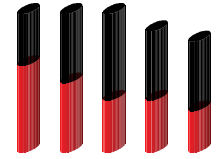
I. Ad Hoc Consulting

PharmaDirections provides scientific, regulatory and project management expertise on an as-needed basis



II. Resource Supplement

PharmaDirections manages assigned program sections with time and cost estimates using PharmaDirectNet resources



III. Full Program Management

PharmaDirections manages full planning and execution with fees based on milestones and success factors

Benefits

- Maximum flexibility
- Access to multidisciplinary pool of experts
- Insert the right resources at the right time

- Fill program gaps with people and resources that specifically match program needs
- Higher level of integrated resources and expertise mitigates risk
- Project complexity, scope, timelines and associative costs are well-defined for better planning and control
- Insert the right resources at the right time, including open and redundant vendor capacity

- Lowest risk to execution due to centralized management and supply chain control
- Limited Client management oversight necessary
- Fee structure based on predetermined milestones
- Insert the right resources at the right time, including open and redundant vendor capacity

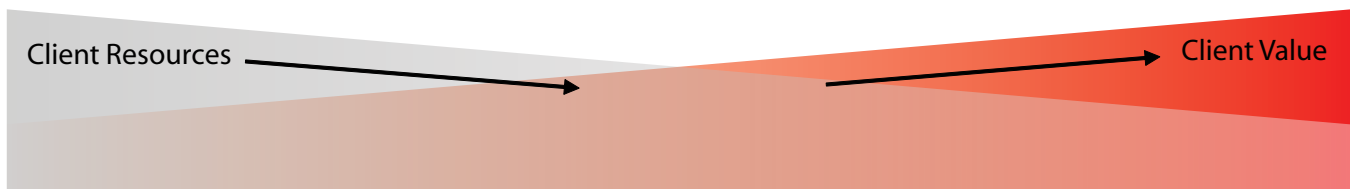
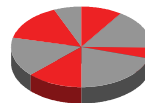
Needs Met

- Client's staff augmented with specialized expertise
- Flexibility to manage scope that is uncertain or uncommitted
- Adaptable solution when not ready for longer-term commitment or investment

- Scientific and project management oversight for specified sections of the program
- Flexibility to manage scope that is partially defined but still dependent on external factors
- Ability to retain current staff and vendor relationships

- Maximum scientific, timeline and budget confidence with PharmaDirections' strategy and planning phase
- Tight project control through to completion
- Turn-key solution

- PharmaDirections Management
- Client Management



▶ What can PharmaDirections do for you?

Experience the power of PharmaDirections in your program:
 A case study of our contributions and benefits for one client.

Before PharmaDirections:

- 3 Staff
 - \$30M raised
 - 2 Phase II products
- Issues:*
- No commercializable products
 - Dose limiting side effect profile
 - Open to generic scavenging

June 2006

After PharmaDirections:

- 25 Staff
- \$200M IPO and follow-on
- 2 Phase III and 2 Phase II products

Results:

- 2 commercial products
- Side effect profile significantly reduced
- New IP generated to prevent generic scavenging

June 2008

Contributions

- ✓ Provided a scalable team of scientists and project managers (up to 15 FTE)
 - **Provided ad hoc and full time access to 39 experts**
 - **Delayed need for internal build-out**
- ✓ Managed all CMC and clinical pharmacology activities
 - **Managed contract research at 27 different vendors**
 - **Minimized overhead until key milestones were reached**
- ✓ Contributed innovative ideas in formulations, pharmacokinetic profiles and manufacturing methods
 - **Inventors of 6 published and pending patents**

Benefits

- ✓ Program was aggressively driven to decision points
 - **CMC teams were scaled up to attack critical problems as they arose thus keeping program on schedule**
- ✓ Royalty free proprietary products were developed
 - **Provided opportunities for building company assets and protecting products from generic scavenging**

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