

# Targeted & Effective Product Development Support

Make Progress,  
Manage Infrastructure

# Pharmaceutical Advisors Support

## The Power of the Network

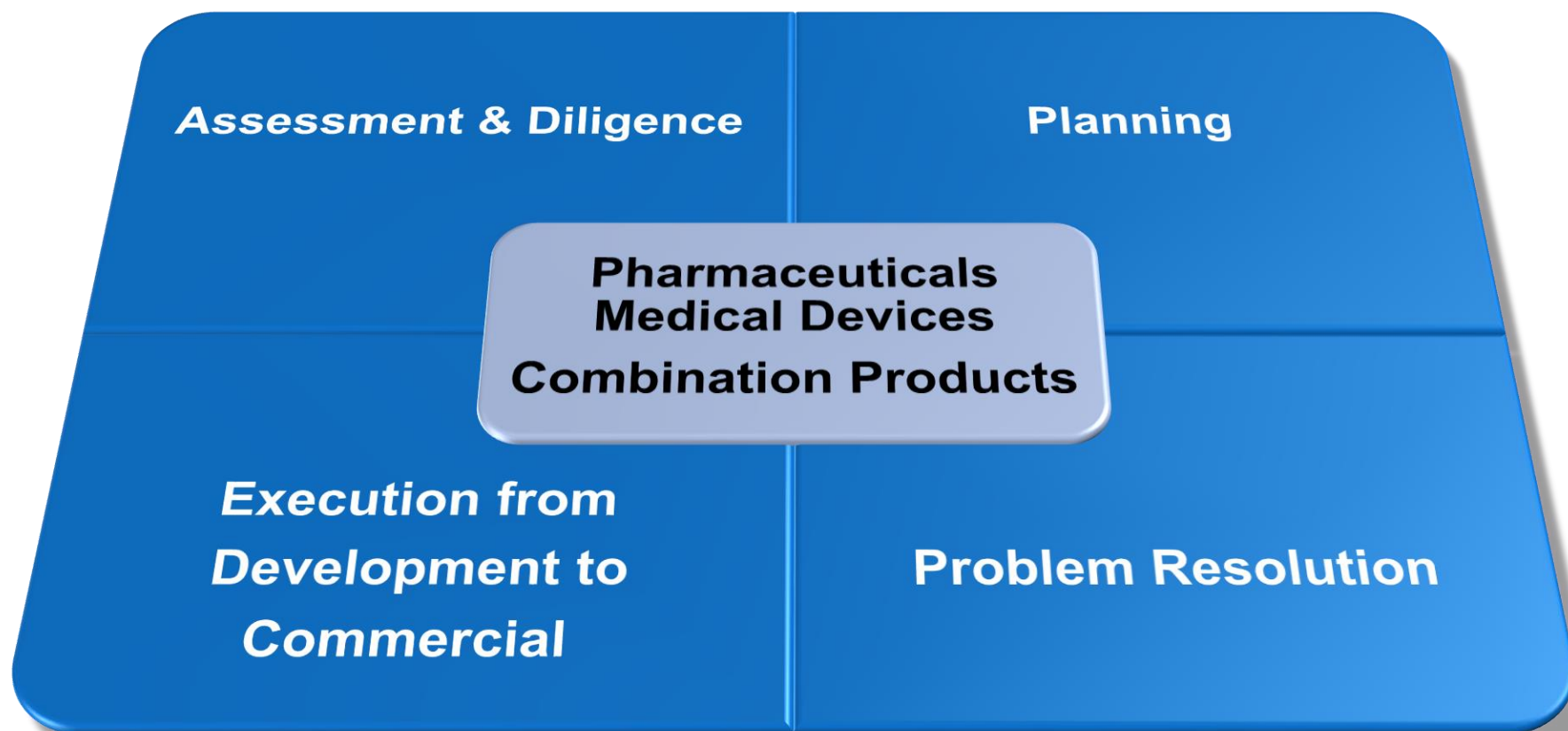
- Since 2001, focus on enabling outsourced development
- Small number of Partners
- Large network team of deep and broad Advisor expertise
- Flexible business model to complement client strengths
- Enable progress while minimizing infrastructure

## The Right Resources at The Right Time

- Your size, stage & business strategy
- TA & technology
- Advisor Experience
- Marketed & development
- Industry & ex-regulator
- Targeted technical and regulatory support of various issues and functions

# Powerful Business Model to Help You

- Flexible resource application to support for all phases product development



# Experience & Expertise to Help

- Our model helps ensure that you have and effectively integrate the right amount of the right resources, at the right time and in the right place
- Proven deep network enables support of tight timelines
- Proven broad network enables targeted experts and constructive business and technical solutions to complex / difficult issues
- Hands-on, or in the background; variable to you but engaged and committed
- Insight and actions based not just on experience, but on having been responsible for such operations and activities
- Provides sound basis for current and future decision making and execution

***Pharmaceutical Advisors Approach  
Helps Manage Risk, Cost and Time***

# Development Accelerator

- Key Acceleration opportunities where people seek our involvement
  - Pre-Candidate Nomination development readiness acceleration and risk reduction
  - IND enabling planning and execution with understanding of “now vs. deferred”
  - Informed and experienced CMO and CRO selection and contracting
  - Phase-appropriate and fit for purpose Quality systems
  - Submission writing and publishing
  - Progression to POC and later-stage trials with track record of FDA success
  - Approval and Launch readiness
  - Backfill / jump in where new functions / skills needed
  - Local in-country auditors to reduce costly travel expenses
  - Support of a bolus of effort or defined program / study
  - Acceleration while suitable hires can be made, help with planning of staffing
  - Help you work through the transitions:
    - Discovery to Development,
    - Early Development to Late Development,
    - Development to Commercial

# Our Rapid Development Approach

- Review status and update plans
  - Readiness gap analysis
    - Risks, strategies and decisions to update development plans and resource assumptions, plans for process and systems
  - Outsourcing strategy and plans to support
  - Hiring strategy, as appropriate
- Flexibility to tailor support to client situation
  - Enable
    - Plans, tools, templates, industry & vendor knowledge, decisions, change mgmt.
  - Do
    - Hands on or support in the background as needed
- Rapid Ramp-Up by experienced experts
  - Immediate involvement to maintain progress if needed
  - Rapid but expert planning for next stage of development to meet objective

# Network Model Enabled Planning

- Informed deep Due Diligence support to complement your team
- FTE requirements over time for one asset or multiple assets
- “Makability” of pipeline products or product enhancements
- Supply-chain risk and cost / time of adding back-up capacity
- Cost effective market research
  - KOL Interviews and analysis
  - Patient-based market models
  - Market-sizing of emergent / difficult to value technologies
- Market Supply / future capacity assessment for CMO / CRO services
- Benchmarking / best practices for organizational development / planning
- Facility requirements / Make vs. Buy
- Technical risk of competitive threat / ease of work-arounds
- Development landscape of potential competitors / sources

# Network Model Enabled Efficiency

- IND to Commercial readiness Gap assessment, planning & budgeting
- Development timeline-shortening strategies
- Planning and execution – in the background or hands-on
- Global vendor and partner selection and interaction
- Local in-market resources for vendor management
- Set up and or running of practical, phase-appropriate SOPs
- Rapid resolution of technical issues
- Virtual expert panels
- Technical assessment of IP
- CRO / CMO market “Weather Report” for specific requirements
- Assessment & planning for application of novel technologies
- Rapid ability to provide expert assessment



# Broad Capabilities on Recent Projects

## Products & Markets

- Broad Therapeutic Area experience
- All CDER Divisions
- Preclinical – Post Launch
- Small molecules
- Peptides & Proteins
- Vaccines, Cell & Gene Therapy, Bacteriophages
- Combination products

## Regulatory Scope

- From INDs to NDAs
- Global reach
- Orphan Indications
- Fast Track Designation
- 505 (b)(2)
- ANDAs & Biosimilars
- Animal Health
- Dietary Supplements

# Targeted and Effective Assessments

- Network model enables fast application of targeted expertise
- Coordination and triage of data rooms for efficient review and analysis
- Tools and expertise to turn technical insight into sound business decisions
- ID early kills or build constructive plans for an accurate NPV and success
- Recent projects include:
  - Late-stage and early stage assets
  - Developability gap analysis and execution plans and costs for mitigation and launch
  - Supply chain readiness to support forecast for a recently approved product
  - Technical and regulatory approval risk of a biosimilar product opportunity
  - Potential to expand claims in certain ex-US markets of a late-stage asset
  - FDA compliance risk for a multi-site manufacturing network
  - Readiness for diligence in advance of out licensing

# We Help You Plan and Execute

| Typical Planning Issues                     | Implications for Action   |
|---|---|
| Candidate Selection                         | <ul style="list-style-type: none"> <li>• Developability input to avoid surprises</li> </ul>   |
| Regulatory pathway and development strategy | <ul style="list-style-type: none"> <li>• ID Gaps in Current data dossiers</li> <li>• Fast / Efficient action plans</li> </ul>                             |
| Synthesis / CMC Strategy                    | <ul style="list-style-type: none"> <li>• Options, resource intensiveness &amp; timing</li> </ul>  |
| Formulation Approach                        | <ul style="list-style-type: none"> <li>• Timing of problem solving vs. PIB</li> </ul>   |
| Quality System and Quality Unit             | <ul style="list-style-type: none"> <li>• Phase-appropriate SOPs, Quality Agreements &amp; Audits</li> <li>• QA Resources for your team</li> </ul>         |
| Successful Vendor Contracting & Management  | <ul style="list-style-type: none"> <li>• Ensure right scope, fit, performance, cost and timing</li> <li>• Leverage CMO database, MSA templates</li> </ul> |
| Multiple Program Leverage                   | <ul style="list-style-type: none"> <li>• Support across programs where appropriate</li> <li>• Build strategic value and tactical efficiency</li> </ul>    |

# Development Plans and Support

**The only constant is change, only certainty is that things will go wrong**

- We provide critical anticipation of risk and options for continued progress
- Our detailed development Gantts and plans are actionable to the task-level
- We bring informed integration across functions to plans and execution
- Include anticipation of often underestimated effort and lead-times e.g. Vendor selection, analytical development, submission authoring
- Our key is early integration & focused application of the right expertise
  - Detailed and practical MS Project Gantts
  - Budget roll-ups and cash burn plans and tools
  - Experienced CMO / CRO and internal FTE estimates by function
  - Expertise to execute or help you to execute
  - Insight into timing of critical hires

# Supported Functions Include

| Function  | Considerations  |
|---|---|
| Chemical Development                                  | <ul style="list-style-type: none"> <li>• Problem solving, Planning &amp; Execution</li> </ul>   |
| Formulation Development                               | <ul style="list-style-type: none"> <li>• Problem solving, Planning &amp; Execution</li> </ul>   |
| Analytical Development                                | <ul style="list-style-type: none"> <li>• Problem solving, Planning &amp; Execution</li> </ul>   |
| Non-Clinical  | <ul style="list-style-type: none"> <li>• Typically tightly defined duration</li> <li>• Problem solving &amp; Planning to Execution</li> </ul>   |
| Quality   | <ul style="list-style-type: none"> <li>• Quality System Design, Audits &amp; Quality System</li> <li>• Local to auditors to cut travel to Europe, Asia</li> </ul>   |
| Regulatory Strategy and Execution                     | <ul style="list-style-type: none"> <li>• Specific regulatory strategy and ad hoc</li> <li>• Tactical execution of regulatory activities</li> <li>• IND, NDA, 505(b) (2), Orphan, Breakthrough,</li> </ul> |
| Senior Development Strategy, Integration & Leadership | <ul style="list-style-type: none"> <li>• Preclinical, CMC and Clinical strategy, execution and integration</li> <li>• Launch &amp; Commercial Planning &amp; Execution</li> </ul>                         |
| Supply Chain / Contracting / Integration              | <ul style="list-style-type: none"> <li>• Business, supply chain and support</li> </ul>  |
| Project & Program Management                          | <ul style="list-style-type: none"> <li>• Project Management, timelines, deliverables driving, tracking and reporting</li> </ul>   |
| Documents / Submissions                               | <ul style="list-style-type: none"> <li>• SME Writing</li> <li>• Report-level publishing and quality control</li> <li>• Submission-ready template packages</li> </ul>                                      |

# Late Development & Launch Support



# What Makes Us Different

- Business model
  - The right amount of the right expertise at the right time
- Business approach
  - Business decisions based on science and business considerations

# Thank You!

*We look forward to exploring how we might add value*

*...What's keeping you up at night?*