



Since 2001, we have offered an innovative approach to providing a broad and deep network of expertise to support clients' drug development, commercialization, and technology assessment.

We help clients make progress while managing the challenges of outsourcing to CMOs & CROs. Our clients are in development, moving from discovery to development or have commercial products but more projects than they can resource. We also help management and investors better understand risk, value and potential.

Our focus is on the critical non-clinical functions - Medchem, CMC, Pharm /Tox, Regulatory & Quality, Engineering, Marketing etc. We also support clinical development planning for a number of therapeutic areas. Our strength is in ensuring an integrated perspective for success.

We address technical issues, find and select vendors, provide customized Product Development, Commercialization & Launch Planning and Vendor Mgmt., as well as Implementation Support that ranges from expert support in the background to turn-key management of programs.

In addition to planning and operational support, our network approach enables rapid and informed, Technical, Operational and "Manufacturability" Due Diligence, Market Assessment, Valuation support for clients in various Life Sciences industries. Our approach to assembling expert teams also helps suppliers to the Life Sciences better understand their customers' needs and how to serve them.

Our team-members are not only experienced, but have been accountable for results in their areas of expertise. We work up-front to ensure that the right resources are applied to support your needs, that budgets are well considered and that technical issues are addressed within your business context. We bring together individuals or teams of experts – the right ones – to offer the integration of expertise needed to deliver business result in the midst of complex technical information. We can help you to succeed with perspective and resources to efficiently plan backward from you objectives and work forward from you current situation.

<p align="center">Markets / Customers Served</p> <ul style="list-style-type: none"> • Human & Animal Pharmaceuticals • Medical Devices • Combination Products • Diagnostics • Chemicals & Related Technologies • Animal Health & Food • Nutraceuticals • Consumer Health / OTC Products • Service Providers to the Life Sciences • Investors 	<p align="center">Expert Functions We Have Applied</p> <ul style="list-style-type: none"> • Analytical • Chemistry & Biologics Development • Cold Chain Management • Dosage form / formulation / pharmaceuticals • Finance • Launch Planning & Commercial planning • Manufacturing • Manufacturing cost accounting & modeling • Manufacturing cost optimization • Medical / Clinical Development • Medicinal Chemistry • Operational productivity improvement • Outsourcing & Vendor Management • Pharmacokinetics • Primary & secondary packaging • Process Development and Scale-Up • Quality Assurance & Quality Control • Regulatory Strategy & Operations • Supply chain / distribution • Technical Operations / Technical Support • Toxicology & Industrial Toxicology
<p align="center">Technologies Addressed</p> <ul style="list-style-type: none"> • Small molecule • Large molecule / biologics • Blood products • Devices • Diagnostics • Combination Products • Antibody Conjugates • Novel drug delivery technologies 	

More Information is Available at www.PharmAdvisors.com

Recent Project Examples Detail

I) Advice on Resolving or Planning Non-Clinical Technical Issues

We support clients in understanding and resolving a wide range of technical / business and regulatory issues to support their success. Issues recently addressed include:

- What "level of GMP" is needed for our current stage of development?
- Is this material usable?
- How / what should we set for product specifications
- Should we be worrying about this impurity now?
- Should we undertake a parallel path, given what the data is telling us?
- Should we move forward on making GMP material or should we wait for more data
- Which formulation should we use for first in man?
- Does this need to be validated now?
- Is this analytical package suitable and if not, what should we do to make it appropriate?

II) Technical Due Diligence and Risk Assessment

We have supported clients Due Diligence assessments with a unique and customized expert team approach that helps them to

- Better understand the true attractiveness of a technology / facility
- Understand the Developability / Manufacturability / Scalability of the technology
- Identify and quantify of risk factors such as facility risk for outsourced business models and technical / development hurdles
- Better estimate true cost and time of development & commercialization
- Develop realistic timelines / action plans to be used for both negotiation and for collaborative planning and execution with the target company
- Merge complex technical and business considerations to create actionable inputs to business cases and valuations
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III) CMC Specific Support

We support clients CMC / Analytical activities with team members who have specific technology and therapeutic area expertise. Recent support activities have included

- Sourcing, Vendor Identification, Selection, Auditing & Management
- Synthetic Route Identification and exploration of alternatives and registration strategy
- Expression system alternatives and registration strategy
- Dosage form problem solving, alternatives and strategies
- Management of formulation development and Clinical Trial Material manufacture at contract vendors
- Strategy and execution of plans to re-purpose existing compounds
- Integration of CMC plans with clinical, safety and commercial plans to overcome problems, accelerate timelines

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IV) Regulatory Support

We support clients with input to their Regulatory strategy from both the practical, operational perspective and agency perspective. Recent support includes:

- Advice on specific issues including
 - What level of GMP is needed for our current stage of development?
 - Is this material usable?
 - How / what should we set for product specifications
 - Should we be worrying about this impurity now?
 - Should we undertake a parallel path, given what the data is telling us?
 - Should we move forward on making GMP material or should we wait for more data?
 - Does this need to be validated now?
 - How will the FDA view this?
 - What should we ask the FDA?
- Preparation for FDA meetings and filings
- Support of FDA meetings
- Due diligence and risk assessment
- Management of submission process through outside vendors

V) Quality Support

We support client efforts to ensure they have appropriate and practical quality systems without the "overregulation" that can be common without the right operational expertise. Recent support includes:

- Advice, design and implementation of practical Quality Systems
- Vendor Audits
- Mock audits & GMP Readiness Gap Analysis and action plans
- Practical, customized cGMP Training & Implementation Support
- Appropriate Quality organization design and alignment with other functions
- Advice on specific Quality issues

VI) Design and Implementation of Critical Functions for Emerging Companies

We help clients balance the use of internal and external resources for optimal ROI by helping them to establish and run critical functions at the appropriate point. We also help coach and develop resources to take on additional / new functions and help clients identify the best positions to hire, given their strategy and resources. Recent projects include:

- Support of Specific Functions
 - Chemical Development
 - Pharmaceuticals, Formulation Development
 - Quality
 - Analytical
 - Toxicology
- Enabling a research stage company to establish forward looking and efficient development decision, planning and execution processes.

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VII) Capital Project Planning & Implementation

We have supported clients with a unique mix of engineering and operations expert team members to overcome typical challenges in design & build decisions, planning and execution. Recent projects include:

- Assembly of expert operational and engineering team members with experience designing and running many types of facilities to:
 - Formally capture key project parameters from a holistic perspective that all sides can understand and use
 - Critique and confirm the business case and help all parties to agree on scope of the project (Operational, Technical, Quality, and ESH) early enough to avoid scope changes later as the project progresses.
- Using Review output to create a User Design Brief that
 - Finalizes an outline of engineering concepts to enable engineers to efficiently apply their expertise (Design Concepts, specific technologies etc.)
 - Provides benchmarking of industry best practice for design and operation
 - Defines project timing boundaries
 - Outlines project cost estimates at a high but actionable level

VIII) Optimization of Service Business Models

Leverage experts who have experience on “both sides of the desk” and have been successful fixing and running contract service business in the life sciences

- Provide benchmarking data with respect to the relevant segments of the pharmaceutical contract manufacturing market (size of market, growth rate, pricing benchmarks, competitors)
- Analyze the position of the client with respect to the overall market and provide recommendations with respect to business strategy, business objectives, pricing, positioning and advertising
- Analyze the operations of the client and make recommendations with respect to policies, resources, business processes and organization structure to optimize the performance of the operation
- Support implementation of effective processes, systems and approaches to improve sustainable revenue & profit
- Leverage our information and data:
 - Contract manufacturers by market segment, with location, capacity and capabilities information
 - Pricing benchmarks (blinded with respect to company)
 - Facility and business operation model – to be customized to reflect client’s resources
 - Database of market data (from multiple sources) and “consensus view” of market size and growth rate not obtainable from market surveys
 - Boilerplate contract documents and Quality Agreements.
 - Database of available production technologies

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IX) Operational Improvement

We support clients with established functions to quickly make effective operational improvements to increase performance, respond to change in strategy or respond to external factors. Recent support includes:

- Assessment and optimization of key functions that can enable speed and efficiency
 - Practical Quality Systems
 - Practical Vendor management systems and approaches
 - Increased efficiency of analytical groups
- Productivity Improvement Gap Analysis
 - Use of expert team to help clients identify opportunities for productivity improvement
 - Help internal teams understand what's been accomplished elsewhere /identify and apply appropriate best practices

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