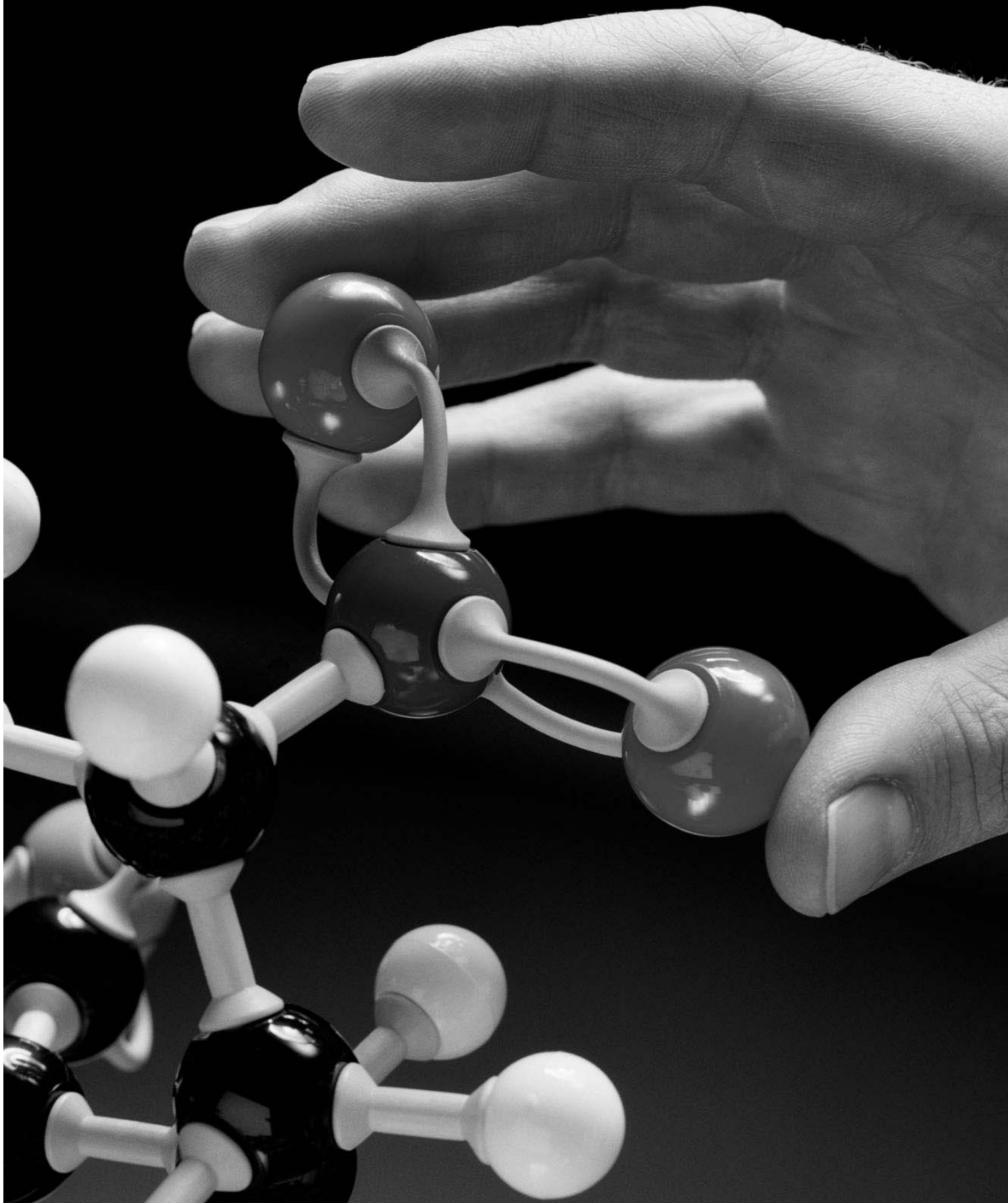


SOLUTIA

Solutia Pharmaceutical Services Division



## **Our Mission**

**Solutia's Pharmaceutical Services Division (PSD) provides integrated services that help our clients reduce the time, cost and risks associated with drug development. A commitment to science, speed and quality underpins all of our activities and ensures that we deliver on that promise.**

### **Science**

Science is fundamental to Solutia PSD. Far more than just a one-time solution provider, we view our role as partner and innovator. We work seamlessly with our clients providing intellectual input that can impact industry processes and shape the future of drug development.

### **Speed**

In today's high-pressure, time-sensitive drug development climate, Solutia PSD focuses on helping clients reduce the time it takes to bring a drug to market. Our leading-edge communication systems, project management techniques and information technology platforms are integrated to ensure the completion of projects efficiently and effectively. The resulting synergy generated from all of these capabilities delivers clients an end product that is greater than the sum of its parts.

### **Quality**

Quality lies at the heart of Solutia PSD. Each one of our state-of-the-art facilities operates to the highest standards of Good Clinical (GCP), Good Laboratory (GLP) and Good Manufacturing Practice (cGMP). Additionally, our long-standing culture of partnership and excellent service is founded on a commitment to "deliver right first time". Enhanced by excellent communication and an ability to adapt within our broad infrastructure to serve clients' changing needs, this commitment translates to high levels of client satisfaction and excellent client retention.

## **Integrated Drug Development from Bench to Market**

**Solutia PSD offers expertise in an array of integrated pharmaceutical services to support faster, safer drug development with improved cost efficiency. This commitment helps our clients make decisions more quickly and progress more candidates through the development pipeline in a shorter period of time. Three areas of concentration define our expertise.**

### **Chemistry**

Our chemistry services focus on offering seamless drug development ranging from chemical process research and development to the supply and manufacture of active pharmaceutical ingredients (APIs) for clinical and commercial use. In addition, we offer Centers of Excellence, which include Fast Track Synthesis, Analytical Chemistry, Chromatography Services and Peptide Chemistry.

### **Clinical**

Solutia PSD provides internationally recognized clinical trial services. Our particular areas of expertise include biostatistics, with a special emphasis in the use of data monitoring committees (DMCs), and data management.

### **Advisory**

Our advisory services offer access to both individual experts and customized teams of experienced professionals. These industry leaders contribute multi-disciplinary perspective and individual solutions to solve a range of issues that span the entire drug development process.

### Solutia Pharmaceutical Services Division

	Research	Preclinical	Phase I	Phase II	Phase III	Market	
Chemistry	Process Research			Process Development			CarboGen AMCIS
	Rapid Supply of APIs (cGMP)			Manufacture (cGMP)			
	Fast-Track Synthesis Analytical Chemistry Chromatography Services Peptide Chemistry						
Clinical				Biostatistics Data Management Internet-Based Clinical Trials Site Management			Axio
				Interim Analyses and Support for Data Monitoring Committees			
Advisory	Expert Support of Pharmaceutical and Biotechnology Development  Hands-on Drug Development Expert Resources Specialized and General Clinicians, Pharmacology, Drug Safety CMC, Regulatory, Quality, Engineering, Sourcing, General Management						Pharmaceutical Advisors

# ADVISORY SERVICES

Go/No Go Decision

	Research	Preclinical	Phase I	Phase II	Phase III	Market
Advisory	Expert Support of Pharmaceutical and Biotechnology Development					
	Hands-on Drug Development Expert Resources Specialized and General Clinicians, Pharmacology, Drug Safety CMC, Regulatory, Quality, Engineering, Sourcing, General Management					

### Critical Support

Solutia Pharmaceutical Advisors was formed in 2001 to provide critical support to complement our clients' internal drug development teams, delivering resources where and when it is required. Our objective is to help clients move forward with reduced risk by taking skills, expertise and capacity off the critical path. We provide the broad perspective needed for success and remove the time-consuming coordination of multiple consultants.

### Pharmaceutical Advisors: Expert Advice in Drug Development

**Solutia Pharmaceutical Advisors help our clients navigate the complex process of drug development. Our large, global network of advisors includes leading experts and hands-on executives who have been responsible for all aspects of pharmaceutical and biopharmaceutical development. We integrate cross-functional perspectives and skills to help clients maximize the value of their investment in the drug development process.**

#### Solutia Pharmaceutical Advisors deliver value when

- You need to transition from discovery to development
- Your expertise is in your technology, not in the complexities of drug development
- You face competing corporate demands while keeping development on track
- You have access to industry experts but lack the time or expertise to integrate their advice
- You have more opportunities than resources
- You need different expertise right-away, or on a part-time basis
- You have had problems, despite access to good advice

### Client Situation 1

Our client, an emerging biopharmaceutical company, was under pressure from its investors who were demanding accelerated progress. Expert in drug discovery and preclinical research, this client lacked the expertise to draw together the necessary planning. Solutia Pharmaceutical Advisors designed a custom team, including drug substance, drug product, drug safety and overall chemical development experts. This team then

formulated an integrated development plan that supported our client's clinical strategy, effectively managed cash burn, and identified key milestones, obstacles and gaps in order to move the lead compound forward quickly. Our client now has a clearly defined drug development plan that will help them anticipate and address issues. The new early development plan considers factors which better support attainment of corporate goals.

### **Right-to-left Thinking™**

Modern drug development is a highly complex, multi-disciplinary process. Lack of resource and time often focuses development activities on near-term milestones without understanding of the downstream implications or the impact on all other aspects of the program. We work with clients to apply our unique, Right-to Left Thinking™, a paradigm that optimizes the drug development process by working backwards from corporate or project goals to identify key tasks, decision points and bottlenecks, leading to sound development decisions.

### **Solutia Pharmaceutical Advisors - Integrating Drug Development**

Keeping drug development on track requires access to the right resource in the right place at the right time. Often, however, this resource is not required on a full-time or long-term basis. Our Advisors are former senior executives and industry experts including presidents and vice presidents from leading and emerging companies. All of our Advisors have proven track records in bringing drugs to market and specialize in key disciplines in pre-clinical or clinical development and are available when and where you need.

We apply all of the critical expertise that reflects key project objectives and complements our clients' own in-house capabilities. We apply Right-to-Left Thinking™, working from the desired outcomes to identify barriers, alternatives and inter-relationships to deliver key milestones and timelines. Our focus is on enabling Integrated Drug Development by ensuring a multi-functional perspective is brought to bear on issues and challenges. Whether it is reviewing toxicology data, auditing an active pharmaceutical ingredient (API) supplier, devising a development plan or carrying out a full portfolio review and prioritization, Solutia Pharmaceutical Advisors have the capacity, experience and expertise required to deliver.

### **Client Situation 2**

Our client had acquired a drug candidate with tremendous potential but with possible safety and bio-availability issues that threatened further development. Our team provided a Chemistry, Manufacturing and Control (CMC) and development review that combined therapeutic, technology, drug substance, drug product, formulation and delivery, toxicology, pharmacology and manufacturing perspectives. The team identified gaps in clinical

work to date. It delivered a CMC focused risk-reduction strategy to move forward prudently, prioritizing the development activities on the project as part of an overall risk management plan to support further development as appropriate. As a result, our client had a basis for further investment. Solutia Pharmaceutical Advisors are supporting the client during implementation, helping the client to move this additional program forward without additional infrastructure.

### **Client Situation 3**

Our client faced conflicting priorities and needed advice on how to prepare the main corporate laboratories and production facilities to meet the company's aggressive growth plans. Because of the significant capital investment, and their lack of experience in this area, our client asked Solutia Pharmaceutical Advisors to review the site development plan and recommend a risk-reduction strategy. Solutia Pharmaceutical Advisors provided

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Advisory	Expert Support of Pharmaceutical and Biotechnology Development					
	Hands-On Drug Development Expert Resources Specialized and General Clinicians, Pharmacology, Drug Safety CMC, Regulatory, Quality, Engineering, Sourcing, General Management					

## Solutia Pharmaceutical Advisors – Services and Capabilities

Our global network has expertise in all aspects of drug development including:

### Clinical Strategy, Pre-Clinical and Development Planning

Efficient paths to IND and NDA, clinical planning to drive development plans

### Drug Substance

Process research and development planning, sourcing and outsourcing, scale-up and security of supply and all aspects of CMC for both small molecules and biologicals

### Drug Product

Formulation, secondary manufacture decisions, drug delivery

### Drug Safety

Toxicology, ADME, characterization, containment strategies

### Quality and Regulatory

Quality systems, quality manuals, regulatory strategies and issue resolution

### Documentation

INDs, CTXs, NDAs, MAAs, Expert reports

### Capital Expansion

Facilities planning strategy, requirements and design review, capital project risk reduction

### Portfolio Management and Business Development

Market & portfolio review, business development strategy

combined engineering, operations, and quality system expertise to lead an operational review in support of our client's decisions. Our Advisors delivered a detailed site masterplan plan to effectively enable faster growth at lower cost, identifying further savings opportunities. The client now has high-added value, lower budget solutions for their expansion. Currently in the detailed design phase they continue to work with Solutia Pharmaceutical Advisors on implementation.

#### Client Situation 4

Our client's lead drug candidate demonstrated evidence of cardio-safety issues that threatened successful further development. Solutia Pharmaceutical Advisors provided a rapid review of the cardiac toxicology studies and recommended that the drug could move forward if certain additional tests were completed successfully. We also included a process chemistry review that identified scale-up risk, demonstrating the need

for more work on a final salt form prior to beginning the additional tox studies. This expert input resulted in the avoidance of further time lost in rework of some of the toxicology studies, avoiding roughly \$400,000 in expense and 9 months of lost time-to-market.





Solutia Pharmaceutical  
Services Division



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