Cardinal Health
Specialty Solutions

Bringing a new drug to life

Regulatory Sciences

CardinalHealth
Essential to care™

How we guided a pharma's breakthrough vision to commercial reality

The right drug can mean the difference between life and death

For patients with severe neuropsychiatric conditions, the right drug was available—but there was a problem. The drug was in hard-tablet form, which often caused an issue with patient adherence. Patients would "cheek the pill," instead of actually swallowing it. As a result, the patients remained at risk and physicians were frustrated. How would physicians get their patients to take their meds?

Two inspired physicians saw the answer, which was as simple as it was powerful: convert the hard tablet into an orally disintegrating tablet. This would solve the adherence issue but would also create a new dilemma. How would these two physicians turn their breakthrough vision into lifesaving reality?

The physicians owned a small, virtual pharmaceutical firm and were experts in the science of neuropsychopharmacology but not in all the aspects of bringing a new drug to market. "We needed a partner that could do it all from A to Z for us, from development through submission to approval," said the firm's vice president of drug development. "It was a huge undertaking and commitment. To whom could we turn to for the help we needed with every aspect?" The firm had many options and needed to decide what would be best for their product.

Solving the puzzle

- Development strategy
- IND preparation and submission
- CMC development
- CRO and CMO management
- 505(b)(2) NDA preparation and submission
- Postapproval support
- MAA preparation and submission

Three directions to approach the puzzle — **one proven way to solve it**

When faced with a development dilemma, companies have three directions to choose from in order to de-risk the drug's development while solving complex regulatory challenges:

Build your own network of independent consultants

This is time consuming and may require knowledge outside of your skill set. Also, you'll have the added risk of not knowing how well the individuals will perform as a team.

Determine if you're a good fit for a big contract research organization (CRO)

This approach may be a challenge if your project doesn't have a scale that attracts the attention of large CROs.

Create an extension of your company

This can be accomplished by choosing a more nimble organization that will dedicate an experienced team to focus on your drug from concept to commercialization. You'll feel as though you've added a new drug development department to your company without the fixed overhead.

This approach—large enough to have premier expertise and small enough to be attentive—is ideal for pharmaceutical, biotech, and medical device companies that want a hands-on partner to solve their product development puzzles while expediting the process and effectively managing risk every step of the way.

For this virtual pharmaceutical firm and its new drug, developing Cardinal Health Regulatory Sciences as an extension of its company was the answer. Cardinal Health Regulatory Sciences assigned a team of experts to work with this client and shepherd the entire three-year drug approval process. It provided the business support needed to allow this client to focus more on what matters most: taking care of patients.

From concept to commercialization

Cardinal Health Regulatory Sciences leveraged decades of development expertise and strong relationships with key agency regulators to get the drug to market as quickly as possible.

Designed the regulatory strategy for US and international markets:

- FDA interactions: Designed the regulatory strategy and product development plan and participated in the pre-IND meeting
- Preparation and submission of the IND application
- 505(b)(2) New Drug Application (NDA):
  - NDA project management, including timelines and task lists
  - Development of content based on customizable annotated Cardinal Health Regulatory Sciences CTD templates
  - Preparation of technical sections and product labeling, as well as submission of NDA to FDA
  - Preparation of Risk Evaluation and Mitigation Strategy (REMS)
- Developed a new child-resistant packaging solution: from concept to approval to manufacturing
- Marketing Authorisation Application (MAA): participation in planning activities, inclusion of technical details, and preparation of documents for MAA submission

Managing Chemistry, Manufacturing, and Controls:

- Secured a contract manufacturer to commercialize manufacturing
- Performed cGMP audits
- Oversight of technical activities of the contract manufacturer, from formulation development to commercial scale-up batches and validation

Guiding the CRO:

- Managed CRO activities to generate data
- Authored clinical reports for regulatory review—demonstrating that the drug is efficacious and safe via well-controlled, prospective clinical studies

Ongoing postapproval support:

- Preparation and submission of annual reports and 15-day adverse event reports
- Evaluation of changes to the product, including new formulations, additional strengths, and other changes
- Maintenance of ongoing regulatory compliance

"You'd be hard pressed to get a big CRO to do all of this for an organization like ours."

Vice President of Drug Development
Virtual Biotechnology Firm

Here for the unexpected

"One never knows all the factors that will go into the process and what surprises can happen along the way," said the client's vice president of product development. One surprise threatened to grind the drug's approval to a permanent halt.

The new tablets were designed to dissolve in the patient's mouth, which meant they were easily breakable. This created an unexpected issue with the packaging, which was originally designed for hard tablets and was not adequate for the new formulation. Also, it did not meet current child-resistance requirements.

"We had to rapidly address the packaging issue, and Cardinal Health Regulatory Sciences was there to actively resolve it," he said. Cardinal Health Regulatory Sciences quickly evaluated and resolved the packaging issue and steered the approval process back on track. "They were impressive."

The single-source solution

For this pharmaceutical firm, Cardinal Health Regulatory Sciences had the capabilities and expertise to effectively coordinate the entire drug submission and approval process from beginning to end. Deep scientific expertise came together with an experienced interpretation of evolving global regulations to navigate a complex and challenging approval process.

"To say Cardinal Health helped us get our drug approved minimizes all the hard work they did."

Vice President of Drug Development
Virtual Biotechnology Firm

"They were involved with every aspect, handling multiple tasks with no worries. We never fought for their attention," the vice president of drug development said. "We always knew what was going on. Not only did they help us get our drug approved, they also filled in all the gaps in expertise that a virtual company would naturally have. *You'd be hard-pressed to get a big CRO to do all of this for an organization like ours.*"

He explained that, although a large CRO may have the expertise required, "who would be the quarterback? I'm not sure we would have received the attention we needed."

This is not an issue for the members of the Cardinal Health Regulatory Sciences team, who are bench scientists themselves. The same consultants worked on the project from start to finish, ensuring the attention to detail and continuity of knowledge that's essential for a process that can take years to complete.

Perhaps the client sums up this value best: "To say Cardinal Health Regulatory Sciences helped us get our drug approved minimizes all the hard work they did."

About Cardinal Health Regulatory Sciences

Cardinal Health Regulatory Sciences provides a wide range of regulatory and scientific consulting services required to obtain marketing approval for drugs, biologics, medical devices, and combination products for the United States, Canadian, European, and rest-of-world markets. Our goal is to help companies bring new therapies to patients and increase the financial returns on their development investments through the design and implementation of efficient global scientific and regulatory strategies. Cardinal Health Regulatory Sciences assists with application preparation and submission through talented regulatory, medical writing, and product development resources.

Accurate. Accelerated. **Approved.**

Learn more about Cardinal Health Regulatory Sciences at:
cardinalhealth.com/regulatorysciences
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