Cardinal Health
Specialty Solutions

# Finding the generic solution

## Regulatory Sciences

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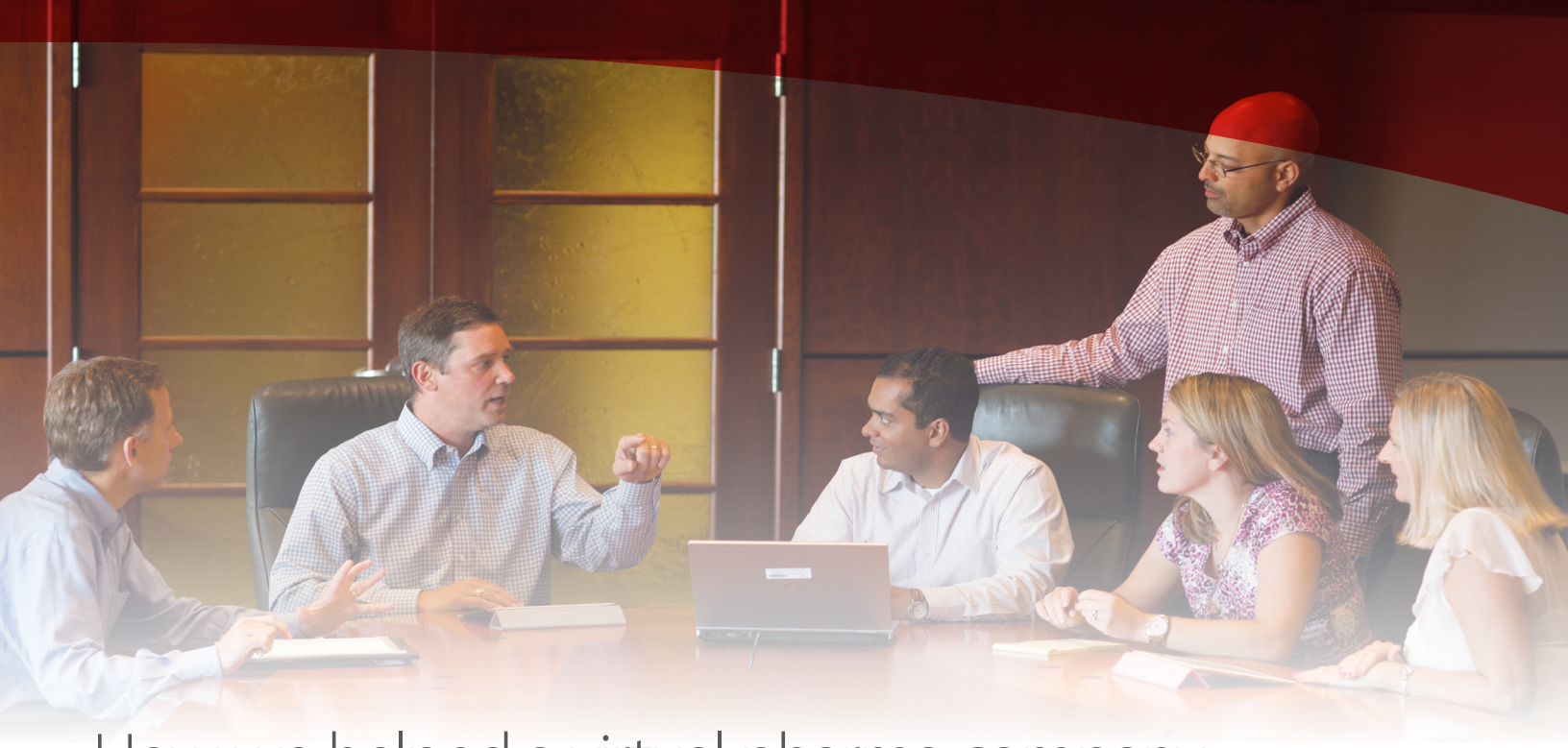

# How we helped a virtual pharma company deliver more value to its patients

## It all began with two brothers who had a compounding pharmacy and a dream

Two brothers wanted to help patients afford their antiviral medication. In the balance was each patient's quality of life. The brothers knew the answer was to bring a generic version of the drug to market. However, they were pharmacists, not experts in drug development and commercialization. At the time, it seemed like an impossible goal; but they succeeded, creating the first generic form of the anti-viral drug.

After this success, the brothers soon discovered that patient adherence would create a new challenge. What could they do to help ensure that patients would take the prescribed doses? Once again, they created the solution, which was a higher-dose tablet that allowed patients to take one daily dose instead of two or three doses each day.

In order to create the generic drug and develop the most effective dose for promoting patient adherence, these pharmacists knew they needed the right partner. Cardinal Health Regulatory Sciences was that partner, and the relationship continues today, even after the acquisition of the brothers' virtual company by a global biopharmaceutical firm.

"Cardinal Health Regulatory Sciences has a team of experts that is always available to us. They tell *us* what our product needs to succeed in the market."

**Senior Director of Regulatory Affairs**
Virtual Pharmaceutical Company

## Guiding every move with confidence

De-risking development was critical, and Cardinal Health Regulatory Sciences has a proven process, with a keen focus on accuracy and attention to detail. "From the very beginning, the Cardinal Health Regulatory Sciences team has helped us navigate unknown waters in a fantastic, non-judgmental way," said the senior director of regulatory affairs for the virtual pharmaceutical company. "They are just so welcoming and easy to work with. Listening to their expertise is reassuring—it's wonderful. They are truly out-of-the-box thinkers. Yet, such good listeners that we're always on the same page."

## Just the right resources, at just the right time

This was a *virtual* pharmaceutical company; therefore, it lacked the in-house resources and capacity needed to bring the generic drug to market. "Cardinal Health Regulatory Sciences has a team of experts that is always available to us," the senior director of regulatory affairs said. "We can literally pick off the shelf the exact expertise that we need, anytime we want. It's a resource that a company like ours couldn't build on its own."

## More than a large contract research organization (CRO)

The senior director of regulatory affairs described her past frustrations with CROs—and why Cardinal Health Regulatory Sciences was a better choice. "I've had negative experiences with large CROs. If you're not a big enough client, they may not take you seriously," she said. "You tend to get lost in the shuffle and are not always given the best people, priorities, and timelines. You simply don't feel like you own your own project."

The Cardinal Health Regulatory Sciences team works closely with its clients to build long-term, trusted relationships, retain critical knowledge, streamline processes, and sustain efficient and effective collaboration. "It's like having an extension of our own staff," the senior director of regulatory affairs said. "They don't hesitate to be transparent in all that they do."

## Providing the solution

- Development and regulatory strategy
- CMC and clinical supply management
- ANDA preparation and submission
- Postapproval support
- MAA preparation

# From vision to reality

Cardinal Health Regulatory Sciences guided the entire development and commercialization process to ensure this new generic drug could make it to market as quickly as possible. Leveraging decades of experience and strong relationships with key regulatory agencies, Cardinal Health Regulatory Sciences provided essential insights, strategies, and high-quality work during every step of development to secure and maintain marketing approvals.

## Planning the drug development and regulatory strategy

- Developed the integrated product development and regulatory strategy plan
- Managed FDA interaction, both preapproval and postapproval

## Managing Chemistry, Manufacturing, and Controls (CMC)

**Drug substance**

- Managed contract manufacturer from development through commercial scale-up and process validation
- Performed Current Good Manufacturing Practice (CGMP) audits
- Prepared, submitted, and worked with three separate companies to coordinate responses to FDA questions about the US Drug Master File (DMF)
- Reviewed and commented on the European Union (EU) DMF for the contract manufacturer
- Prepared the drug substance sections of the Abbreviated New Drug Application (ANDA), with appropriate references to the DMF
- Conducted the Preapproval Inspection Readiness assessment of the contract manufacturer; there were no Form FDA 483 observations
- Reviewed the annual reports and amendments to the US DMF

**Drug product**

- Managed the contract manufacturer (formulation development, pilot scale, and clinical supply manufacture for bioequivalence studies) through commercial scale-up batches and process validation
- Helped guide batch record creation and review, analytical method validation, manufacturing process protocol development review, and process validation report review
- Performed a CGMP audit of the drug product manufacturer
- Prepared the drug product sections of the ANDA
- Prepared the CMC section of the Marketing Authorisation Application (MAA)

# From vision to reality, cont.

## Results

- Successfully managed the contract manufacturer
- No FDA Form 483 observations
- ANDA approved in 11 months
- Received European approval

## Preparing and submitting the ANDA *(approved in 11 months)*

- Prepared complete ANDA in electronic format for FDA submission
- Prepared draft labeling, including package insert, medication guide, container labels, and side-by-side comparison based on the approved reference-listed drug
- Reviewed the draft and helped prepare the final bioequivalence study report and summary for the ANDA
- Completed a full quality assurance (QA) review of the ANDA
- Electronically published and submitted the ANDA
- Prepared and submitted seven ANDA amendments in response to FDA questions regarding labeling and bioequivalence (there were no questions related to CMC)

## Coordinating ANDA postapproval support

- Continued maintenance of the complete regulatory file
- Preparation and submission of three Postapproval Supplements (labeling changes, Structured Product Labeling, and optional bulk packaging)
- Reviewed change control requests from the manufacturing and packaging site to determine regulatory impact and approved the requests
- Prepared Prior Approval Supplement for manufacturing site change

## Preparation of Marketing Authorisation Application

- Identified revisions to convert ANDA to MAA based on EU requirements
- Prepared CMC section of MAA
- Received approval in Europe through Mutual Recognition Procedure

Cardinal Health Regulatory Sciences became an extension of this virtual pharmaceutical company to fill its gaps in resources and expertise to move this generic drug to commercialization as quickly as possible. Cardinal Health Regulatory Sciences provided precisely the right level of support to help make this company's dream a reality and built a successful partnership. The senior director of regulatory affairs said, "Cardinal Health Regulatory Sciences is always responsive. You feel like a true partner, not just another number."

## 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
or call 913.451.3955

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