

# The Benefits of CDMOs as Strategic Partners

Commercial partnerships are on the march in the pharmaceutical and nutraceutical industry spurred by dynamic market conditions, increasing interest in personalized and user-friendly products and not least by the surrounding clinical, technological and regulatory environment. Additionally, the COVID-19 pandemic has highlighted the importance of a robust value chain due to disruptions in supply chains around the world, calling for new strategies and new way to reach consumers.

These market dynamics have driven pharmaceutical and consumer healthcare companies to look into strategies that will secure or expand their position in the market. Outsourcing through integrated partnerships with Contract Development and Manufacturing Organizations (CDMOs) has shown to be a successful strategy. There are several reasons why healthcare companies increasingly turn to CDMOs to bring their products to life. First, it enables them to focus on their core competences such as scientific research and marketing; and second, outsourcing and partnering with CDMOs can speed up time to market and help gain strategic advantage in improve return on capital employed.

In the past, outsourcing was primarily perceived as an operational strategy to cut costs. During the last decades, however, partnerships have developed into strong, strategic pillars, where close relationships, shared culture and strategic fit have become just as important as technical capabilities.

This article unfolds eight key areas that characterize strong partnerships, highlighting the potential value added by CDMOs. The information is based on knowledge and experience collected by Fertin Pharma, a strategic CDMO serving the global market for oral dosage formats for more than three decades.

## Creating value through strong partnerships

When a pharmaceutical or nutraceutical company decides to establish a partnership with a CDMO, there are several fundamental parameters to consider such as culture fit, quality standards, experience and reputation. However, in order to select a partner that will enable the organization to grow and evolve, other decisive parameters are crucial in the selection process .



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### Fast track innovation

'What's next' is a key question best answered in close collaboration with partners upstream and downstream in the value chain. Developing novel, consumer-friendly formulations and products depends on continuous innovation driven by skilled scientists, proven processes as well as access to the latest technologies and operational efficiencies. Partnering with CDMOs allows healthcare companies to focus on own core competencies, while reducing the lead time and making the most of the resources every step of the way.

### Customer and consumer insights

Profound knowledge of market, consumer preferences, industry needs and technologies form the basis of successful partnerships. Close dialogue and mutual trust allow the partners to work as ONE team with common processes and a shared vision to fulfil the needs of the consumers in the best possible way.

### One-stop-shop with wide service offering

The best CDMOs handle the entire lifecycle of the product from sourcing of ingredients to shelf-ready packaging to ensure a speedy and seamless market launch. The service portfolio of the strategic CDMO comprises highly specialized R&D teams, integrated laboratories, state-of-the-art manufacturing and packaging facilities, advanced sensory analysis set-ups as well as full regulatory and clinical services that support the documentation process.

### Agile and flexible cooperation

Agility and flexibility in the supply chain allow healthcare companies to respond quickly to changes in the dynamic healthcare market and in the complex regulatory framework surrounding the pharmaceutical industry. Operational flexibility, scalability, tailored services, and fast prototyping are basic requirements all the way from first idea and development of formulation to manufacturing, packaging and distribution.

### Specialized capabilities and technologies

CDMOs with a strong industry network and capacity to invest in modern and customized technologies ensure a head start in the product development process. These cost and process efficiencies translate into business opportunities and market differentiation.

## Case Study One

# Joint innovation process resulted in novel, consumer-friendly oral dosage format

INNOVATION • ONE-STOP-SHOP • AGILE AND FLEXIBLE COOPERATION

### Situation

A global consumer healthcare company wanted to extend one of their brands to enable consumers to use the product in a new way.

### Approach

The company partnered with Fertin Pharma to innovate the dosage format to provide a new mouthfeel experience while still delivering the same benefits of the active ingredients as in the original format.

The new format required new manufacturing and packaging facilities. Once the contract was in place, the construction of the new manufacturing and packaging facilities started, involving authorities in the approval process to ensure compliance and achieve the final registration.

### Outcome

14 months after the contract was signed, the new product was available for consumers at retailers' shelves. Following a successful launch in several countries, product extensions with new flavours, ingredients and functionality are in the pipeline.



## High-level quality and compliance

Quality and integrity are fundamentals in any partnership, not least in the healthcare industry that has to protect the health and well-being of consumers. In order to ensure regulatory compliance and high quality at the lowest possible cost, the CDMO must adhere to customer quality policies and conduct fail-safe audits and inspections from customers as well as regulatory bodies. Furthermore, formalized processes for continuous improvement and training of staff are prerequisites to achieving high efficiency and low cost without compromising safety.

## Sustainable and responsible production

Sustainability and good business results go hand in hand, and consumers increasingly prefer brands that take responsibility. Collaboration with CDMOs with a sustainable mindset are key for innovative, responsible and circular solutions, secures license to operate and provides competitive advantage while minimizing the impact on climate and environment.

## The value of Intellectual Property (IP)

In today's globalized and competitive market place, IP rights are more important than ever. With a strong set-up for the filing of patents and securing IP rights, customers are guaranteed a unique, high-quality and proven product. A professional IP set-up at the CDMO also minimizes the risk of violating competitors' IP rights.

## Case Study Two

# From formulation to launch in just nine months

**SPECIALIZED CAPABILITIES AND TECHNOLOGIES • ONE-STOP-SHOP • AGILE AND FLEXIBLE COOPERATION • HIGH-LEVEL QUALITY AND COMPLIANCE**

### Situation

A global pharmaceutical company wanted to extend a popular healthcare product by adding a chewing gum variant to the portfolio of oral formats containing active pharmaceutical ingredients listed in the US Monograph for launch in the US.

### Approach

Working with Fertin Pharma that develops and produces its own gum base and offers profound understanding of different APIs, release profiles and mouthfeel, allowed the company to accelerate the new product development process from first idea and formulation to commercial manufacturing and launch.

In close cooperation, the partners went through prototyping and early consumer tests to optimize and lock the formulation. When this was in place, the packaging set-up and Quality by Design (QbD) processes were defined to move into full-scale manufacture. Later, the final submission for production and process performance qualification (PPQ) were carried out alongside stability testing to become ready for commercial production and market launch.

### Outcome

Thanks to the close collaboration between all stakeholders, it was possible to launch two flavor variants based on the formulation, leading to a better shelf space at retailers.



# Your one-stop-shop for innovative dosage formats



Fertin Pharma is a contract development and manufacturing organization (CDMO) specialising in innovative oral and intra-oral dosage formats with nutraceutical and pharmaceutical ingredients, aimed to give a pleasurable experience to consumers.



Consumer Insights



Quality control & Assurance



Research & Development



Manufacturing & Packaging



Sensory Optimisation



Intellectual Property



Regulatory & Compliance

## Consumer-friendly technologies

Our versatile dosage formats are designed to provide a convenient and pleasurable intake of pharmaceutical and nutraceutical products. Most consumer healthcare areas and age groups can be targeted based on their needs, preferences and behaviours:

Immune Support · Vitamins and Dietary Supplements · Oral Care · Energy Management · Cough and Cold · Allergy Care · Nicotine Replacement Therapy · Cannabinoid Applications · Digestive Health · Pain Management ...and many others

### ZAPLIQ® CHEWABLE TABLET

The next generation of chewable tablets

- Easy to swallow as a sip of water
- Unique mouthfeel
- Excellent taste-masking properties
- Wide range of flavours, colours, textures and shapes



### COMPRESSED CHEWING GUM

Controlled release of active ingredients

- Allows separation of sensitive actives
- Soft and chewable texture
- Wide range of flavours, colours, textures and shapes
- Excellent taste-masking properties



### POWDER

Provides new mouthfeel experiences. Can be used by mixing in water or directly in the mouth



### EXTRUDED GUM

High quality chewing gum, based on decades of confectionery and pharmaceutical experience



### LOZENGE AND FDT

Fast or slow dissolving compressed tablets for a controlled release



## Why choose Fertin Pharma as your CDMO of innovative dosage formats?



### Heritage

Fertin creates effective products with a pleasant taste and mouthfeel, building on 100 years of history in chewing gum and more than 30 years' pharmaceutical experience.



### Quality

We ensure reliable and consistent quality in every product leaving our facilities. Our manufacturing facilities and standard production routines comply with the rigid cGMP (current Good Manufacturing Practice) and the highest EU standards.



### Proven Track Record

Fertin works with leading global brands as well as store labels. Our products are used by consumers all around the world.



### Innovation & Uniqueness

Fertin products are developed based on consumer insights and protected by a strong portfolio of patents. We have been granted more than 100 patents, including some regarding taste masking and release profiling.