

# CASE STUDY: Pediatric Dosage Formulation



A U.S.-based global biopharmaceutical company known for its successful anti-infective products for adults was looking to reformulate the product into an age-appropriate dosage form for young children and pre-teen patients. The adult formulation was well established, as was the small scale pediatric formula development, when the sponsor began to look for a contract manufacturing partner to manufacture dosage forms for children up to age 12.

## Maintain the Equipment Train

The sponsor company established a list of criteria for selecting a CDMO partner. Among its operational priorities, it identified:

- Maintaining as closely as possible the train of equipment used to manufacture its adult and adolescent formulations
- Proven blending, compression, and coating capability, particularly of micro-tablets and oral granules
- Ability to handle a variety of batch capacities: engineering, design of experiment protocol, clinical batch, registration, and validation; scaling to commercial production runs
- International regulatory and significant commercial operational expertise
- Expertise in cleaning requirements for low-dose formulations

The sponsor also wanted the CDMO to be flexible, responsive, and cooperative, and to engage in communications at the highest levels of the organization. In addition, they requested to be onsite during manufacturing to address any issues in real time.

Halo Pharma initially emerged as a candidate because its 226,000-square-foot GMP facility in Quebec, Canada features the necessary equipment to handle a range of batch sizes, from 10kg to 900kg. In addition, Halo Pharma has in place all the quality systems to support the registration of the sponsor's product in multiple markets worldwide, including the U.S., Canada, and throughout Europe.

## Invest for the Win-Win

Halo Pharma was selected because it demonstrated flexibility, responsiveness, and cooperation. As a result, Halo Pharma ultimately received multiple pediatric formulation projects from the sponsor, in part because it was willing to make modifications and invest in new equipment to mimic the manufacturing process train for the adult formulation. For one of the projects, the sponsor contributed to a major investment in equipment components and modifications in the process train to more effectively contain the active ingredient.

## OVERVIEW

A global biopharmaceutical company with a successful adult anti-infective product franchise was looking to create a pediatric formulation to meet U.S. FDA regulatory requirements, expand patient access to children in an appropriate dosage form and strength, and to extend patent protection of its flagship product line.

## CHALLENGE

The pediatric formulation and dosage form(s) in development at small/lab scale did not fit the plant equipment profile used to manufacture the adult dosage form at the sponsor's facility. The sponsor, therefore, required a high-quality, agile CDMO with experience supplying international markets that could manufacture its pediatric formulation on the same equipment train used for manufacturing its adult dosage form.

## SOLUTION

Halo Pharma was selected because it could most closely match the train of equipment, as well as for its expertise, quality systems, international regulatory expertise, and flexibility to allow the sponsor to meet its internal and external regulatory commitments and short delivery deadlines.

## RESULTS

Halo Pharma is now working concurrently on multiple pediatric formulations and has been recognized by the pharmaceutical sponsor as a Pediatric Center of Excellence – a reliable partner in its ongoing efforts to bring pediatric formulations to market to address unmet medical needs.

“We were handling high-value API for each batch, so having an efficient transfer system for the API and blended powder was very important to not only transfer the product completely but also contain the product,” said Maryse Laliberte, general manager at Halo Pharma’s Quebec facility.

When it was discovered that aqueous coating would not handle the necessary taste-masking, Halo Pharma and the sponsor worked together to fund additional modifications to two manufacturing suites within Halo Pharma’s facility to allow for solvent coating of the tablets using explosion-proof technologies and new solvent-coating machinery.

“It’s a win-win situation because for us, we are getting a new capability with the new XP coating, and on their side, because it was not something they could find anywhere else, they are now able to achieve the full process all at Halo Pharma Mirabel, including the alcohol-coating for two of the pediatric products at one site,” Ms. Laliberte said.

## On Track

Halo Pharma’s collaborative approach extends to clear, joint goal setting to achieve milestones and enable the customer to file regulatory submissions within stated deadlines. The projects are all on track and Halo Pharma has met all of its commitments to the sponsor because of manufacturing schedule flexibility, quick turnaround with documentation, sharing best practices, and drawing from the sponsor’s product knowledge to allow for a smooth process.

“We have been able to turn around and make the batch, or change the batch size, and deliver the product, as needed, on the days they have requested,” said Ms. Laliberte. “If our customers need to work on a fast-track project, we are equipped and we have the team to deliver.”

## Measuring Success

Halo Pharma is measured by the sponsor against key performance indicators based on the speed of its execution, compliance with quality systems (Halo Pharma’s and the sponsor’s), the quality of its work, and its ability to resolve issues quickly and with transparency.

The sponsor has been so pleased with its relationship with Halo Pharma that it has deemed the CDMO its main pediatric manufacturer and has extended the products placed at Halo Pharma for other adult formulations/products.

“They see us as an extension of them, not only as a service provider,” Ms. Laliberte said of the sponsor. “We have built a relationship where both teams – theirs and ours – exchange best practices to achieve the goals of both companies.”

**Experience flexible outsourcing for pediatric dosage formulations. Get started at [www.halopharma.com/pediatric](http://www.halopharma.com/pediatric).**

**“Halo Pharma is very open to work in a collaborative way with our customers. It’s not, we do what we think, and if we fail we do it over. Instead, we work together, getting the customer’s input, and we do it right the first time.”**

— MARYSE LALIBERTE

### MAKING IT WORK

Based on Halo Pharma’s success with this sponsor, Ms. Laliberte suggests that pharmaceutical companies looking for CDMO partners to deliver pediatric formulations consider the following:

- Keep the formula as close to the adult formula as possible
- Maintain the same train of equipment when possible; or if necessary work with your CDMO to look for synergistic investments that can solve commercialization challenges
- Leverage data and knowledge from the adult formulation scale/process
- If the adult dosage form is in a solid oral dose formula, choose mini-tablets or oral granules over liquid formulations to minimize variables during development

## About Halo Pharma

Halo Pharmaceutical is a rapidly growing contract development and manufacturing organization (CDMO) that provides scientific and development expertise as well as a wide spectrum of manufacturing services from its locations in Whippany, New Jersey USA and Montreal, Quebec Canada to its international client base. Halo offers fully integrated capabilities in a variety of dosage forms including tablets, capsules, powders, liquids, creams, sterile and non-sterile ointments and suppositories. The company is registered to work with any of these dosages in the CI-CV DEA designations. Halo Pharmaceutical’s capabilities in the areas of tech transfer, process and product development, production, scale-up/validation and analytical method development allow us to partner with clients from development through commercialization or at any point along the way. For more information please contact [services@halopharma.com](mailto:services@halopharma.com).

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