



Wavelength Pharmaceuticals Resolves a Major Supply Crisis for a Leading API Manufacturer

Introduction

When you're jostling for market-share in a high-growth, highly competitive pharmaceutical arena, you need a CMO you can rely on. Without that, you may find yourself hamstrung at the very moment when demand for your product skyrockets.

That's what happened to this leading global API developer and manufacturer. Just as they doubled down on their commitment to supply the market with life-saving products, two of their CMOs dissolved. They needed to find a new partner, and fast. It had to be someone who could handle not only a complex tech transfer and cGMP scale-up, but who could do it at hyper-speed—all while protecting product quality. Just as the impossibility of this task sank in, they found Wavelength Pharmaceuticals.

How To Recognize A Reliable Partner

Because of their past experience, the company's leadership undertook a thorough assessment of Wavelength's capabilities before proceeding.

"We knew that Wavelength offered a strong R&D service to enhance their core manufacturing operations, but did that mean they could deliver on our expectations where others have not?" asked the company's Director of Manufacturing and Technical Operations, recalling their approach to qualifying Wavelength's capabilities.

To know for sure if they would be in safe hands, the company assessed Wavelength against three key criteria:

A perfect compliance track record.

Wavelength has been at the forefront of the API business for over 30 years. More than 250 pharmaceutical manufacturers around the world rely on them to develop, manufacture and supply generic APIs. When they developed their Contract Development and Manufacturing value proposition, they brought with them the same strong culture of quality and regulatory compliance that has served their API business for decades. As a result, Wavelength's CDMO customers are well assured of continuous regulatory compliance and uninterrupted supply. No warning letter has ever crossed their threshold, and over 100 audits in the past five years confirm their spotless reputation—including recent audits by the US FDA in 2018 and an EU-GMP audit in 2019, both of which concluded with no observations.

THE CHALLENGE

When two of their key CMOs crumbled under escalating reliability and quality issues, this leading global API developer and manufacturer needed a new plan for ensuring the continuous, reliable supply of their strategic products. They looked for a partner with a flawless compliance record, proven capabilities and customer focus. History, they vowed, would not repeat itself.

THE SOLUTION

What began as a search for a new CMO shifted when this company found Wavelength Pharmaceuticals, an API CDMO—"D" for Development, signifying Wavelength's internal capacity to problem-solve their way through complexity. With a strong reputation among international regulators and a client list that includes some of the largest pharmaceutical companies in the world, Wavelength had what this company needed to navigate a very challenging time.

THE OUTCOME

The first product transfer was successfully completed on an aggressive timeline, despite multiple technical gaps left behind by the previous CMOs. A ten-year contract now secures this partnership, with four multi-ton strategic products planned for the near future and two new pipeline products under discussion.

“A top-notch compliance record is what first attracted us to Wavelength,” says the Director. “They’re in excellent standing with regulators in the USA, the EU, Japan and many other countries around the world. It gives us **peace of mind**, knowing that our customers can trust our product because we, in turn, can trust our CDMO.”

A proven ability to execute on time, every time.

The customer knew that a reliable CDMO is one with the flexibility to meet shifting customer needs while maintaining product quality and strict regulatory compliance—delivering on time, in full and with all the required documentation. Was Wavelength collaborative and agile enough to adapt to new requests and unforeseen challenges, without compromising product quality? Could they get the job done, no matter what?

Wavelength’s approach to flexibility starts with its people. “They’re problem-solvers, not order-takers,” says the Director. “When it became clear that the protocols they inherited from our previous CMOs were incomplete, Wavelength’s team had the know-how to quickly fill those gaps and keep moving ahead. And because they do everything from gram scale to multi-ton manufacturing, we’ll never have to go through that transfer process again. They have all the required capabilities and the flexibility to accommodate our growth.”

Wavelength’s commitment to deliver above expectations extends beyond their own walls. They’ve simplified their supply chain by internalizing key services that others typically contract out, like using advanced particle design and micronization technologies to produce unique material physical properties. When external partners are required, they employ a rigorous approach to de-risk their vendor list, far beyond typical prequalification exercises. This means that while other CMOs skid around in the slippery aftermath of global disturbances (like, say, the COVID-19 pandemic), Wavelength can keep moving forward. They have enough reliability built into their supply chain to get the job done, regardless of market turbulence.

An experienced and committed professional team.

The company could have considered one of the more monolithic drug companies as their new CMO, but they feared their needs and concerns wouldn’t get the right management focus within a mass of other clients. By contrast, Wavelength’s carefully curated customer list and “Always Aligned” philosophy of customer service seemed promising. But could Wavelength deliver on that promise?

“From day one, it was obvious that our business mattered to everyone there, including the top decision-makers,” says the Director. “Their CEO and entire top management team were heavily involved from the start, working with us to ensure that our goals and their services were aligned. The beauty of that is also embedded in their name: we were on the same wavelength, right from the start.”



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**DIRECTOR OF MANUFACTURING
AND TECHNICAL OPERATIONS,
WAVELENGTH CUSTOMER**

Moving Fast Toward A Bright Future

The company could see that Wavelength had the compliance record, the flexibility and the professionalism they were looking for. That left just one very important question: could they move fast enough?

“We began our first product transfer in May 2019,” explains the Director. “Despite multiple challenges and gaps in the previous process, Wavelength successfully completed that transfer in just seven months.”

On the shoulders of this success, the company signed a ten-year agreement with Wavelength for four multi-ton strategic products. Tech transfer and validation of their second and third products are on track for completion this year, with their fourth one coming in early 2021 and two additional pipeline products under discussion.

“You’d be hard-pressed to find a CDMO anywhere that can solve problems and execute on a plan as quickly and as completely as Wavelength,” says the Director. “Our top management team is thrilled with the end-to-end speed and quality of this transfer. We’ve got big plans for our future with Wavelength.”

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FOR MORE INFORMATION

To learn how Wavelength Pharmaceuticals can solve your custom API development and manufacturing challenges, visit wavelengthpharma.com/services.



Wavelength is a world-class developer and manufacturer of Active Pharmaceutical Ingredients (APIs). It is the independent company of choice for pharmaceutical industry leaders that require advanced API solutions to gain sustainable competitive advantage. The company is on the same wavelength as its customers—a partner in tune with the results required to better support their needs. Founded in Israel in 1987, with more than 250 customers in 50 countries, Wavelength employs a highly skilled team with all the expertise required to advance products to market. Its cGMP-compliant facility is a first-class operation recognized for excellence in safety and environmental stewardship. Wavelength has achieved an exceptional track record for more than 30 years with all leading global regulatory authorities, including USFDA, EU-EMA, PMDA, TGA, KFDA, ANVISA and COFEPRI. The company includes experts in complex chemistry, innovative process development, crystalline forms and particle design, and offers customized solutions to meet individual customer requirements including full spectrum API CDMO services from pre-clinical grams to multi-ton commercial scale.

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