



**An altogether  
different kind  
of CDMO**



**Kalamazoo**

**API & Intermediates | Small Molecule API**



# Welcome

Welcome to Pfizer CentreOne's manufacturing site in Kalamazoo, Michigan, the largest API manufacturing plant in Pfizer's network.

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Let's collaborate

[Click here](#)

Discover how  
Kalamazoo is  
**altogether  
different**



# Who we are

## Our purpose

Patients are at the core of everything we do. Our API & Intermediates enable our customers to continually deliver vital medicines to patients

## Our vision

We aim to be your trusted API supplier of choice and serve as your reliable, long-term supply chain partner.

## Kalamazoo in numbers:

- **1M** kg of API annually
- **10M kg** of intermediates annually
- Began operations in **1948**
- **\$1B** invested in the site over the past 10 years
- **4M** sq. ft site

## Our contribution to global health

With a long legacy of innovation, quality, industrial safety, and regulatory compliance, we produce approximately 1 million kg of API and 10 million kg of intermediates every year. Many of them are key medicines deemed essential by the WHO and used by patients across the globe each and every day.



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I am proud to be a part of such a significant site for global API production. Thanks to our location in America's heartland, reliability and quality are at the core of what we do, meaning our customers can have confidence that we will deliver what is expected, when it is needed. We play a vital part in our customers' supply chains so this trusting partnership is critical. After all, together we are aiming to ensure continued, reliable supply of vital medicines.

**Andy Anderson, Global Head  
of Strategic Account Management**



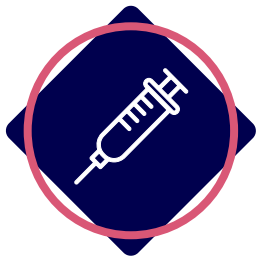


# What we offer

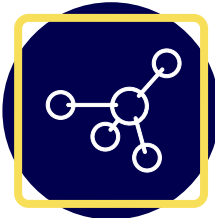
Kalamazoo is the largest pharmaceutical manufacturing plant of its kind in the US, with facilities spanning a total area of 90 acres.

We manufacture all our API & Intermediates with Pfizer's industry leading quality standards. As your partner, we provide you with access to high-quality products, technical and quality expertise, global regulatory support, and long-term supply.

At Kalamazoo we produce a specific segment of complex compounds:



Cortico- and hormonal steroids

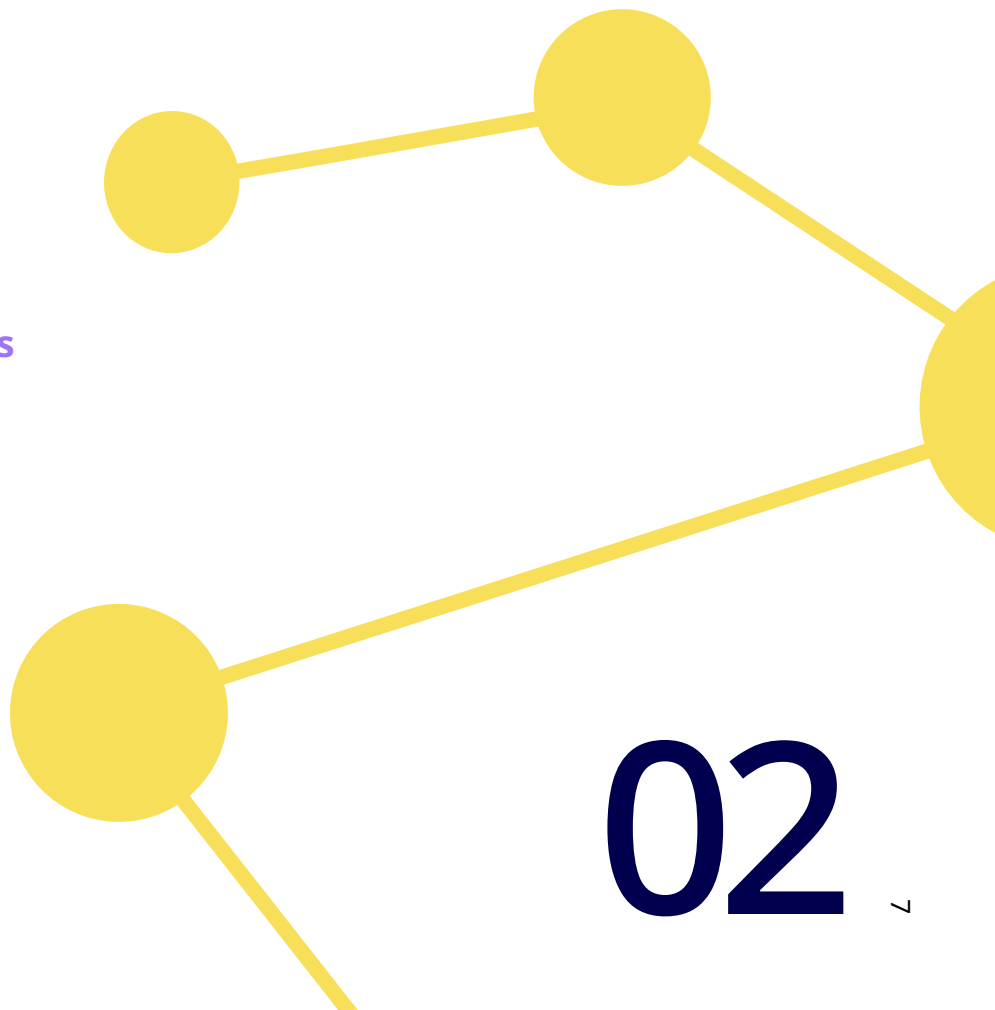


Prostaglandins



Antibiotics

*Co-located with Pfizer's drug product operations, we offer you a deep technical and scientific base on-site.*



# Heritage and innovation

Located in southern Michigan, our Kalamazoo facility has a 70-year legacy and pioneered the chemistry used to make complex steroids and hormones, including progesterone. We continue to lead the industry by investing in next generation processes. The American Chemical Society has designated the Kalamazoo site as a National Chemical Historic Landmark in honor of the innovative groundwork established here for modern steroid medicine.



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We have invested more than \$1B in the past 10 years alone and there are plans to invest at an even higher rate in the coming five years. This commitment ensures the right technology and capabilities are continually being added and upgraded so we remain at the forefront of small molecule API manufacturing.

### **Secure supply**

In an evolving global industry, diversifying your supply chain has never been more important. Our Kalamazoo site has been delivering API and customer confidence for over 50 years. From raw ingredient to API, we can secure a safer supply chain, highest quality API, regulatory support, and transparent timelines. Now is the time for companies to consider that a diverse supply chain adds to your ability to be agile and enables you to better meet the needs of your customers.

# Customer service at Kalamazoo

As a leading supplier of API & Intermediates we understand the importance of meeting your API requests to the right specification and quality standards. You can count on us to deliver you a high-quality molecule over the long term and be ready to adapt to your changing timelines and needs.

Our supply chain is like few in the industry. We produce our API from basic raw materials, with rigorous sourcing standards.

*Developing our intermediates in-house allows us to build quality and reachability into our entire supply chain.*





# Green Chemistry

The team in Kalamazoo developed Enviero® progesterone, the first compound to be launched from Pfizer CentreOne's green-chemistry program.

The API is produced by a first-of-its-kind progesterone synthesis process that reduces waste, greenhouse gas emissions and the use of hazardous solvents, and is now authorized for pharmaceutical use in North America and the European Union. Developed during the last decade, this represents a step change in

progesterone API synthesis. Manufactured via a proprietary biocatalytic process based on plant sterols, efficiency and sustainability results have been exceptional, including cutting the carbon footprint of the progesterone manufacturing process by more than 70 percent and eliminating the use of metal catalysts.

Read Greener by  
Design article [here](#)





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View Enviero®  
brochure [here](#)

# Regulatory track record

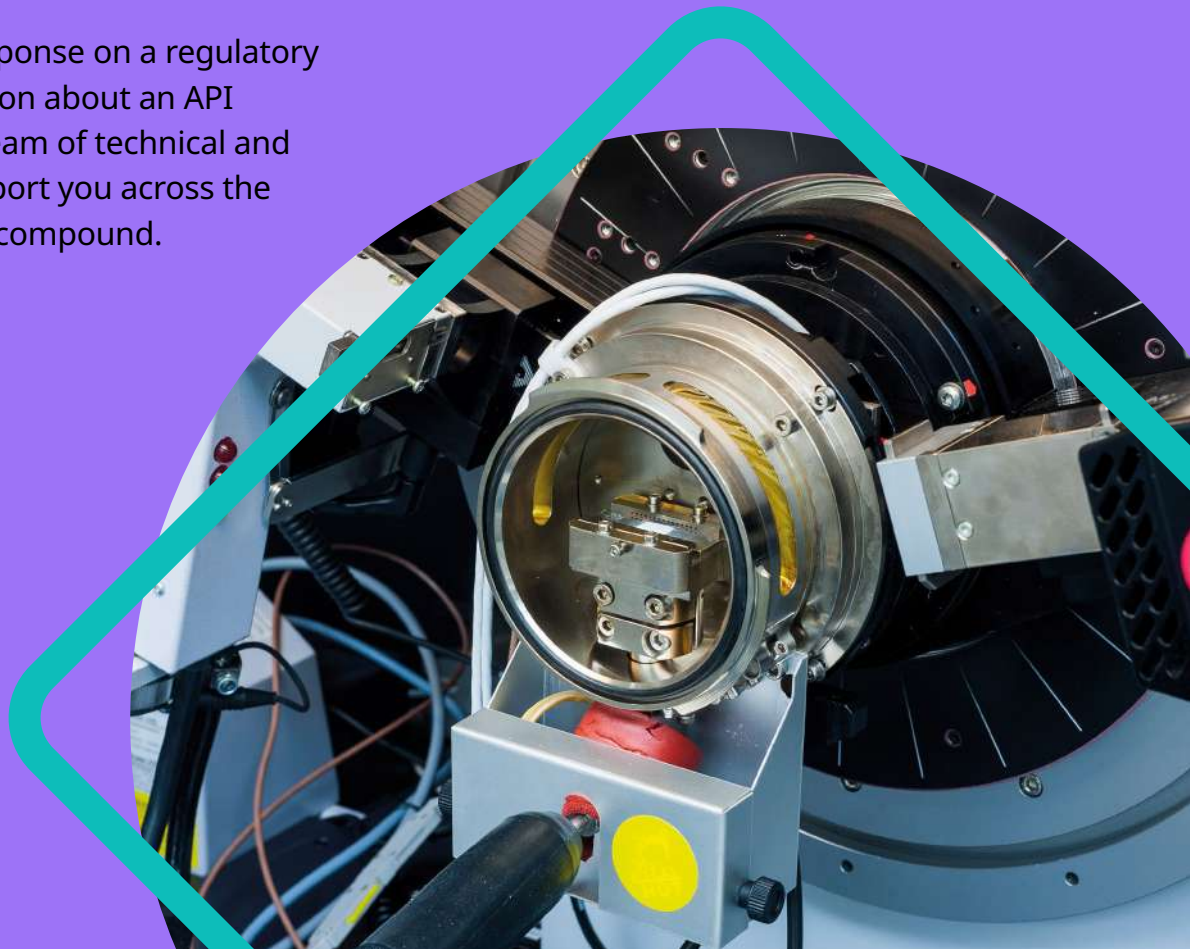
Manufacturing regulatory filings and submissions for complex API & Intermediates requires extensive knowledge of the regulatory landscape. The team in Kalamazoo provides you with access to global regulatory expertise and support, helping to navigate your products through launch.

We adopt a proactive approach to early engagement with regulators. This, combined with our knowledge of the regulatory impact of manufacturing changes in each market, ensures we provide customized support for every API & intermediate.

Whether it's a quick response on a regulatory issue or simply a question about an API impurity, a dedicated team of technical and regulatory experts support you across the entire life cycle of your compound.

Our Kalamazoo site is inspected on an ongoing basis by regulatory authorities from around the globe and is committed to patient safety and product quality at every step in the manufacturing and supply chain process.

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<b>Regulatory Body</b>	<b>Inspection Date(s)</b>
Therapeutic Goods Administration / TGA (Medical Device)	April 20–24, 2015
FDA, CDER (Drug Product and API)	June 23–July 9, 2015
MHRA (Drug Product)	September 8–11, 2015
FDA, CBER (Drug Product)	November 3–12, 2015
ANVISA (Drug Product)	April 25–29, 2016
MHRA (Drug Product – Biologics)	May 16–20, 2016
EMA (Drug Product – General GMP)	October 10–14, 2016
Turkish Ministry of Health (MOH) (Drug Product)	December 5–8, 2016
Ministry of Industry and Trade of the Russian Federation (MOITRF) (Drug Product)	February 14–16, 2017
Korea Ministry of Food and Drug Safety (MFDS) (Drug Product)	August 7–11, 2017
FDA, CBER (Drug Product)	October 30–November 7, 2017
FDA, CDRH (Class I and III Medical Devices)	December 18–22, 2017
Ministry of Healthcare of the Republic of Kazakhstan (Drug Product)	February 5–8, 2018
Ministry of Health of the Republic of Belarus (Drug Product)	April 3–4, 2018
Pharmaceuticals and Medical Devices Agency (PMDA) (API and Drug Product)	April 16–20, 2018
Ministry of Industry and Trade of the Russian Federation (MOITRF) (Drug Product)	May 29–June 1, 2018
FDA, CDER (General GMP – Drug Product and API)	September 10–21, 2018
FDA, CDRH (Class I and III Medical Devices)	November 26–December 10, 2018
Ministry of Industry and Trade of the Russian Federation (MOITRF) (Drug Product)	August 20–22, 2019
Eurasian Economic Union (EAEU) (Drug Product)	October 7–16, 2019
Federal Agency for Medicines and Health Products (FAMHP)	June 16–July 6, 2020

# Customer testimonials

Don't just take our word for it, find out what our customers have to say about us.



*Pfizer CentreOne has helped us at every step in the synthesis, from providing the initial intermediate through refinement of the steps leading to the API. We have faced a number of challenges with the manufacture of the API and the team has come up with creative solutions that show real scientific flair.*



**Michael Zasloff, MD, PHD,  
Co-Chairman and CSO of Enterin**



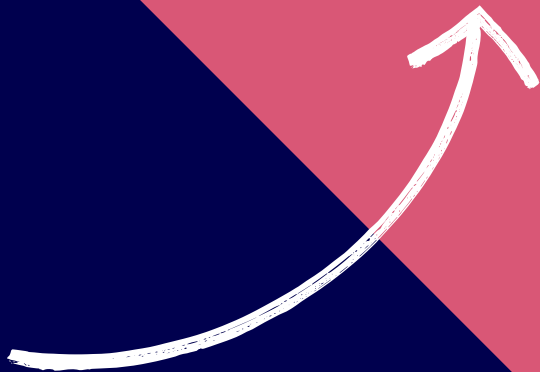


*I've been doing business with Pfizer for a number of years. Over the years Pfizer CentreOne has gone above and beyond to make sure Sparhawk has received raw material for my production needs. Notably this year during the pandemic I noticed little to no disruption in service.*

*If all of our suppliers were this attentive, my job would be much easier. Keep up the good work and as always, thank you.*



**Bert Hughes, President,  
CEO Sparhawk Labs**



# Small molecule API

If you require development, scale-up and manufacturing of your proprietary molecule, custom API contract manufacturing is one of our Kalamazoo site's core competencies.

## We have expertise in:

- Complex organic synthesis
- Large-scale fermentation, enzymatic conversions and biotransformations
- Milling and micronizing
- Tech transfer, optimization and scale-up of complex small-molecule processes

Our multi-disciplined teams can review any proposed manufacturing process, and then run it through our established techniques and screening capability to find ways to improve it.

View our aligning drug strategy with partnering strategy white paper [here](#)





**Pfizer**  
CentreOne

Small molecule  
**APIs made with**  
compelling science

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Discover our Small Molecule capabilities [here](#)



# Our commitment

At Kalamazoo, we are united by a clear sense of purpose. We aspire to be the API supplier of choice and a reliable, long-term supply chain. Delivering the highest quality molecules, we ensure the continued supply of vital medicines across the globe.

# Discover how we're altogether different

**For more information on Kalamazoo's services, please contact:**

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For more information, visit  
**[pfizercentreone.com](https://www.pfizercentreone.com)**