



# Regulatory affairs

Meeting the highest standards,  
for your global needs



Navigating the complex world of regulatory compliance requires expertise and experience. Powered by Pfizer, we provide you access to some of the best regulatory minds in the industry, designed to help you navigate the regulatory landscape with confidence.

Our team of established regulatory affairs professionals, continuously refine practices that ensure continued collaboration, excellence and unwavering compliance with over eight decades of combined experience and in-depth knowledge of regulatory requirements in over 150 countries.

With a dedicated advisor to guide you through submission and commercialization, you'll benefit from Pfizer's extensive expertise in successful submissions and regulatory approvals across a wide range of modalities:



Oral solids



Sterile  
injectables



Biologics

Learn more →



Access to the exceptional regulatory expertise of Pfizer's Global Regulatory Science network



Rely on a trusted partnership with Pfizer CentreOne regulatory affairs experts



Eliminate unnecessary expenses by partnering with our team of CMC regulatory affairs consultants and project managers.



Simplify your budgeting with predictable monthly costs tailored to your project's needs.

# Helping to navigate your **regulatory affairs journey** with confidence to overcome your challenges with:

1



## A partner you can trust to meet your unique needs

Leveraging our experience handling CMC regulatory affairs issues, we help you find solutions that fit your needs.

2



## A partner that will keep your intellectual property safe

Our well-established systems help protect your intellectual property information.

3



## Guidance on the **quickest regulatory pathway**

We partner with you to expedite your regulatory pathway toward approval, helping your therapy reach patients sooner.

4



## Help with getting your asset registered in **global markets**

We offer access to all the latest regulatory requirements to enable commercialization across the globe.

5



## Fully published **Module 3 section (CMC)**

You will get a Module 3 section that fits your needs – all you need to do is implement the CMC module into the rest of your application.

6



## Discover a **leading CMO powered by Pfizer**

Giving you the regulatory insight, security and expertise to help ensure a smooth path to market.

## Worldwide expertise

Utilizing Pfizer's Global Regulatory Science network, our regulatory team is well-equipped to support submissions to worldwide health authorities, including:

- ANVISA (Brazil)
- European Medicines Agency
- EU Nationals
- FDA (CDER & CBER)
- Health Canada
- NMPA (China)
- PMDA (Japan)
- TGA (Australia)
- Many additional agencies



## The strength of Pfizer supporting your vision

Discover how we can help you overcome your regulatory affairs challenges and support you around the globe.

Get in touch →