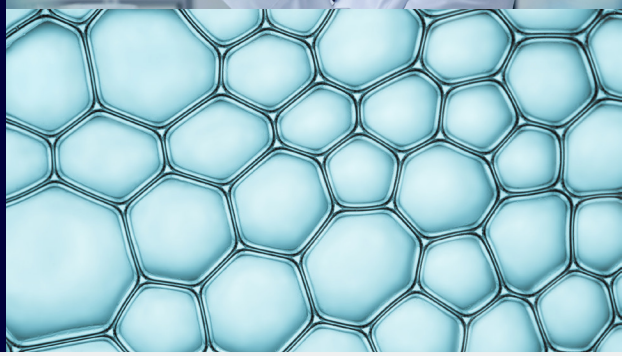
Pfizer CentreOne



Regulatory Affairs

Supporting consistent standards for your global needs

Navigating the complex world of regulatory compliance requires expertise and experience. Powered by Pfizer, we leverage long-standing regulatory experience to provide knowledgeable support throughout your journey, designed to help you navigate the regulatory landscape with confidence.

Our team of professionals continuously refine practices to support unwavering regulatory compliance and the most up to date knowledge within the changing regulatory environment to consistently meet global regulatory expectations.

By leveraging Pfizer's global expertise, to assist you through submission and commercialization, you'll benefit from Pfizer's extensive success with regulatory approvals across a wide range of modalities:

- Oral solids
- Sterile injectables
- Antibody drug conjugates
- Microbial fermentation

Learn more →

Worldwide expertise

Utilizing Pfizer's global network, our teams are well-equipped to support submissions to worldwide health authorities, including:

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

Helping to navigate your regulatory affairs journey with confidence:

1

A team you can trust to meet your unique needs

With deep CMC and regulatory experience across global markets, we provide reliable technical input and historical perspective to help inform your regulatory documentation.

2

Providing confidentiality and the security of your intellectual property

Our well-established and secure systems help protect your intellectual property within a corporate culture of confidentiality.

3

Support aligned with your regulatory strategy

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

4

Getting your asset registered in global markets

We can fulfill all necessary regulatory requirements to enable commercialization across the globe.

5

Module 3 section (CMC) collaboration

Manufacturing and technical expertise combined with historical regulatory knowledge help support a Module 3 section that will meet your needs.

6

Discover a leading CMO powered by Pfizer

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

The strength of Pfizer supporting your vision

Explore how our global regulatory knowledge and site-based expertise can support your regulatory activities.

Get in touch →