Pfizer CentreOne

Regulatory affairs Support around the globe

Navigating the complex world of drug development and regulatory compliance requires expertise and experience. At Pfizer CentreOne, our best-in-class, end-to-end regulatory service is designed to help you navigate this journey with confidence.

Our team of seasoned regulatory affairs professionals brings over 80 years of combined experience and in-depth knowledge of regulatory requirements in over 150 countries.

With a dedicated advisor to guide you from development to submission and commercialization, you'll leverage our extensive expertise in successful submissions and regulatory approvals across a wide range of modalities:

- **Small molecule active pharmaceutical ingredients (APIs)**
- **Biologics**
- **Oral solids**
- **Sterile injectables**

Learn more

Access the **best-in-class** regulatory expertise of Pfizer's Global Regulatory Science network

Rely on a **trusted partnership** with Pfizer CentreOne regulatory affairs (RA) experts

Eliminate **unnecessary expenses** by partnering with our team of CMC RA 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

With access to some of the best regulatory minds in the industry at Pfizer, we can help you overcome your regulatory affairs challenges with:

1.

A partner you can trust to guide you through development

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 (IP) 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)

Just like Pfizer, 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 CDMO powered by Pfizer

Worldwide expertise

With access to Pfizer's Global Regulatory Science network, the Pfizer CentreOne 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

An altogether different approach to global regulatory affairs

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

Learn more