OVERVIEW

Regulatory Affairs Solutions

Government and Public Health Services

Responding to the specific needs of our government and public health services clients is a proud commitment PPD has been fulfilling for over 25 years.

Since 1990, PPD's dedicated government and public health services group has successfully delivered clinical research services to the U.S. government, nongovernmental organizations and academia. We have worked in U.S. government prime and subcontracting models, public and private partnerships, and commercial subcontracting on U.S. government-funded projects.

Our dedicated staff serving global government and public health clients has experience in working with:

- Biomedical Advanced Research and Development Authority (BARDA)
- National Institutes of Health (NIH)
- Department of Defense (DoD)
- Nonprofits and academia

PPD Effectively Monitors the Regulatory Landscape

PPD® RegView is a one-stop system that allows our regulatory team members to source actionable intelligence to better support clients. The system provides information on regulations, guidance and best practices, and is used to support clinical trials, marketing authorization, lifecycle management, safety reporting and CTMS document requirements. In addition, PPD® RegView is used to educate internal expert groups on the latest trends, including new developments in global and regional regulatory affairs and the competitive landscape.

4,300+ CTA/INDs

25,100+ CTA/IND Updates

40+ Rare disease submissions

1,400+ New marketing expansion licensing

200+ Agency meetings

100+ NDA/MAAs

31,800+ Post-licensing submissions

Delivery across **160+** countries

Comprehensive Regulatory Services and Experience

PPD offers a complete spectrum of regulatory services including:

- Clinical trial applications
- Marketing applications
- Labeling
- Publishing and submissions
- Preclinical and CMC consulting
- Agency interactions
- Strategic consulting and intelligence
- Quality review
- Training

Specialized areas:

- Advanced therapies
- Biosimilars
- Gene & cell therapies
- Generics
- GMOs
- Medical devices
- Vaccines

775+ regulatory staff

in **47** countries

average **22** years of industry experience

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