



PREMIUM SOLUTIONS PARTNER



# Regulatory Consulting and Regulatory Affairs

Accelerated and Assured Regulatory **Submission Success**

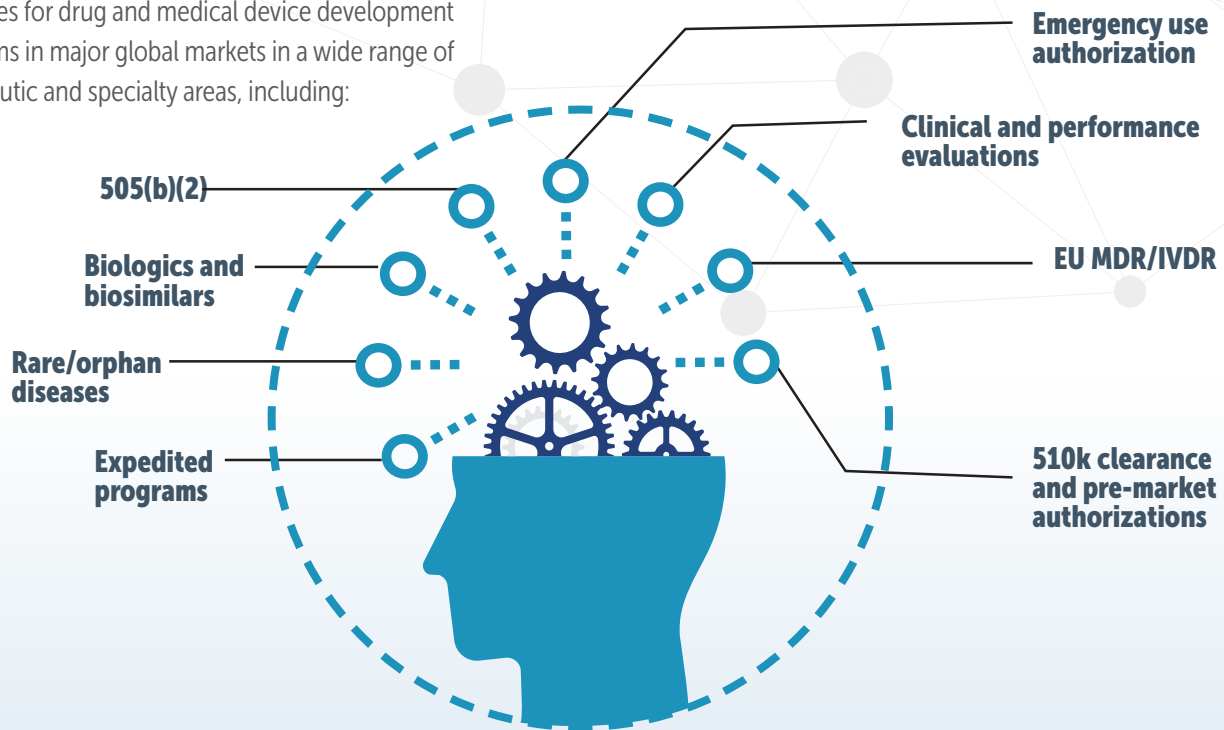
## Increase program success

Regulatory approval procedures are becoming increasingly stringent and time-consuming. Not having the right regulatory strategy in place will cost time and money, and may result in the failure or delay of your drug development program.

Global program development guidance from seasoned experts from industry and regulatory agencies will increase your program's chance of expedited success. Certara's integrated team of regulatory strategists provides regulatory strategy, consulting, and regulatory submissions support for drug and device development programs from preclinical through late-stage, post-marketing.

### Deep specialty area expertise

Certara's experts in regulatory strategy create efficient strategies for drug and medical device development programs in major global markets in a wide range of therapeutic and specialty areas, including:



**○ Leverage a robust submission strategy**

We have proven frameworks and processes to craft the best regulatory strategy, product development and clinical plans to meet your needs.

**Gap analysis of development programs, global dossiers and regulatory agency correspondence**

**Consideration of expedited regulatory pathways**

**Due diligence assessments for in-licensing and partnering, including proposals to increase value proposition**

**Global submission strategy, preparation and leadership focused on incorporation of regional regulatory requirements [IND/ IMPD/NDA/BLA/ MAA/510(k)/PMA]**

**○ Expert communication and collaboration are essential**

Our experts in regulatory strategy include ex-industry and regulatory agency staff with decades of experience successfully engaging with key stakeholders.

- **Agency engagement preparation, communications and leadership**
- **Labeling consultation, preparation and negotiations with regulatory agencies**
- **Proactive stakeholder consultation to achieve alignment**

**Our regulatory experts have provided guidance, writing, and submission support for 58 marketing applications over the past 3 years.**