Catalent®

GLOBAL REGULATORY PLANNING

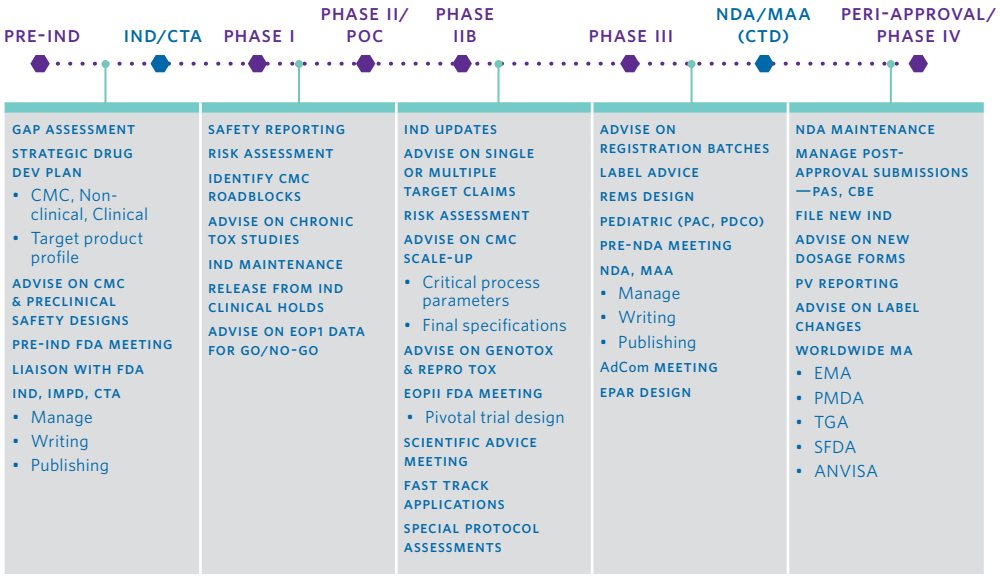
Our strategies begin with the end in mind.

Deliver more drugs to market faster, avoiding costly delays. Our Regulatory Consulting Group brings the tailored global expertise necessary to ensure your regulatory plans, non-clinical, manufacturing, clinical studies and regulatory filings are strategically sound, robust and ultimately acceptable to Regulatory Authorities—getting you and your products to the next milestone faster.

Trusted & Flexible

Experienced Team Our dedicated regulatory experts have on average over 20 years of regulatory and drug development experience, and engage in projects ranging from gap assessments to filing regulatory submissions to comprehensive consulting services, involving full teams supporting our clients' development of pharmaceuticals, biologicals and medical devices.

End-to-End Tailored Solutions With our diverse team and industry resources, we can quickly assemble the specific expertise and knowledge to lead the market, no matter what phase of development you are in.



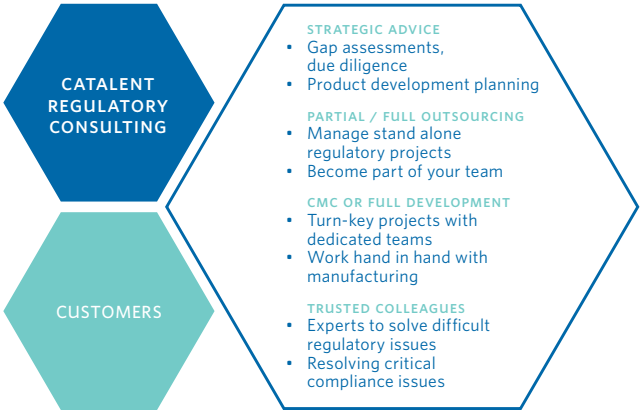
DEVELOPMENT DELIVERY SUPPLY

Multi-market Approach

FDA, EMA, MHRA, BfArm, Afssaps, PMDA, and Others Our regulatory consultants have submitted hundreds of regulatory applications globally, ranging in type from enabling the initial clinical trial to full marketing applications across a wide array of indications and dosage forms.

How We Do It

Our unique approach is partnering. A combination of strategic consulting paired with practical, hands-on implementation improves the speed, efficiency and quality of the entire product development process.



Proven Results

Global Successes Our team has the combined experience of more than:

120+ Product development plans
150+ FDA/SA meetings
100+ INDs/IMPDs & maintenance
20+ NDAs/BLAs/MAAs and maintenance
200+ PAS/CBEs/variations

Our Consultants at Work

	Client A	Client B
Situation	Potential Product Acquisition	Simultaneous Marketing Application in US & EU
Solution	Due Diligence involving • Regulatory gap assessment • CMC and nonclinical gap assessment • Coordinate with Assessments from other disciplines (clinical, marketing, finance, etc.) • Final Risk Assessment Report	Joint US and EU regulatory team with CMC, Nonclinical and Clinical subject matter expertise and solid project management Drove the process by initiating a submission project plan after conducting a thorough gap assessment and risk mitigation strategy Solved NDA/MAA delay issues to maintain timeline Right-First-Time NDA/MAA submission

Let Catalent's proven consultants go to work for you. We will design a milestone-based development program tailored to the client's needs, whether you wish to submit a marketing application or are seeking help to develop your product to a Clinical Proof of Concept stage for out-licensing/acquisition.

Discover more solutions with Catalent.

more products.
better treatments.
reliably supplied.™

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