Catalent®

REGULATORY SUPPORT SERVICES

Global regulatory affairs expertise for contract manufacturing clients

DIVERSE & GLOBAL EXPERTISE Our regulatory team completes over 150 agency submissions each year, supporting all stages of the product lifecycle. We assign a dedicated regulatory professional to each of our clients and work directly with our manufacturing facilities to provide turn-key solutions. With over 15 years of experience in regulatory services, Catalent is well-equipped to handle a wide variety of projects:

- Small & large molecule
- Sterile & non-sterile
- Consumer health / OTC
- Regulatory strategy planning
- Updates & maintenance
- Regulatory triage
- Submission authoring
- Submission review
- eCTD & publishing support
- Gap assessment & advisement

We regularly support submissions to worldwide health authorities, including:

- FDA / CBER / CDER
- EMA
- EU national authorities
- Additional agencies
- Health Canada
- ANVISA
- TGA

COMPLETE DOSSIER AUTHORING Catalent's regulatory affairs team provides complete CMC writing services, as well as submission review, for a broad array of regulatory filings:

- Investigational new drug applications (e.g. IND / IMPD / CTA)
- Marketing authorization applications (e.g. NDA / MAA / NDS)
- Generic drug applications (e.g. ANDA / ANDS)
- Biologics license applications (e.g. BLA)
- Drug Master Files
- Global expansion filing support documents for ROW submissions
- Lifecycle submissions such as annual reports, renewals and post-approval changes (e.g. CBE-0 / CBE-30 / PAS / sANDS / EU variations)

PARTIAL OR FULL OUTSOUCING We provide flexible levels of support depending on the client's need. Whether a client is looking to develop a full strategic regulatory plan with complete authoring services, or simply looking for review and alignment, Catalent will provide a tailored solution.

REGULATORY SUPPORT & ADVICE Our experts can advise on CMC strategy and considerations specific to Catalent manufacturing and development technologies. For clients looking to generate their own regulatory submissions, or utilize third-party consultants, Catalent will review dossiers to ensure alignment with manufacturing sites and services.

- Define regulatory requirements and recommendations for new products, regulatory filing strategies and post-approval changes
- Review of QbD (Quality by Design) / QbR (Question based Review)
- CMC Module 3 gap assessment (product development and existing dossiers)
- CMC Module 3 pre-submission dossier review

REGULATORY PUBLISHING Catalent provides full publishing services available for various international health authorities, many via electronic gateways.

- eCTD and non-eCTD electronic submissions (NeeS)
- Paper to eCTD conversions
- Collation and compilation of complete dossiers Module 1 through 5

HEALTH AUTHORITY MEETINGS We can prepare correspondence documents and participate in pivotal meetings with health authorities for Catalent technology development projects throughout the development process.

CLINICAL SUPPORT & LABELING Catalent helps clients prepare for regulatory hurdles through integrated clinical support services.

- Labeling assistance for clinical trial material (test and reference)
- Regulatory label review for US, EU, Israel, Eastern Europe and Russia, Canada, Australia and New Zealand, Asia Pacific and Latin America
- Translation and back-translation coordination

We offer a full spectrum of global integrated services for every stage of your product's lifecycle.

more products.
better treatments.
reliably supplied.™

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