



Liquent Direct™

Leveraging proven expertise for competitive advantage

Liquent Direct™, a component of Thomson Regulatory Solutions, combines the power of the industry's leading regulatory publishing software with unparalleled regulatory and submission experience. Whether your organization is preparing one submission each year or multiple submissions, *Liquent* offers a true end-to-end solution including electronic Common Technical Document (eCTD) submission publishing, eCTD demos, legacy document scanning, high-speed printing and all the critical steps in between.

Liquent Direct can provide:

- Submission publishing consulting resources at your site
- Publishing centres of excellence in the United States or Europe to complete your submission.

Outside help, inside control

Liquent Direct manages the entire process from end-to-end, from scheduling and costs to logistics and final deliverables. The team meticulously defines and implements project phases such as planning, analysis and definition, regulatory demos or pilots, professional consulting services, report publishing, production, system delivery and scanning, and printing services.

Whether you need to manage multiple, simultaneous submissions on an ongoing basis or want a complete, immediate solution for a one-time project, *Liquent Direct* provides a flexible solution to address your regulatory challenges.

Unparalleled track record, unsurpassed global expertise

The *Liquent Direct* team has never missed a deadline and has never experienced cost overruns. Here is just a sample of some of the submissions that *Liquent Direct* has completed:

- 350 volumes to the FDA's Division of Dermatologic Drugs
- 132 volume eCTD to the FDA
- 300 volume paper CTD to the FDA
- 300 volume paper CTD to EU
- 15 Global CTDs (EU, CA, US)
- 3 eCTD demos to the FDA
- 3 eANDAs to the FDA
- 1,112 volume NDA to the FDA (one of the largest-ever NDAs)
- 150 volume NDA for pediatric indication of an existing drug
- 123 volume electronic BLA
- 100 volume and 300 volume NDA to Health Canada
- 100 volume CTD to Europe
- Over 65 eNDAs filed to the FDA
- 43 Marketing Authorization Applications, including a 540 volume MAA of over 3.6 million pages
- 38 submissions to European, Australian and New Zealand authorities, and 15 CTDs.

On the other hand, no project is too small. From reports to Investigational New Drug applications, every project in both Europe and the U.S. has been completed on time and within budget, keeping our 100% success rate intact.

At our publishing centers, we manage projects from beginning to end, while ensuring the security of all proprietary information.

Beyond offering publishing support during peak submission deadlines, using *Liquent Direct* services helps minimize the risk of 'Refuse to File' notifications and ensures guidance-compliant submissions.

Outsourcing specific operations enables organizations to meet critical challenges such as augmenting staff for peak business cycles, allowing internal resources to focus on core competencies or alleviating the pain associated with reduced staff. Whether an organization performs a handful of submissions a year or many, having the right tools, hardware, software, and staff, when and where you need them, can make the difference in how fast a product development lifecycle advances. In this way, *Liquent Direct* can help life science organizations, whether they have one product in development or hundreds increase overall productivity, reduce costs, and speed time to market.

To find out more about *Liquent Direct*, please contact your regional Thomson Scientific office, e-mail us at liquent.info@thomson.com or visit:

www.liquent.com

Thomson Regulatory Solutions



Technology



Services



Intelligence

Critical support and guidance in a shifting regulatory landscape

The Thomson Regulatory Solutions Group provides **technology** to plan and manage your registrations, dossiers and documents, expert **services** to help you compile, design, write and deliver quick, accurate submissions, and the strategic **intelligence** to stay informed on your ever-changing regulatory responsibilities.

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