



WHY YOU SHOULD USE LIQUENT *DIRECT*

- Dramatically increase submission success rates
- Resolve resource constraints
- Reduce infrastructure and resource overhead
- Streamline internal processes
- Ensure guidance compliant submissions
- Access to regulatory expertise you may not have on staff
- Easily transform legacy data into an electronic submission

WHAT LIQUENT *DIRECT* DOES

- Develop regulatory strategies and identify submission options
- Create content for all submission types with content development services
- Perform quality assurance audits of source documents and regulatory submissions (print and electronic)
- Reduce submission preparation timelines by providing regulatory expertise gained from 15 years of working with clients and regulatory authorities
- Prepare FDA submission data (CRT)
- Convert submission data to CDISC formats
- Plan and prepare for regulatory authority meetings
- Prepare and file all types of applications from the investigational phase through commercialization including lifecycle updates

THE COMPLETE
REGULATORY SUBMISSION
PARTNERSHIP SOLUTION

LIQUENT *Direct*

PROFESSIONAL GUIDANCE IN THE SHIFTING REGULATORY LANDSCAPE

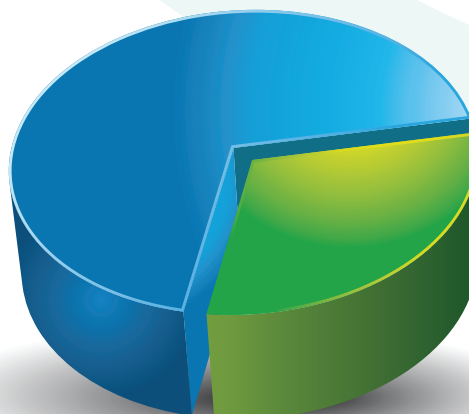
There are numerous steps to ensure that your regulatory submission will be accepted — get one thing wrong, and it could result in added costs and delays to your product's launch. LIQUENT *Direct*, an extensive collection of expert writing, outsourcing, staff augmentation, and educational services from LIQUENT, is designed to help organizations be successful in this process.

From start to finish — from initial protocol development, investigator brochures, report creation through submission filing — you'll have a trusted advisor on your side. LIQUENT's team of regulatory experts will analyze and define each phase of the project, allowing you to decide what assistance you need to supplement your resources. Then, when the correct plan has been agreed upon, we'll develop, implement and execute it, with your sign-off at every milestone.

Unparalleled Track Record

LIQUENT *Direct*'s 15 years of experience in all aspects of regulatory submissions is unmatched in the Life Sciences Industry. Whether it is tier1, mid-level or emerging pharmaceutical/biotech organizations, LIQUENT *Direct* has assisted organizations of every size to successfully achieve their submission goals.

- Supporting over 160 companies worldwide in over 2,000 projects
- Never receiving a Refusal to File
- Never missing a deadline
- Completing nearly 100 Original eCTD Applications
- Filing over 1,200 Lifecycle Sequences



- Regulatory Outsourcing
- Regulatory Consulting





Whether you need us to manage multiple, simultaneous submissions on an ongoing basis, or you want a complete, immediate solution to a one-time project, no task is too small, or too large. Many of our clients that utilize LIQUENT **InSight**[®] software also use LIQUENT **Direct** to supplement their regulatory submission knowledge and processes.

UNSURPASSED GLOBAL EXPERTISE

Whether LIQUENT **Direct** simply supplements existing resources at peak times, helps personnel acquire knowledge or provides complete submissions outsourcing services, we can help increase your efficiency related to achieving your project goals.

In today's ever evolving regulatory environment, LIQUENT **Direct** offers access

to recognized industry specialists that, when combined with proven software solutions, delivers compliant, timely and effective submissions to regulatory authorities throughout the world.

If you're preparing your first regulatory filing or just need help with your workload, LIQUENT **Direct** can help you with defining strategies and standards, improving internal processes, training, software tools, and regulatory expertise.

LIQUENT **Direct** specialists work with client teams to create the optimum solution for every situation. As industry experts in regulatory submissions (both electronic and paper), LIQUENT **Direct** combines technical competency with our industry leading software solutions together with extensive experience working with large and small clients in a variety of roles.

