DELIVERING QUALITY AND FLEXIBILITY WITH TAILORED SOLUTIONS

Life sciences companies across the globe face unprecedented challenges in meeting the increasingly stringent demands of regulatory submissions. CSC offers a full range of regulatory outsourcing services to save life sciences companies time and money by performing essential tasks on their behalf, which frees personnel to work on drug development or focus on other strategic projects.

CSC’s full range of business process outsourcing (BPS) solutions for global regulatory submissions deliver flexibility, scalability and, above all, quality. And, our global presence gives us a deep understanding of regional nuances so we can provide our clients with the insight and tools to guide their organizations to success.

KEY BENEFITS

Cost Savings. Staffing a regulatory affairs department is costly and labor intensive, and the work is inherently complex. By leveraging CSC’s regulatory submissions services, companies pay for only what they need, and get access to valuable expertise and experience that would be expensive to develop in-house.

Flexibility. CSC’s vast resources, deep experience and broad range of offerings give our clients the flexibility to choose solutions that meet their needs and budget. We have the capabilities to leverage different types of industry tools, and our deep experience in the ever-changing regulatory environment lets us stay ahead of the game.

Global Presence. With members strategically located around the globe, our regulatory submissions team publishes in all corners of the world. Clients benefit from the two-pronged capabilities of offshore support and local expertise. Our knowledge of the filing process and regulations at various agencies enables us to manage submissions across multiple geographies.

Quality. Our quality-first approach and close attention to detail make CSC the go-to provider for regulatory submissions services. Quality is built into every step of our review and submission process and ensured with a set of checks and balances. Our record demonstrates this unwavering commitment to quality.

Scalability. Our size and global presence enable our clients to scale up or down as needed and to leverage resources from the location that serves them best. Clients can use CSC’s regulatory submission services as an end-to-end solution covering all aspects of the process, or choose service components as needed.

Tailored Solutions. At CSC, we take great pride in working with our life sciences clients to gain their trust and satisfaction. Much of our success is centered on the ability to work with clients to identify what is required and tailor our solutions to meet those specific needs. We are also poised to adapt when necessary.
KEY FEATURES

Content Development
CSC’s content development capabilities range from a review of client-authored documents to more complex development of product and submission strategies, including writing and review of documents. Our services also include preparing briefing packages, regional documents, and correspondence. CSC’s submission support includes M2 summaries and M3 documents. Our reporting encompasses protocols, narratives and nonclinical documents.

Data Entry and Management
CSC employs a global team of publishers responsible for processing data entry requests, including any required data extraction and formatting tasks. Capabilities include entering and managing regulatory information management (RIM) and master data management (MDM) data. Our data management experts can also handle documentation involving identification of medicinal products (IDMP) standards and schemas, such as the extended EudraVigilance Medicinal Product Dictionary (XEVMPD).

Dossier Filing
CSC is deeply familiar with the electronic submission gateways (ESGs) at all agencies, and our experts stay abreast of changes in regulatory filing requirements. Once a submission is ready to be filed, CSC can guide the process and coordinate all steps required to ensure successful and timely submission. Our submission managers are well versed in all aspects of dossier filing, from media creation and verification to using couriers to transmit the paper or media materials required for submission.

Dossier Publishing
CSC provides document-level publishing capabilities with compliance navigation for submission of materials, such as clinical study reports (CSRs) and summaries. We can guide the publishing process for any format, including electronic Common Technical Documents (eCTDs), non-eCTD electronic submissions (NeeS) and paper submissions. Our services include review of documents and submissions, validation of submissions, post-application support, archiving and indexing.

Drug Safety
As it is essential to closely monitor the life of the product and ensure the quality of individual Case Safety Reports (ICSRs), CSC performs a full ICSR compliance review, as well as ICSR tracking and transmission to determine whether a complete picture of the drug experience has been documented. We are intimately familiar with electronic submissions, including the FDA Adverse Event Reporting System (FAERS) and CSR testing processes, and we provide support for developing periodic safety update reports (PSURs).

Formatting and Quality Control (QC)
CSC can handle submission materials from multiple sources and compile additional materials, such as appendixes. In addition, we can prepare writers and develop style guides to ensure consistency in formatting and a standardized document voice. Our dedicated quality services team provides an additional QC step to ensure that deliverables meet CSC’s high quality standards of a less than 1% error rate.

Regulatory Guidance
CSC’s regulatory consultants are distinctive. They have hands-on experience leading submission teams and the ability to form enduring working relationships with clients and regulators. Our regulatory strategists can work alongside a company’s in-house experts or serve as a company’s regulatory representatives to provide planning, strategic guidance and project management. We can perform comprehensive medical reviews and audits, submission analysis and verification, and coordination for translations and reviews.

CSC’S REGULATORY SUBMISSION APPROACH
At CSC, our focus is on quality. We take great pride in delivering high-quality regulatory submissions services to our life sciences clients. Our suite of services, carried out by subject matter experts, addresses the many complex issues involved with regulatory submissions. Our approach is to serve as a trusted partner that provides deep regulatory expertise and experience.

To date, not a single regulatory submission managed by CSC has been subject to an RTF action. This exemplary publishing record is a result of our rigorous quality process, modeled after the ISO 9001:2008 Quality Management System that includes standard operating procedures. Our close attention to quality ensures that projects comply with industry standards and meet our clients’ expectations.

To learn more about CSC’s Global Regulatory Submission Services, visit csc.com/life_sciences.

WHY CSC?
With operations ongoing 24x7 in more than 70 countries across the globe, we offer clients a local presence, as well as the ability to take advantage of established offshore centers. Life sciences companies wanting to go to market with their products in different regions of the world can count on CSC to help them do so as quickly as possible.

An ideal partner is one that can plug in on Day 1 and make an immediate impact, while adapting to ever-changing industry demands. CSC offers a proven, well-rounded suite of tools and services to address the complexities of regulatory submissions.

Many of our regulatory submissions experts have worked in the life sciences industry, and they know what it takes to navigate through the difficult process. Once a submission is ready to be filed, CSC can guide the process and coordinate all steps required to ensure successful and timely submission. Through it all, our chief focus is on achieving a workable balance between speed and quality.