

Transform regulatory processes for better patient care

DXC Business Process Services: Life Sciences

Optimize your regulatory submissions while reducing costs and enhancing revenue opportunities.

Life sciences companies are increasingly challenged by time- and resource-strapped environments, making it difficult, if not impossible, to achieve the right staffing balance to manage the ever-changing regulatory compliance requirements and the peaks and troughs of product submissions. Unique skills are often required at various stages of the process, making it profoundly difficult to make the right resources available at the right time.

Regulatory affairs and operations departments are faced with varying regulatory requirements paired with aggressive internal timelines to market their companies' products on a global level. At the same time, departments are faced with lean staffing and highly varying workloads, which are difficult to manage in a fast-paced environment.

Life sciences companies today need a partner that understands the business in its entirety, from operations to systems, and processes to goals. They need a sizable team of SMEs paired with a flexible yet robust technology infrastructure that can be implemented quickly. An ideal partner is one that can plug in on day one and make an immediate impact while adapting to ever-changing industry demands.

Save money, bring your products to market faster and focus your teams on what they do best

While 76 percent of large life sciences companies have tried to outsource regulatory operations, less than 20 percent of their budgets have been outsourced. When organizations need a credible and trusted partner to ease the resource constraints, they turn to a proven technology partner. DXC Technology helps life sciences companies transition from in-house regulatory publishing to fast and accurate outsourced services.

DXC Business Process Services: Life Sciences manage the life cycle of regulatory-related requirements from the beginning of the research and development process through product development, marketing and ongoing maintenance. DXC has a business process services solution that can increase your organization's efficiencies at multiple levels.

Get the right blend of life sciences and technical expertise to help you seize growth opportunities and facilitate process transformation.



DXC offers world-class, on-time metrics (>99.5 percent) and outstanding quality results (>99.7% right-first time rates).

DXC helps life sciences organizations save money, bring medicine to market faster and free up personnel to focus on strategic projects. We offer a full range of global regulatory submission solutions that deliver flexibility, scalability and, above all, quality. In addition, our global presence gives us a deep understanding of regional nuances to provide clients with the insight and tools to guide their organizations to success.

At DXC, we take our clients' needs very seriously and treat their problems as our own. We find the best-fitting solution to complete the task at hand in the most efficient and cost-effective way. We are not just delivering services to our clients, but also providing a long-lasting partnership. Our technology and services meet the highest quality standards in the industry.

Why partner with DXC Life Sciences for Business Process Services

DXC offers globally situated strategic teams and innovative software to proficiently support the various stages of the regulatory submission process, with our clients often achieving an average of 30 percent in cost savings. We can scale our involvement from simple staff augmentation to full-blown outsourcing of the entire regulatory operations department, so that your organization can focus on what it does best, such as creating innovative medicine that will help improve care outcomes and make patients' lives easier.

Examples:

- For a drug grossing \$1 billion per year, that's \$2.7 million per day. Every day an application is submitted earlier to the health authority means another \$2.7 million in revenue.
- DXC has saved major pharma companies 20 to 30 percent vs. in-house regulatory publishing while increasing quality and speed.
- DXC, along with Novartis, was the first company in the world to electronically submit a New Drug Application to U.S. Food and Drug Administration (FDA) in 1996. Working with our team gives you access to world-class software tools in the cloud such as eCTDExpress, Toolbox and Publisher.
- From simple staffing solutions to end-to-end outsourcing, DXC has you covered. Furthermore, in the 65,000+ submissions we've made to regulatory authorities, we've never received a Refusal to File decision.
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Delivering quality and flexibility with tailored solutions

DXC can address clients' needs in the most flexible, efficient and cost-effective manner, thanks to our expert team of industry professionals and our established onshore and offshore operating model. Regardless of whether you are using full or shared business process services, our team will be with you every step of the way to ensure that the job gets done. Our philosophy is to be your life sciences services partner, not just a service provider.

DXC Business Process Services: Life Sciences offer a proven, well-rounded suite of tools and services, including:

- **Document and dossier publishing.**

DXC provides document-level publishing capabilities with compliant navigation for submission 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. DXC also has specific knowledge of the document templates required in different countries' dossier formats.

- **Formatting and quality control (QC).** Another crucial aspect of the submission process is formatting documents correctly to meet submission requirements. DXC has the capability to handle submission materials from multiple sources and compile additional materials, such as appendices. In addition, we can develop writers' and style guides to ensure consistency in formatting and a standardized document voice. We can also conduct an advertising content review to ensure that promotional materials meet regulatory standards. Our dedicated quality services team adds another QC step to ensure that deliverables meet DXC's high standards of quality.

- **Dossier filing.** Once a submission is ready to be filed, DXC can guide the process and coordinate all steps required to ensure a successful and timely submission. Our project managers are well versed in all aspects of dossier filing, from XML verification to transmission of final

approved submissions through agency gateways. DXC is deeply familiar with the Electronic Submission Gateways (ESGs) at all relevant agencies, and our experts stay abreast of ongoing changes in regulatory filing requirements.

- **Post-marketing drug safety.**

Companies must accurately document human reactions to drugs submitted for approval. Therefore, it's essential to closely monitor reactions throughout the life of the product and ensure the quality of Health Level Seven International (HL7) Individual Case Safety Reports (ICSRs). DXC 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 reports (PSRs).

- **Data entry and management.** DXC employs a global team of publishers responsible for processing data entry requests, including required data extraction and formatting tasks. Capabilities include entering and oversight of regulatory information management (RIM) and master data management (MDM) data. Our data management experts also have the capability of handling documentation that adheres to Identification of Medicinal Products (IDMP) standards and schemas such as the eXtended EudraVigilance Product Report Message.



With members strategically placed around the globe, our regulatory submissions team publishes in all corners of the world.

Key benefits

- DXC employs a combination of local staff and well-established offshore services centers in major time zones around the globe, enabling flexible and efficient ways to address our clients' needs. DXC's services team is available for support 24 hours a day, 6 days a week. This ensures that we are available to quickly respond to a client's urgent request, often in less than a day.
- DXC's Business Process Services team consists of 200+ professionals with backgrounds in the pharma, biotech, IT and consulting industries who collaborate on best practices and quality to ensure consistency across the globe.
- DXC Business Process Services offer flexible solutions to meet our clients' requirements and needs, typically following two main workstreams. We offer end-to-end services and flexible solution models to address client requirements, such as high-peak coverage and process outsourcing, as well as requests for rapid project turnarounds.


Why DXC?

DXC delivers peace of mind and a cost-effective business process suite of services that lead to optimal business results. With more than 20 years of experience delivering state-of-the-art regulatory services, DXC has not only been first in many areas of publishing and compliance, but has worked with nearly every system on the market to enable regulatory compliance. This combination of experience, methodology and proven success, along with our keen focus on client return on investment, puts DXC in a unique position. When our clients succeed, we succeed.

DXC clearly understands the many challenges life sciences companies face when it comes to regulatory affairs.

Our suite of services, carried out by SMEs around the world, addresses the many complex issues involved with regulatory submissions. Several key attributes differentiate our offerings from others in the market. These include:

- **Cost savings.** Staffing a regulatory affairs department is costly and labor-intensive, and the work is inherently complex. By leveraging DXC's regulatory submissions services, companies pay only for what they need, and gain access to valuable expertise and background experience that would be expensive to develop in house.
- **Flexibility.** DXC'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 kinds of industry tools, and our deep experience in the ever-changing regulatory environment ensures that we stay ahead of the game.
- **Global presence.** With members strategically placed around the globe, our regulatory submissions team publishes in all corners of the world. Clients get the two-pronged capabilities of offshore support and local expertise. Our knowledge of the filing process and regulations at various agencies gives us the ability to manage submissions across multiple geographies.
- **Quality.** Our quality-first approach and attention to detail make DXC the go-to provider for regulatory submissions services. Quality is built into every step of our review and submission process and backed by a set of checks and balances. Our unprecedented track record demonstrates this unwavering commitment to quality.



Learn how to accelerate the regulatory process to get medicines and remedies to those who need them faster, which will lead to improved clinical outcomes and patient care.

- **Scalability.** Our size and global presence enable our clients to scale up or down as needed and leverage resources from the location that serves them best. Clients can use DXC's regulatory submission services as an end-to-end solution covering all aspects of the process or choose individual service components as needed.
- **Tailored solutions.** At DXC, we take 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 needs.

Experienced resources with global reach

As one of the leading business process services providers to the life sciences industry, DXC can help you seize growth opportunities and introduce new technology and solutions that can enhance care delivery and improve patient outcomes. We have established global centers of excellence in the United States, China and India, and each is supported by local resources.

DXC's team of experts includes former pharma, biotech, IT and consulting industry professionals, trained in different regulatory requirements and DXC-defined business processes

tailored to the life sciences services industry. DXC uses a quality process modeled after the ISO 9001:2015 Quality Management System standard, which is formally certified in the United States and China. Our first-rate system and proven business processes are reflected in the fact that our deliverables meet the highest quality standards in the industry.

Engage with a successful partner

By partnering with DXC, your organization has access to a variety of options that deliver immediate results and pave the way for agile scaling to meet your business needs. Businesses that seize the opportunity first can secure a competitive advantage and take a leading position in their market. Now is the time to start the conversation about improving your processes with DXC Business Process Services: Life Sciences.

Learn more at www.dxc.technology/lifesciences

 **Get the insights that matter.**
www.dxc.technology/optin

About DXC Technology

As the world's leading independent, end-to-end IT services company, DXC Technology (NYSE: DXC) leads digital transformations for clients by modernizing and integrating their mainstream IT, and by deploying digital solutions at scale to produce better business outcomes. The company's technology independence, global talent, and extensive partner network enable 6,000 private and public-sector clients in 70 countries to thrive on change. DXC is a recognized leader in corporate responsibility. For more information, visit www.dxc.technology and explore thrive.dxc.technology, DXC's digital destination for changemakers and innovators.