parexel®

Making your regulatory data work for you

Liquent InSight®

Let us put your data to work so you can get treatments to those who need them

Regulatory compliance requires generating and storing massive volumes of data. It's a necessary part of doing business. But what if, in the process, you also freed up valuable time to create, manage, analyze, communicate, and understand all that information? Once you have stored the reams of regulatory content you are required to maintain to meet compliance mandates, is it out of sight, out of mind? Or have you thought about using it to derive further value as information available to be mined? Why not use your regulatory data to learn from experience, anticipate regulatory requests, reduce time from study completion to submission – and ultimately, get treatments approved faster to help improve people's lives? Like the sound of that? Let us guide you on the way.

With Heart

Liquent InSight can help you transform your data into the lifeblood of your organization

The Liquent InSight platform supports regulatory information management (RIM), revealing and maintaining that treasury to enable your organization to go far beyond compliance – by activating that content to transform your operations.

Parexel offers not only the technology, but also the people and process expertise that will help you realize the value of your investment along the product lifecycle. Whether your company is a start-up with a germinal concept for treating an unmet need, a midsize firm poised for market expansion, or a multinational corporation with a broad portfolio, Parexel's scalable offerings will help meet your requirements. And we'll stay with you as your trusted partner for as long as you need us.

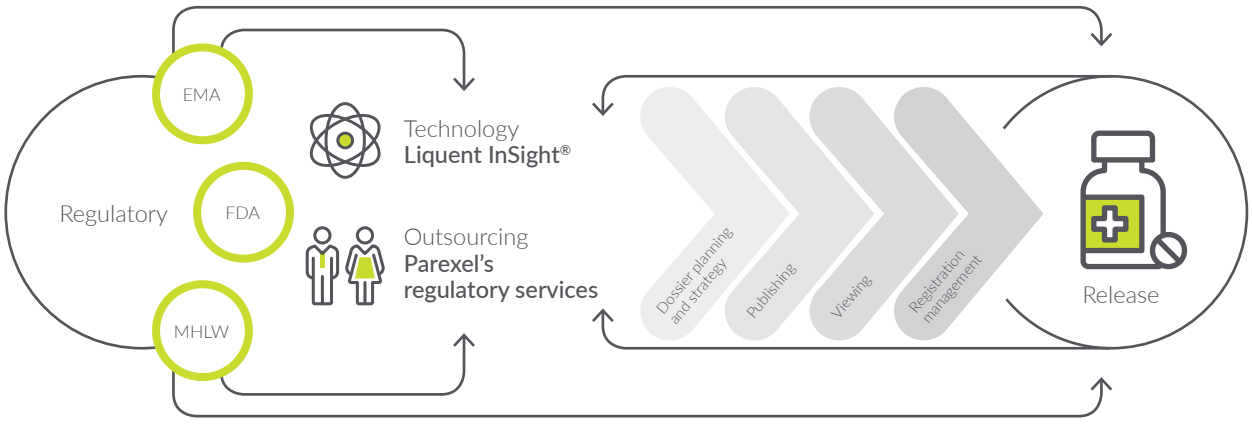
Let's look at regulatory intelligence in an entirely new way

Deriving insights from massive volumes of data is not a new concept. In fact, organizations across all industries recognize the immense value of their data when sophisticated analytics are applied. So let's start thinking about regulatory content in an entirely different way – not just as a mandated element of compliance, but as a priceless treasury of information to support process improvement and decision-making.

Simplifying and streamlining, providing intelligent insights, and easing the burden of compliance

At Parexel, we define RIM as a discipline created to support end-to-end regulatory processes. Even as regulations and agency requirements continuously evolve, the basic processes have not actually changed much. Despite the increasing complexity of the design and function of medicinal products and devices, and the ever-growing role of technology in drug-delivery systems, management of regulatory information generally follows a standard process.

This concept is essential to understanding the true value that the Liquent InSight solution provides and is intrinsic to its longevity as a leading RIM platform. The value comes in the many ways the Liquent InSight platform can be used to simplify and streamline the very complex processes involved in day-to-day operations, to provide intelligent insights, and to ease the burden of maintaining compliance.



Our technology continues to lead the industry

The best practices that are fundamental to the RIM discipline form the heart of the InSight system. These processes have been industry tested with our clients.

Our solid structure is agnostic to the source repositories that may be used to enhance and feed it with regulatory data, and therefore works with your preferred enterprise content management system.

Structural agility is essential, since many different types of biopharmaceutical products commonly need to be tracked simultaneously. Data fields differ for each product type – for example, a medicinal treatment versus a diagnostic. Yet even though processes are complex, thousands of people will interact with your RIM system, making usability essential. Liquent InSight is designed with that in mind, with continuous updates to incorporate productivity tools to support efficiency, starting with the launch of Liquent InSight for Office 365 in 2019.

Liquent InSight is also robust in managing process data – the proper relationships of data and processes and a design that captures the nuances of a workflow are critical. Process data encompasses, for example, dates and progress status. Workflow information can track users who are performing various tasks, as well as actual work time, to determine issues and increase efficiency.

Now, you can leverage this operational data to generate detailed reports and define business-critical metrics and indicators to measure performance objectively. Integration with Microsoft's Power BI is an essential building block in providing key insights about your data. Using at-a-glance dashboards, you can see information that impacts your business in real time to support decision-making.

At the heart of the Liquent InSight platform is a robust, highly agile, and enterprise-tested data management structure and logic engine for defining products and managing the regulatory lifecycle.

Let our implementation experts guide you along the way

Building in the proper data-process relationships, capturing nuances, defining metrics, generating reports… this is where our implementation experts are an essential element of the RIM discipline.

When we begin a relationship with your organization, we work closely with you on strategy and planning, and on understanding your objectives and your company- or product-specific workflows throughout the entire product lifecycle.

Master your product data with Liquent InSight – complete regulatory information lifecycle management

Our implementation specialists help bring new efficiencies to your processes to enable you to derive insights with sophisticated analytics that can inform other products in development and future initiatives. For example, you can see the pathways that led to a successful filing and duplicate them elsewhere. Detailed information captured in the manufacture and labeling of one chemical compound becomes a key component in change control and managing large-scale manufacturing information and compliance.

Helping you stay future-ready; building the latest requirements into new releases

Just as regulatory compliance is a fact of life in our industry, so too is constant change in regulatory requirements.

To cite one current example, the European Union (EU) Clinical Trials Regulation 536/2014 coming into effect introduces fundamental changes to the submission process for Phase I to IV interventional clinical trials. We have been anticipating sponsors' need for support in adapting to the new regulation since its initial publication in 2014. Since then, our consultants have been proactively monitoring the national implementation strategies and readiness of EU member states.

This is simply one example of how our surveillance on new guidance can help you stay ahead of new data initiatives from regulatory agencies. New releases of Liquent InSight accommodate new regulatory changes that our customers need for compliance. In short, we enable you to respond quickly to requests for more and different types of data, building the data structure into the RIM platform so it's relevant to your products and workflows.

We are helping to transform our client's regulatory operations – designing a platform to support not only today's reality, but also the realities of the future.

Our technology partnerships are part of our commitment to, and passion for, innovation

Liquent InSight runs in the Perceptive® Cloud, offered by Parexel in alliance with Microsoft – indicative of our longstanding and ongoing drive toward innovation. Built on Microsoft Azure, an open, enterprise-grade, secure cloud computing platform, Perceptive Cloud brings together Parexel's global biopharmaceutical expertise with Microsoft, the world's largest software company. This enhanced cloud architecture is designed to deliver cost-effective innovation while safeguarding sensitive information, and ensuring that data are properly managed and protected in a dedicated, private environment.

Join the industry leaders who we've already helped to succeed

As one of the leading global biopharmaceutical services organizations, we are respected worldwide for our comprehensive product development and commercialization support. The industry's top 20 companies all run Parexel technologies as a trusted foundation of their clinical and regulatory infrastructure.

For more than 35 years, Parexel has defined advisory excellence and innovation. This reputation enables us to attract some of the finest leaders in the industry: people who have, for example, served in policy development and decision-making roles with regulatory agencies including the U.S. Food and Drug Administration (FDA), European Medicines Association (EMA), and National Medical Products Administration in China (NMPA).

We take great pride in our ongoing endeavor to engage our clients with the ever-changing and fluctuating needs of the regulatory environment, providing advanced technology, people and subject-matter expertise to meet their various needs. Our focus is on helping you succeed.

Activity volume from four example Liquent InSight customers*:

160,800
applications

165,000
product detail sets

1.9
million events

173,500
registrations

495,500
sequences

9.8
million leafs

*Based on four top 20 pharma client datasets

Change the way you work

Parexel and Microsoft together are delivering new capabilities to the market which will change the way you work.

Liquent InSight for Office 365 surfaces key tasks and workflows directly within Microsoft Office 365, bringing InSight functionality to where the users already work.

Through system automation, machine learning, and “smart” templates, Liquent InSight for Office 365 brings exciting productivity innovations for the users of Liquent InSight, simplifying the job of RIM.

Here's what the Liquent InSight RIM platform includes:

- **Product and registration management** to track licensing information across geographies, along with specific details related to the licenses
- **Submission management** to track the planning, submission creation, sending and approval of regulatory actions, both for individual agency submissions and across geographies
- **Dossier planning** to create and manage assemblies to support global submissions, with workflows ensuring that the right documents are attached in each assembly package of content for a specific region or purpose (and connect to electronic document management systems and fileshares)
- **Submission publishing**, which puts the assembly content in a compliant published output to send to the authorities, with tools that can publish globally, electronically, eCTD, and paper from a single assembly
- **Dossier viewing** for review, consumption, and collaboration of existing dossiers
- **Analytics and reporting** to break down information silos and enable flexible, easy and intuitive query and visualization
- **Regulatory updates** to support the latest requirements, including creating XEVMPD and IDMP files and inclusion in submissions and tracking
- **Content management** to define products and manage workflows. This content management element serves as the content repository – the single source of truth – that unifies clinical and regulatory documents. Companies often use the content management component as a product master file or a master data management tool

Your Journey. Our Mission.®

We're always available for a conversation

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