Maintain control over your regulatory path and mitigate compliance risks

Regulatory Services

Regulatory and Access

Our team is here to help you navigate today's regulatory environment

The drug development and manufacturing journey has been disrupted. Globalization has brought extended supply and value chains, exposing developers to risks beyond their control. Patient power has grown, creating a new cohort of stakeholders whose voice must and will be heard. Scientific advances have changed the way that clinical trials are designed and run. And payers are scrutinizing drug costs and their benefits much more closely than ever before. We're here to support you in your quest to get new, much-needed medicines to patients, quickly.

With Heart

In today's environment, knowledge needs continuous updates. At Parexel, we keep pace with developments to help shape and implement new regulations

We'll help you accelerate your therapy's journey

Our unmatched regulatory and commercial expertise is over 35 years in the making. That's why you can be sure that we will help you maintain control of your regulatory pathway. Let us help you start planning early to maximize the value of your clinical trial data, and convert end-to-end clinical development and commercial expertise into actions that speed the delivery of your therapy to the patients who need them.

Because knowledge can quickly become outdated in an environment like this, it's more important than ever to work with professionals who are continuously updating their knowledge in complex product development and applying that knowledge to help both shape, and implement new regulations. That's Parexel.

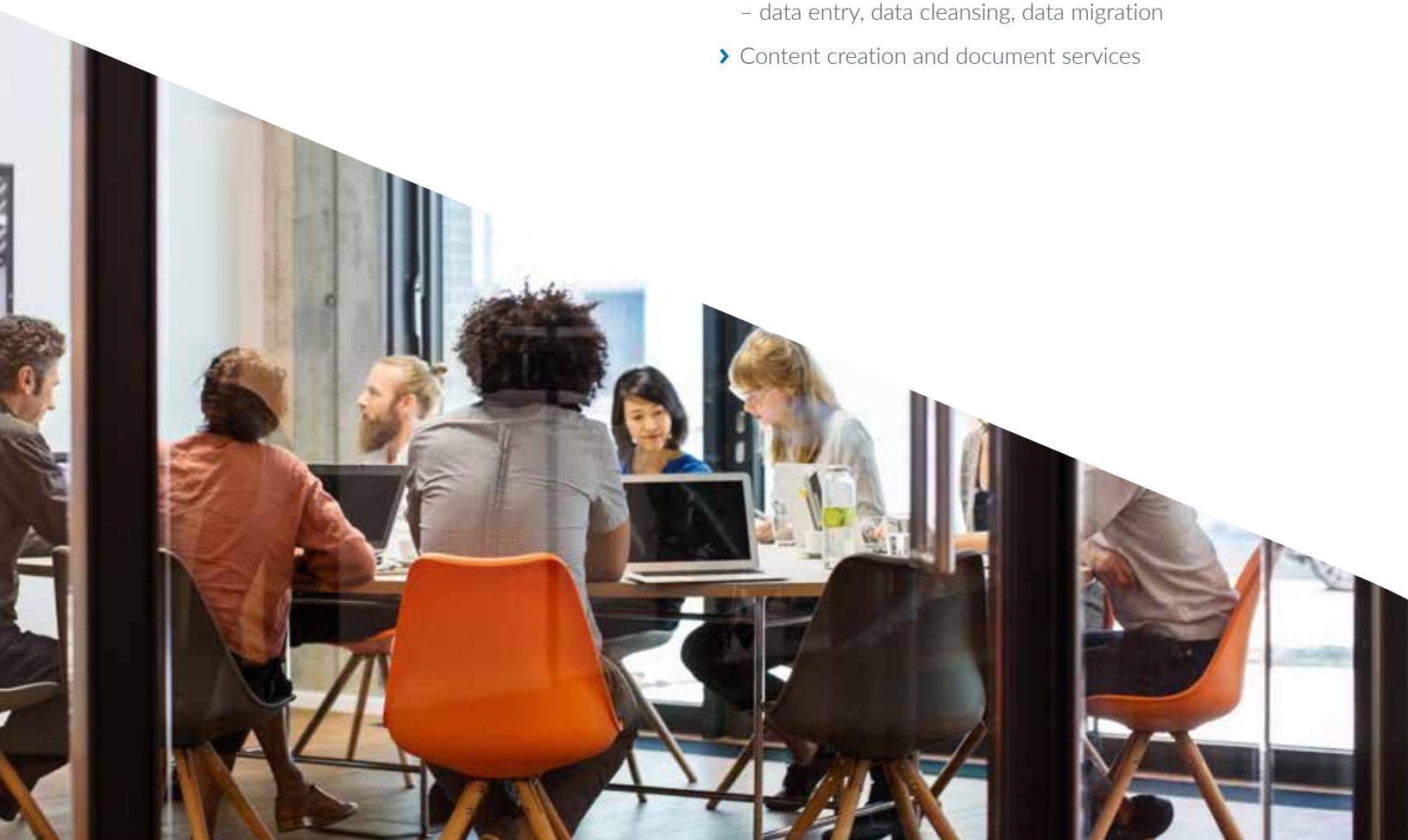
Take a look at our consulting services

Regulatory Affairs support

- Regulatory strategy: global product development strategy, clinical, non-clinical, CMC and regulatory gap analysis, due-diligence, product and indication prioritization, regulatory pathway optimization and acceleration strategy, global labeling (CCDS updates), marketing authorization applications (US, EU, China, Japan, Canada and emerging markets-ROW), submission planning (eCTD), patient-focused development
- Health briefing authority meetings: preparation support, briefing documents, rehearsals, meeting attendance and health authority liaison
- Quality systems: inspection strategy and inspection readiness
- Strategic compliance and risk management: facility remediation and audits
- Submission support: storyboarding/key messaging, core submission preparation and authoring, original application publishing with lifecycle maintenance, lifecycle publishing, global dossier management, RTQs, CTA core dossier development
- Stakeholder management: drug safety, technical operations, medical, commercial, CMOs
- Mergers and acquisitions: planning, submission authoring, dossier collection and stakeholder management

Regulatory Operations support

- Investigational submission management
- Regulatory dossier compilation, publishing and dispatch
- Investigational submissions and lifecycle maintenance
- Market authorization submissions and lifecycle maintenance
- Post-approval lifecycle maintenance
- Report compilation and publishing and archiving
- Regulatory information management – data entry, data cleansing, data migration
- Content creation and document services



We have the most experienced professionals ready to guide you

50+
former regulators
from around the world

110
countries covered

15+
global development plans per year

Meetings with
80+
global regulatory authorities
(FDA, EMA, PMDA, CFDA, etc.) per year

100+
marketing applications and submissions
(NDA, BLA, ANDA, MAA, JNDA, 501(k), etc.) per year

1,000+
regulatory experts

1,350+
annual product reviews and annual reports
written and submitted per year

We'll help you optimize your regulatory pathway to maximize the value of your product

Regulatory strategy and development planning

Our aim is to help you maintain greater control over your regulatory path and mitigate compliance risks, especially when pursuing worldwide launches. Our experts can provide an intimate knowledge of requirements in different markets and help chart the best path for you. We can interpret and support implementation of diverse regulatory guidance all around the world, including in new high potential markets such as China.

Our Regulatory Consulting Services group contains experts with decades of regulatory experience from the FDA, EMA and other regulators. They have deep industry experience in drug development and can offer insights into the competitive landscape, helping your teams interpret new and existing guidance at every step, in any location in the world.

Our former FDA, EMA and NMPA regulators have the expertise to help you avoid delays

Regulatory compliance

Our global compliance team are here to help you resolve regulatory issues. It's vital that you have the trust of regulatory agencies, so let our Strategic Risk and Compliance Management team help. They can guide you through remediation and data integrity audits, and help shift compliance responsibilities from regulatory agencies to drug manufacturer, to give you first-mover advantages with proactive, built-in compliance.

We have expert-led agency readiness services to help assure that high-quality, timely dossiers are submitted, and cGMP-compliant facilities are used to ensure regulatory success.

We can help you ensure readiness while controlling the costs of mature programs

Regulatory partnerships

Let us take the effort, uncertainty and overhead out of managing mature products. We will match the requirements of each drug in your portfolio to the skills of our team. Having an experienced regulatory operations team working on your behalf ensures maximum readiness and data integrity for any regulatory inspections. It also positions you to take advantage of regulatory reforms as they happen.

Maximum flexibility with minimum disruption

Whether you need a few people to review and scrub data for consistency, a global network of experts schooled in emerging offshore regulatory concerns, or something in-between, our team is always ready to serve. We only charge for the resources you need – and only when you need them. If your needs change mid-stream, we will add, remove or redeploy staff as required.

We'll help you improve your forecasting for greater efficiency

With Parexel, you'll always get the latest thinking and technological advances on your projects, with the attention of experts in on-going licensing support. We'll also streamline business processes. Switching from a full-time employee model to a unit transactions model will help you better understand the true effort put into meeting regulatory needs. Coupled with our regulatory information management software that tracks regulatory effort over time, you'll also be able to create more accurate forecasts, estimates and budgets.

We'll help you submit timely, cost-effective, compliant applications anywhere in the world

Clinical Trial Regulatory Services

Parexel's Clinical Trial Regulatory Services can provide you with a seamless global footprint. Whether you're using the latest medical technology or submitting in ascending regions such as Asia, our experience ensures the journey is smooth. Our innovative, centralized solutions have revolutionized the collection, management and sharing of data.
By coordinating multiple, simultaneous submissions with Parexel's Clinical Operations, we help you achieve fast trial start-up and follow-through. We also offer labelling services, either standalone or integrated into a full-service clinical trial management solution. So you can have anything from single labels to a full library, wherever you need them.

You may be working with multiple partners on your study. That's fine. Our processes and solutions can fit in with that. Whether you, Parexel, or a third party manages the trial, our Clinical Trial Application hubs are completely flexible with fast, cost-effective submission solutions. From clinical trial submission plan, assembly and application management through delivery to trial master archiving, all steps reside in the hands of one dedicated team.

Combine your experience with ours to accelerate your drug development journey

Ready for a faster, smoother development journey? So are we.

Your Journey. Our Mission.®

We're always available for a conversation

www.parexel.com/regulatory

To learn more about our Regulatory Services, please contact:

Parexel International Corporation
195 West Street, Waltham, MA 02451, USA
+1 781 487 9900
info@parexel.com

Offices across Europe, Asia, and the Americas
www.parexel.com

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