Maximize the efficiency of regulatory operations with five key competencies

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More than a year since the COVID-19 outbreak began, the pharmaceutical industry has shifted its focus to vaccine development for infectious diseases while continuing its pre-pandemic efforts to develop novel innovations to address unmet needs across a broad spectrum of indications. Large and small firms alike are now directing top talent and resources, including regulatory, to those efforts.

At the same time, companies cannot afford to neglect the mature products that provide the revenues to fund R&D. One way to balance these conflicting demands is to streamline the regulatory maintenance of approved products. By honing these five competencies, companies can manage post-marketing regulatory requirements better and more efficiently:

1 Operational excellence

There are two primary elements to regulatory compliance - submitting high-quality documentation and doing so in a timely manner. Typically, global regulatory affairs staff at the headquarters support filings in all markets. They produce a global submission dossier and gather the required supporting documents, such as good manufacturing practice (GMP) and certificate of pharmaceutical product (CPP). Central coordination of regulatory operations represents best practice because it allows for strategic management and oversight.

Centralizing regulatory operations is not sufficient to guarantee efficiency. Centralized compliance processes that involve too many steps or sign-offs will still interfere with continuous improvement efforts. The solution is to establish harmonized processes for all products and regions to produce consistent regulatory dossiers and accurate, compliant registration tracking.

Mergers and acquisitions present significant additional challenges for regulatory operations. The maintenance processes, systems, and vendors surrounding acquired products are likely different than those used for

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in-house products. If those disparate elements are retained, the resulting complexity and heterogeneity can produce regulatory submissions of inconsistent quality, detail, and style.

To avoid that pitfall, organizations should apply the same processes and systems to every product in their portfolio, no matter its origin. Centralizing support for functional administrative tasks such as registration tracking and publishing can strengthen accuracy and consistency. Companies should assess whether they have the internal capacity to keep up with all applicable regulatory requirements and hire external resources if needed.

As companies revise their commercial plans, they must consider the downstream repercussions, including modifications to the supply chain, packaging changes, label expansions, or new country approvals. Companies need to determine what type of regulatory submissions are required to support any such changes for specific products and markets. They should develop comprehensive plans to compile, publish, and submit applications to the relevant regulatory agencies.

2 Data management

Companies can achieve better compliance and reduce costs by adopting master data solutions and integrating workflow-enabled systems. That way, any proposed changes to products could be linked seamlessly from change control to all impacted dossier sections and all the way to published regulatory submissions.

By centralizing data entry, companies can consolidate and clean their data to establish a single source of truth. Regulatory safety, quality, and manufacturing teams can then use the same data sets, boosting cross-functional interactions and driving down error rates.

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In Europe, for example, Qualified Persons (QPs) must certify each batch of drug product before it is released. Instead of QPs sifting this data manually, companies can improve the efficiency of the certification process by giving QPs direct access to the automated data within their Regulatory Information Management (RIM) systems.

Companies can use structured authoring and AI solutions to prepare submission documents faster and more consistently. Intuitive systems can create draft content plans and prepopulate the relevant dossier sections, significantly reducing the hands-on time that regulatory professionals need to spend on each submission. Smaller biotechs with fewer products may find it more cost-effective to use external resources instead of building and maintaining an in-house team of regulatory publishing experts with the necessary geographic reach.

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Many companies could make queries more efficient and populate templates more quickly and easily by improving the way they structure their data. In some cases, companies do not have any structured templates for regulatory submission documents. By structuring their data and creating proprietary templates, companies can automate some steps in the regulatory process and conduct faster, more thorough impact assessments.

The often-postponed Identification of Medicinal Products (IDMP) legislation is now slated for 2022. When it launches in Europe, IDMP will increase data submission requirements substantially and impose new requirements on how companies structure their data. These changes to submission formats and data flows will have a significant impact on marketed products. Companies can get ahead of the IDMP curve by structuring their data now rather than scrambling to do so when the new regulations come into force.

3 Regulatory expertise

Regulatory statutes and requirements differ among countries, regions, and localities. And they continuously change, which has an impact on both mature and pipeline products. Accordingly, companies need both the tools and expertise to meet regional requirements. For example, the electronic Common Technical Document (eCTD) has recently expanded to China, Taiwan, and the Eurasian Economic Union. To utilize eCTD, regulatory staff need to know the submission specifications, translation requirements and be proficient in local languages.

By analyzing their baseline regulatory footprint to map out where they have internal resources on the ground or trusted vendors and distributors, companies can pinpoint any gaps. Then they can decide whether to outsource certain regulatory tasks or hire talent to bolster their capabilities.

In some countries, there could be a strong business case for building an internal regulatory team. At the same time, in other geographies, companies will likely find it more cost-effective to work with external partners. Suppose a company has a product on the market in 130 countries. In that case, the product's revenue stream likely will not be big enough in every one of those countries to support an internal local regulatory group.

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The best approach is for companies to consider their international strategic objectives over the next 5 to 10 years and then build out the regulatory expertise to meet those goals. For example, if a company wants to launch products In China, it will need to devote sufficient resources to support that effort across its portfolio. Since China proposed mandatory eCTD submissions, companies and regulators have been on a steep learning curve, and regulatory expertise to optimize regulatory submissions in China is scarce. In the short term, companies could fill that gap with vendors, but building internal expertise in China may offer a strategic advantage in the long term.

4 Integrated development

The best way for regulatory affairs teams to maximize efficiency and maintain compliance is by integrating their work with the efforts of clinical, safety, technical, manufacturing, commercial, and supply chain teams. This integration depends on well-defined processes and contact points for each business function, alongside a framework for regular communications and coordinated action. Patient health depends on these interdependent groups functioning in harmony to ensure an uninterrupted supply of drugs that complies with all safety and quality regulations.

What are the implications if a company decides, for example, to switch from manufacturing a drug in the UK to sourcing the product from a less expensive facility in India? If multiple products contain the same active pharmaceutical ingredient (API), there can be massive downstream consequences from switching the manufacturing site.

Before making such a change, companies must engage a cross-functional team capable of evaluating and answering vital questions such as:

- What are the regulatory approvals and associated timelines needed for the API manufacturing change across dozens of markets?
- How long will the technical operations group need to perform QA/QC testing on the new API?
- How much inventory will be needed (and how long will it take to manufacture) to ensure the supply chain functions smoothly without interruptions during the changeover?

Companies often assume that mature products can be easily maintained through the repetition of routine operational tasks. Unfortunately, this is often not the case. A product that has been on the market for years might suddenly produce a new adverse reaction. In that case, the product label may need a significant revision, which requires tight coordination among multiple groups, including:

- The safety team that collects the raw data
- The regulatory team that files the updated label submissions globally
- The packaging team that redesigns the label with additional information
- The medical information team that updates physician materials
- The manufacturing team that produces new batches with the revised labels
- The supply chain team that has a limited time to track down all batches of the product with the old label and relabel or discard them

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We strongly encourage cross-functional collaboration to improve efficiency and ensure that regulatory activities support the larger strategic plan and get patients the medicines they need.

5 Cost control

Companies often struggle to predict the volume and total cost of global regulatory submissions for both marketed and pipeline products. As a result, they tend to estimate FTEs on the fly rather than using planned activity data. A lack of transparent pricing models and accurate budget forecasting makes it difficult for them to control costs.

Outsourcing regulatory functions compel companies to improve the way they plan and allocate resources because costs align with trackable vendor activities. For example, instead of paying 50 full-time employees to handle 200 products, they pay for regulatory maintenance on an itemized basis with per-product breakdowns. This level of detail and transparency helps companies make more informed decisions and gives them a deeper understanding of actual costs.

At Parexel, when we partner with a client to manage multiple products across dozens of countries, we provide detailed metrics on the regulatory submissions required to keep that portfolio in compliance. Companies can easily see whether product maintenance costs outweigh revenues in a particular market and decide whether to exit that market. Annualized cost projections help companies plan and invest strategically, rather than putting out fires or experiencing unexpected shortfalls.

Structure regulatory operations to maximize ROI

Regulatory teams play a vital role in every pharmaceutical company. When appropriately structured to execute well on all five core competencies, regulatory affairs can run smoothly and efficiently. More than that, regulatory excellence can help companies make informed, data-driven decisions about where to focus resources to achieve major strategic goals.

A partner you can trust

With a 35+year heritage supporting regulatory services, Parexel can help you navigate complex global regulations, compliance, and continuity of supply for your products. Whether you are looking for a few regulatory specialists to scale up existing operations or a whole team of experts, we have the global infrastructure and local knowledge to meet your needs – taking effort, uncertainty, and overhead out of managing your products. Visit **www.parexel.com/regulatory-outsourcing** to learn more.

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