White Paper

The Future of Regulatory Operations

Adapting to emerging trends in lifecycle management for biopharma

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Table of contents

Introduction **2**

- Why is implementing proactive regulatory strategies important when considering how to optimize an asset over its lifecycle? 2
- Is the approach to regulatory strategy and regulatory affairs different among companies of different sizes? 3
- What are the key trends driving regulatory strategy decisions in 2024? 4
- How is the lifecycle management workstream evolving to improve reliability? 4
- How is automation in publishing and labeling changing? What does this mean for investment in some of these different technologies? 4
- What trends are you seeing in terms of flexible operational models? 5
- What makes a good regulatory operations strategic partnership and how does that benefit an organization over a tactical fee for service work alone? 5
- How can regulatory providers manage and improve collaboration with an organization? 5
- How are advanced analytics improving insights in labeling and publishing specifically as well as other areas of regulatory affairs? 6
- What sorts of governance structures are organizations implementing to ensure continuous improvement in lifecycle management and other areas of regulatory affairs? 6
- If a client is looking for help with their labeling strategy amid a legal entity change, what steps would you recommend to stay compliant? 7
- How do you see AI and ML technologies augmenting human expertise in regulatory operations in the next year? 8

About the authors **9**

About IQVIA **10**

Introduction

Building a robust and adaptable regulatory strategy to ensure proper lifecycle management for a therapeutic is a critical step for biopharmaceutical companies. Depending on the size and budget of a company, sponsors have the option to conduct their regulatory management in-house or partner with an experienced regulatory services provider. In a recent panel discussion, IQVIA Regulatory Affairs, and Drug Development Solutions leaders, Marcela Miño, Senior Director and Global Head of Lifecycle Management; Rama Mohan Rao Chikkam, Senior Director of Global Regulatory Operations and APAC RA; Keith McDonald, Head of Drug Development Strategy; and David Cameron, Senior Director and Global Group Head, Novel Trial Design Solutions, discussed emerging trends in lifecycle management, labeling, and publishing, and how drug developers are adapting their regulatory strategies to accommodate them.

Why is implementing proactive regulatory strategies important when considering how to optimize an asset over its lifecycle?

Miño: Due to the nature of regulatory lifecycle maintenance and regulatory operations, it is key to have a strategy that includes all stakeholders and helps you succeed in planning and execution. It also requires consideration of the regulatory strategy not only in terms of lifecycle management and operations but also in manufacturing, supply chain, artwork creation, labeling updates, and pharmacovigilance. Embedding these factors into the regulatory strategy is essential for planning what is needed across the organization and executing that plan accordingly.

Chikkam: Creating a regulatory strategy in advance will help identify potential issues early, reducing the risk of delays and setbacks during the asset's lifecycle. You should consider the evolving regulatory landscape, identify potential regulatory hurdles, and implement risk management strategies. By taking a proactive approach, companies ensure their assets are optimized for success.

McDonald: Regulatory strategy impacts the pathway to approval and continues to influence post-approval regulatory compliance. For example, an expedited regulatory approval approach may be viable, and if that approval is based on surrogate endpoints, then post-confirmatory studies would likely be a condition of that approval. You should also think about the use of early access or expanded access schemes that might be considered when a product addresses an unmet need and allows real world evidence to be collected to support a subsequent health technology appraisal.

ICH quality guidelines have provided options for a risk proportionate approach to post-approval, change control, and reporting. In some regions, there are opportunities to include design space or established conditions that significantly reduce post-approval filings or downgrade prior approval to notification.

Is the approach to regulatory strategy and regulatory affairs different among companies of different sizes?

Miño: Yes, this is due to a company's global footprint, markets of commercialization, and how those factors impact the size of their regulatory team. In general, smaller companies start with their own regulatory team and centralize it in specific critical markets. When they start to span other geographies, they either have new subsidiaries or opt to find a local partner to support local activities. Medium to large pharmaceutical companies are already spread across multiple countries. Some may have their own regulatory structure but will need support when expanding into new markets and new geographies. Having a huge in-house regulatory team may prompt a sponsor to consider looking for solutions outside of the company.

Chikkam: Smaller organizations could have limited resources that require them to outsource their regulatory activities or rely on external regulatory consultants, whereas larger organizations may have more resources to invest in regulatory compliance and strategy development. Larger organizations may also have extensive regulatory affairs activities to manage. These companies tend to outsource operational regulatory activities to reduce their burden and concentrate on strategic initiatives.

"Regulatory strategy impacts the pathway to approval and continues to influence post-approval regulatory compliance."

— Keith McDonald, IQVIA

McDonald: All organizations are interested in the most efficient pathway to the marketplace and rapid patient access to novel therapies. Small organizations may also be able to benefit from incentives in certain jurisdictions. That said, organizations tend to target particular markets for first approvals, and as the geographical outreach of those approvals expands, the resources required for maintenance of compliance across multiple geographies increases.

Cameron: Mid-size organizations typically haven't made huge investments in technology, so the strategy tends to take on a different bent, whereas larger organizations are typically well invested in technology and looking for a hybrid model. Mid-size organizations sometimes bundle regulatory partnerships with other functional areas, including niche expertise they may not have in house.

What are the key trends driving regulatory strategy decisions in 2024?

McDonald: Changes across the global regulatory landscape will have an impact on strategies. These changes could include:

- A new international recognition scheme launched in January 2024 in UK; not only will this influence how companies strategize their filings for the UK, but it could also affect how authorities consider reliance on other global regulators.
- The addition of the EU as an observer with the FDA Project Orbis.
- Joint consultation pilot in Europe between regulatory authorities and HTA [health technology assessment] bodies in preparation for the mandatory joint scientific consultation in 2025.
- A new clinical trial regulatory framework implemented in the UK.
- The EU completing its transition from CTR [Clinical Trials Regulation] for ongoing studies by 2025.

How is the lifecycle management workstream evolving to improve reliability?

Miño: The pathway to enhancing reliability and efficiency requires embracing technology and process improvement. For lifecycle management activities, which involve multiple regulatory submissions, different product types, and different countries, it is critical to ensure that standardized processes and up-to-date regulatory intelligence are used. It is also fundamental to guarantee compliance and first-time-right submissions.

AI [artificial intelligence] tools provide reliable, real-time intelligence, allowing faster work and a single source of truth. Continuous improvement should be a central part of the culture of a company. Encouraging teams to raise ideas that could improve existing processes is fundamental for partnership success. Working this way in conjunction with technology enables customers and teams to continuously evolve and improve.

"With increasing regulatory data and strict deadlines coming from health authorities, companies are investing in automation to streamline their processes, reduce risks, and ensure there are no rejections, especially in the publishing process."

— Rama Mohan Rao Chikkam, IQVIA

How is automation in publishing and labeling changing? What does this mean for investment in some of these different technologies?

Chikkam: With increasing regulatory data and strict deadlines coming from health authorities, companies are investing in automation to streamline their processes, reduce risks, and ensure there are no

rejections, especially in the publishing process. When it comes to the creation of initial regulated documents, automation enables quick generwwwation of package labeling inserts and product inserts using templates and automated workflows. This not only saves time but also reduces risk since the system will automatically validate the data and achieve compliance with health authority requirements.

Most companies have started using machine learning [ML] and natural language processing [NLP], which automate the process of identifying and extracting information from source documents. This reduces the need for manual data entry and enhances accuracy and efficiency. Companies are also investing in automation tools and platforms like document management systems, labeling software, and automated publishing tools.

What trends are you seeing in terms of flexible operational models?

Cameron: We see three types of models from our customers:

1. A staff augmentation where resources are provided and assimilated into the client's organization.
2. Functional service provider outsourcing, which takes certain resource development responsibilities and shifts them to the partner.
3. A typical full-service model where the partner provides all services and deliverables.

Once the right model is chosen, there are several flexible elements: pricing, oversight, accountability, governance, and geographic and organizational alignment. Sometimes we have partnerships that have broader, deeper strategic types of governance models that we need to fit into. The goal is to meet the client where they are and create the best model to reach their objectives while also being able to flex rapidly as customer objectives evolve.

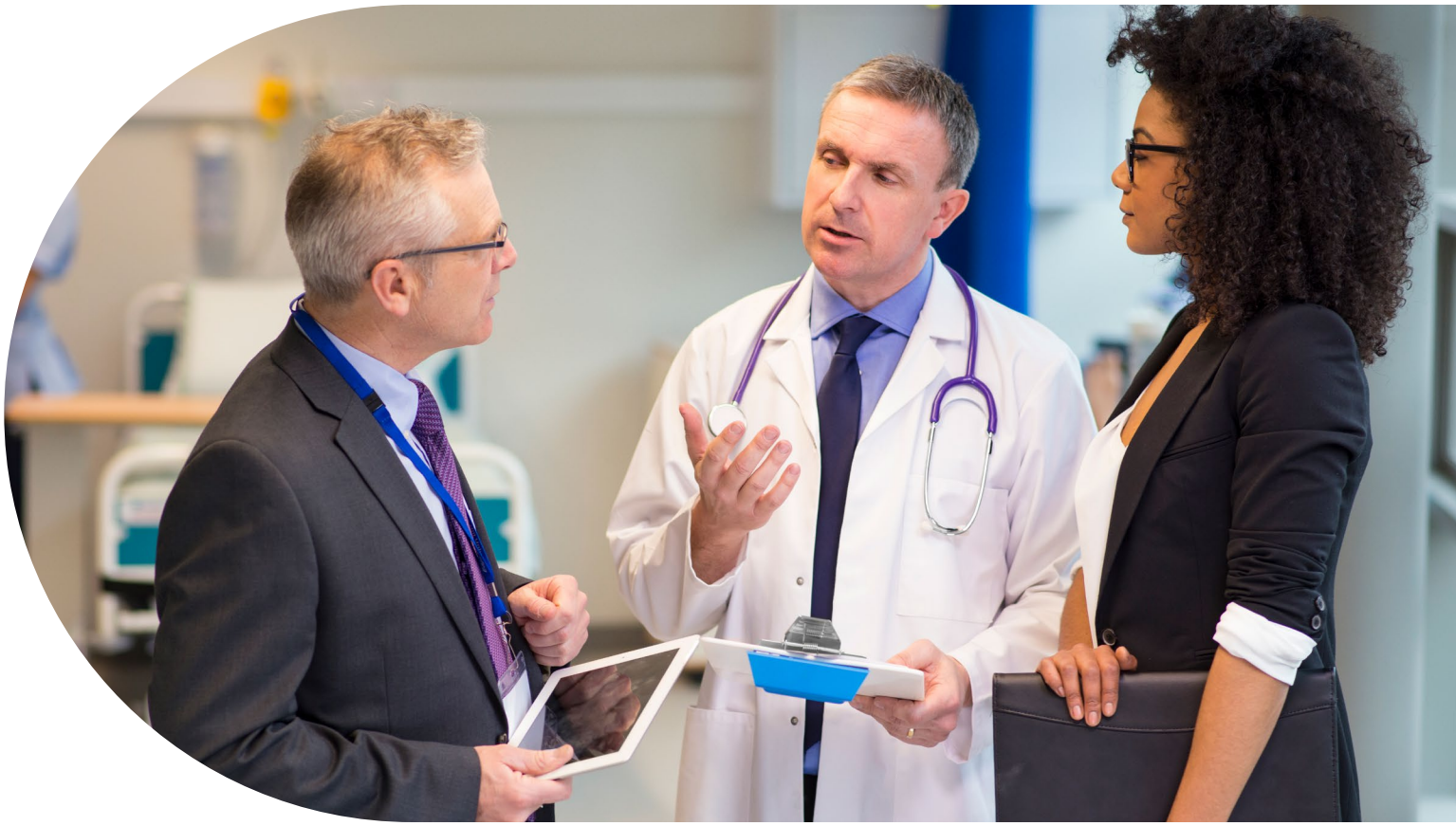
What makes a good regulatory operations strategic partnership and how does that benefit an organization over a tactical fee for service work alone?

Chikkam: The right partnership can bring numerous benefits to an organization. A strong regulatory partner will leverage a collaborative approach with the organization to understand their unique needs and challenges and develop a regulatory strategy that is aligned with their business objectives. Flexibility is critical to adapt to the changing needs of the organization and allows the regulatory partner to provide tailored solutions.

A strong strategic partnership goes beyond the tactical fee and creates long-term value for the organization, which can include cost savings, improved efficiency, increased regulatory compliance, and enhanced competitiveness in the market. There are two groups of experts at your service — regulatory and technology. Regulatory experts with a deep understanding of the landscape provide guidance on regulatory challenges; technology experts help to streamline regulatory operations and improve efficiency by using advanced tools and automations.

How can regulatory providers manage and improve collaboration with an organization?

Miño: There are three key elements a regulatory provider must do to manage and improve collaboration. First, the regulatory provider must listen to the customer and understand their needs, constraints, and workload. Second, they need to set clear expectations and priorities to meet regulatory timelines while mitigating resource constraints. Finally, the regulatory provider must add value by proposing improvements, implementing new technologies, and creating efficiencies for both teams.



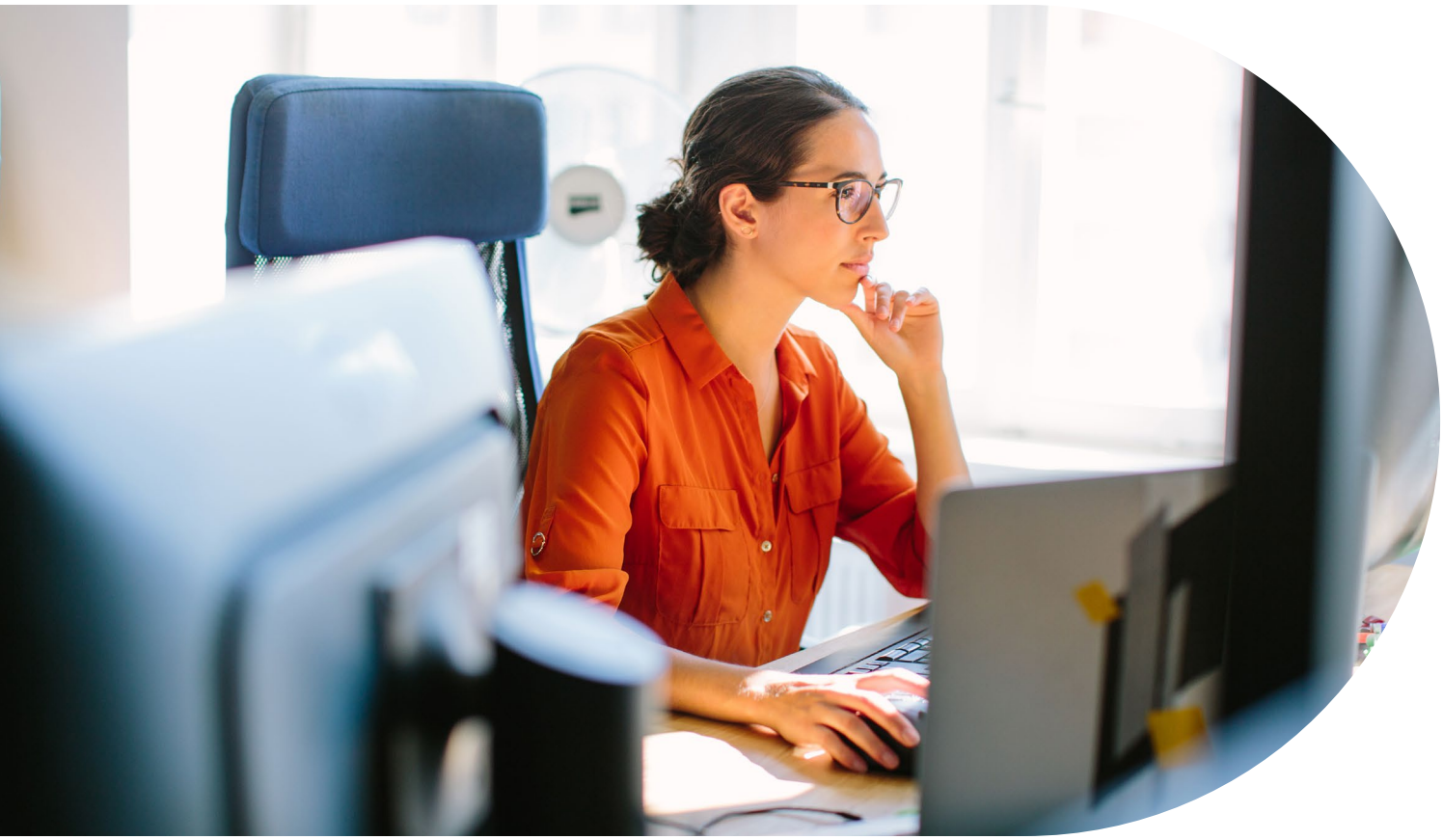
How are advanced analytics improving insights in labeling and publishing specifically as well as other areas of regulatory affairs?

Chikkam: Predictive analysis is being used to identify patterns in data to help regulatory professionals make more informed decisions, and data visualization tools are being used to present complex data in understandable formats. These advanced analytics help regulatory affairs professionals quickly identify trends and make proactive decisions to reach the market and support patients as soon as possible.

Many companies are also moving forward with [ML] algorithms, which are being used to analyze large amounts of data. Using real-time data analysis, regulatory professionals can make decisions based upon the most up-to-date information available.

What types of governance structures are organizations implementing to ensure continuous improvement in lifecycle management and other areas of regulatory affairs?

Miño: Governance approaches vary based on customer, company size, project complexity, delivery volumes, and any existing engagement between that organization and other groups in the partner organization. At IQVIA, we seek to establish the most convenient governance structure, and assign a project manager who is responsible for project delivery, finances, quality, performance sourcing, and oversight. In addition, the steering and executive committee at both organizations must be established for specific projects. For existing engagements, we leverage the established governance structure to gain efficiency and broad oversight.



If a client is looking for help with their labeling strategy amid a legal entity change, what steps would you recommend to stay compliant?

Chikkam: A legal entity change requires careful planning and coordination. First, identify all the products affected within the company. This includes products currently on the market as well as products in development. Secondly, review all labeling components for affected products to determine if they are accurate and up to date, including package inserts, product labels, and any other labeling used for a product. Next, update all labeling components of affected products to reflect the legal entity change. This may include updating the name of the company and address of the new legal entity, as well as any other changes required by the regulatory agencies.

"AI and ML technologies play a vital role in monitoring compliance and regulatory requirements in real time, alerting regulatory professionals to potential issues and providing recommendations for remediations."

— Rama Mohan Rao Chikkam, IQVIA

Companies submit updated labeling to the relevant regulatory agencies for approval. Upon approval, they monitor compliance to ensure all products are labeled correctly and updated with the approved information to meet regulatory requirements. They can also work closely with regulatory agencies and legal counsel to follow all relevant requirements and guidance.

How do you see AI and ML technologies augmenting human expertise in regulatory operations in the next year?

Cameron: Our customers are looking to use these technologies to enhance productivity by applying them deliberately. While we are able to use a broad range of technologies, depending on customer preference, we don't outsource technology development and have a robust technology development initiative that takes applications such as regulatory intelligence and looks carefully at potential implementation of AI, ML, and Large Language Modules to provide value for our customers.

McDonald: AI and ML offer fantastic possibilities to improve the understanding of disease and increase the efficiency of drug development possibilities, thanks to their ability to analyze and interpret real-world evidence and data from digital health technologies.

Chikkam: AI and ML technologies play a vital role in monitoring compliance and regulatory requirements in real time, alerting regulatory professionals to potential issues and providing recommendations for remediations.

"Flexibility is critical to adapt to the changing needs of the organization and allows the regulatory partner to provide tailored solutions."

— Rama Mohan Rao Chikkam, IQVIA

About the authors

DAVID CAMERON
Senior Director and Global Group Head, Novel Trial Design Solutions

David Cameron joined IQVIA in 2007 and provides global go-to-market strategy and oversight for all of RADDS. In this role David is responsible for collaborating with internal and external stakeholders to ensure that the RADDS offerings support our customers' ability to bring innovative products to patients. Located in Durham, North Carolina, David has a background in economics and epidemiology with over 17 years of global Research and Development experience in all phases.

KEITH MCDONALD
Head of Drug Development Strategy

Keith McDonald is Head of Drug Development Strategy, within the Regulatory Affairs and Drug Development Solutions organisation in IQVIA. His regulatory experience spans some 26 years, including over 20 years at the UK Medicines & Healthcare Products Regulatory Authority with operational responsibility for clinical trial and marketing authorisations approvals. He was vice-chair of the Coordination Group for Mutual Recognition & Decentralised Procedures, UK delegate to the Notice to Applicants working group and Rapporteur for the International Conference on Harmonisation guidance on Development & Manufacture of Drug Substances (Q11). Keith has been awarded fellowships of the Royal Pharmaceutical Society and the Faculty of Pharmaceutical Medicine (honorary).

RAMA MOHAN RAO CHIKKAM
Senior Director of Global Regulatory Operations and APAC RA

Rama Mohan Rao Chikkam is IQVIA's Senior Director managing Global Regulatory Operations & APAC RA and leading the GRA-India division for Global Regulatory Services and Technology. Rama Mohan Rao acts as the business domain expert between Regulatory Affairs and IT divisions for implementing RA Life Science IT tools and driving change for global operating models by connecting technology with pharma's strategic priorities.

MARCELA MIÑO
Senior Director of Regulatory Affairs and Drug Development and Global Head of Lifecycle Management

Marcela is the global head of marketed pharmaceutical products' lifecycle maintenance business at IQVIA. Marcela is the global lead of a high-performance regulatory team, supporting all global regions. Located in Argentina, she holds an MBA and has over 18 years of regulatory experience with IQVIA and 10 years of prior experience in the pharmaceutical industry.

About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry. IQVIA creates intelligent connections to deliver powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients. With approximately 86,000 employees, IQVIA conducts operations in more than 100 countries.

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