SUPPORTING SUCCESSFUL COMMERCIALIZATION WITH INTEGRATED COMPLIANCE

EVERSANA™

Nina Lahanis, Associate Vice President, Safety Science

Compliance is an integral part of the entire biopharma, medical device and SaMD (Software as a Medical Device) product life cycle, yet it poses one of the biggest challenges for our customers. While they try to focus on driving value, innovation and patient centricity, customers find that much of their effort and finances are still being invested in managing regulatory obligations.

Challenges are spread across internal factors, such as obsolete and disconnected platforms, multiple silos and manual processes, to external factors like the changing regulatory landscape and increased scrutiny of regulators. These challenges prevent our customers from moving the needle of compliance from cost to value.

In building an **integrated compliance platform**, EVERSANA has addressed the market dynamics that challenge clients' ability to provide real insight to products, innovation and patient centricity. Our holistic model advances life sciences compliance to deliver and commercialize safer and better products, allowing customers to stay focused on what matters most: *helping patients live healthy lives.*

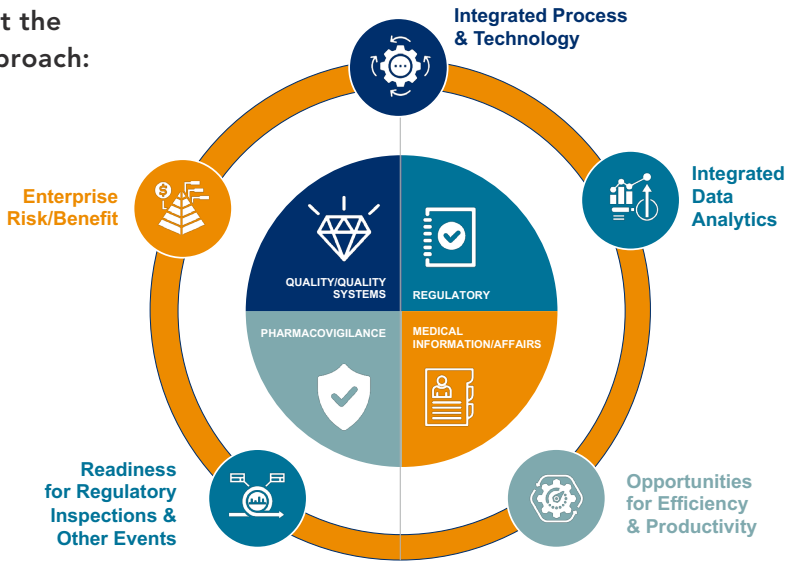
Shifting Toward a New Compliance Model

When owning and driving solutions from strategy to execution, end-to end compliance is the differentiating path forward and one that ensures that companies are regulatory inspection-ready 365 days of the year. As a result, the entire compliance framework becomes embedded into the organizational culture and proves to be a leading force for innovation and developing better drugs for patients.

Successful compliance relies on four integrated services: **Pharmacovigilance, Medical Information/Affairs, Regulatory, and Quality Assurance and Quality Systems.**

The image to the right identifies the five value creation areas we've implemented throughout the compliance paradigm to drive this holistic approach:

1. Integrating technology and automation
2. Driving value out of the data through proactive analytics
3. Streamlining and integrating processes for efficiency and better productivity
4. Ensuring regulatory inspection readiness 365 days a year
5. Evaluating enterprise risk/benefit associated with a product or a portfolio in real time



With a larger commercial platform, such as that offered by EVERSANA, Compliance is integrated within Patient Services, Channel Management, Data and Analytics, Digital Medicine and Field Solution services. This new global approach as a single partner brings the best solutions across business processes, technology and people into one integrated solution that is flexible and can be customized for different sizes and types of organizations.

EVERSANA also provides technology solutions that can vastly improve both efficiency and quality – namely, technology solutions in the broad categories of integration and automation. The key outcome of any automated solution should be maximized efficiencies and cost reduction with a corresponding increase in quality and data integrity achieved through the reduction of manual tasks. Moving toward an integrated compliance model, powered by rich datasets and end-to-end services automation, creates the highest levels of efficacy, effectiveness and safety. This, in turn, enables the digital transformation of safety and pharmacovigilance services, ultimately leading to safer, more effective healthcare for patients worldwide.

Establishing Medical Affairs for a Strategic Product Launch

An experienced Chief Medical Officer (CMO) leading Medical Affairs is a critical part of the strategy that helps companies ensure the successful launch of their new drug, biologic or medical device.

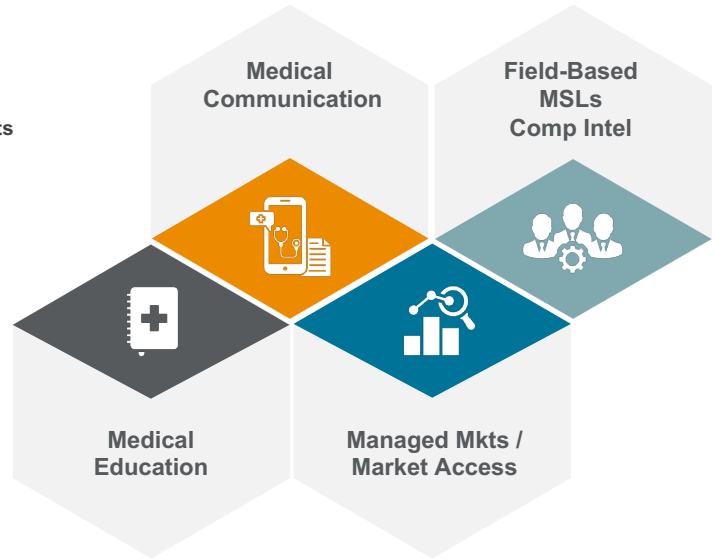
In the age of Big Data, digital technologies, complex personalized approaches to medicine and real-world evidence generation, healthcare providers are finding it increasingly difficult to navigate the vast amounts of data needed to make the best therapeutic decisions for their patients. Medical Affairs teams equipped with extensive product and disease knowledge are well positioned to be the conduit by which necessary data, along with fair and balanced scientific evidence and insights, is communicated while providing healthcare professionals and payers information needed to make informed decisions and drive early adoption. Leveraging the full potential of a Medical Affairs team is no longer an option but a requirement for successful commercialization.

Another core feature to Medical Affairs is the Medical Information (MI) Contact Center. The MI Contact Center plays a central role in establishing a well-defined and seamless workflow between the center and any patient services or hub support contact centers, as well as providing a direct channel for healthcare professionals to receive information. This integrated approach increases successful customer experiences while maintaining compliance and provides customers a clear route to report adverse events and product quality complaints.

Medical Affairs Strategic Plan – Key Business Questions

How will you respond to unsolicited requests for information from HCPs, **patients and consumers concerning the safe and effective use of your product**?

How will you educate physicians and other key HCPs about the overall place of your product in **treatment in order to drive adoption**?



How will you engage KOLs and bring field-derived medical insights back to your company in order to **integrate this information with key messaging**, clinical trials and real-world evidence?

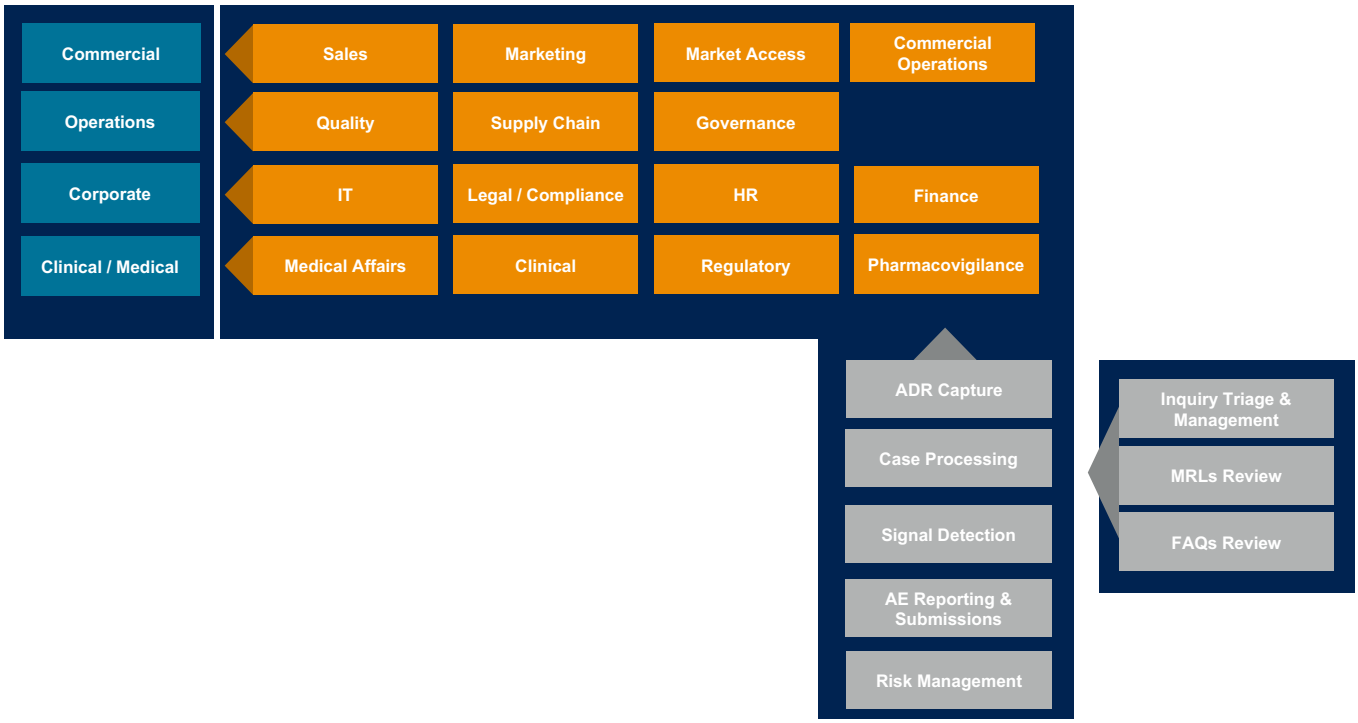
How will you respond to payer needs for comprehensive information about your product in order to make formulary decisions **while meeting regulatory requirements**?

Ensuring Pharmacovigilance: The Key to Product Success

Managing the safety profile of a product is key to the overall compliance strategy for an organization looking to launch a biopharmaceutical product. A pharmacovigilance (PV) plan and execution strategy that incorporates all aspects of the product's safety profile provides the strong foundation for an effective and efficient approach that also meets all compliance requirements.

Implementing the PV plan includes detailed step-by-step tactics on who will manage the following responsibilities: what will be managed within the organization vs. outsourced, what oversight will need to be in place for any outsourced activities, and what systems will be utilized for safety reporting and managing safety trends. The PV plan needs to efficiently and seamlessly coordinate all safety activities across medical information, quality management and regulatory affairs functions successfully in order to drive the goal for 100% compliance.

Integrated Pharmacovigilance Strategy



Differentiating Your Product With Quality Assurance

The ability to identify the appropriate quality and regulatory strategy early in the product life cycle provides the appropriate scope and framework to reduce time, regulatory/business risk and overall cost to launch – key differentiating factors for a successful commercialization. Challenges that arise due to noncompliance include:

- Rejected product and/or adulterated product leading to complaints, leading to adverse events, leading to recall and agency action.
- Remediation of agency action ranging from the hundreds of thousands of dollars to millions of dollars.
- Product recall and remediation never planned or staffed for; significant internal and external resource burden required.

To cover the elements of quality for a medical device, pharmaceutical, biologic, tissue or combination product, it is important to establish a Quality Management System (QMS) that outlines and governs each element as it relates to the company and the product.

EVERSANA supports not only the development of the quality strategy but execution of all activities required to run a successful quality department. Quality Strategy, Quality Management System and Quality Management Software should be acknowledged early to achieve successful commercialization.

Successful Commercialization Relies on Regulatory Strategy

These factors could be considered the "pillars" of regulatory launch readiness, and within each of these pillars are various activities and milestones that must be achieved.

1. **Regulatory strategy**
2. **Regulatory project management**
3. **Product label management**
4. **Regulatory intelligence**
5. **Submission management**
6. **Registration management**

The key to properly addressing a regulatory strategy that supports product development is to start early – years before expected product approval. This strategy should be written to address product launch and post-market, necessary cross-functional areas, such as reimbursement, marketing, legal, etc., so when product launch is imminent, those ancillary factors are accounted for. It is important to note that the regulatory strategy is a living document, and as policy, regulations and guidance evolve, so must the regulatory strategy.

A suitable regulatory strategy is a major component of an integrated product launch solution. A deficient regulatory strategy can single-handedly derail a product launch and/or compromise prosperous commercialization. It's critical to ensure the regulatory factors are identified, addressed early on and updated throughout development to account for the ever-changing global regulatory landscape.

Ensuring Product Success

Overall, to ensure successful product commercialization, integrating processes, technology and people is essential. With support from EVERSANA, properly integrating compliance into your commercialization will lead to increased efficiency, reduced costs, reduction in manual errors, faster processing time and, ultimately, increased safety and quality of your products for patients. responsibilities: what will be managed within the organization vs. outsourced, what oversight will need to be in place for any outsourced activities, and what systems will be utilized for safety reporting and managing safety trends. It must also provide details on how the plan and systems will meet the requirements for all countries targeted for product approval. The PV plan needs to efficiently and seamlessly coordinate all safety activities across medical information, quality management and regulatory affairs functions successfully in order to drive the goal for 100% compliance.