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A TOPIC
TO SEE HOW
IT CONNECTS

How Commercial Operations Connect with COMPLIANCE



Connecting **Data Management** WITH COMPLIANCE

In the digital age, how can we ensure that risk assessment, governance and technology are integrated into a broader organization vision, supported by a sturdy architecture and managed via a detailed plan of action based on the product/service life cycle? What can be done to lessen the vulnerabilities created by an explosion of personal communication devices and less than perfectly integrated systems, to say nothing of the potential security threat created by the “internet of things” amidst lagging security standards? In order to succeed and remain compliant, individual organizations must initiate, plan, develop and implement a structured regulatory response framework using proven technology to manage and ensure the integrity of its data based on their business priorities and societal obligations.

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Connecting

Transparency WITH COMPLIANCE

Federal and State transparency reporting initiatives are based on the premise that government and the public need more insight and transparency into relationships between manufacturers and healthcare practitioners (HCPs). Harmonizing processes for compliance to the requirements and establishing internal policies and procedures governing engagements with HCPs is very much a cross-functional responsibility. Whether a lunch and learn in an HCP office or vetting and contracting with an HCP consultant, compliance and commercial operations must coordinate the oversight and monitoring of HCP interactions to ensure adherence to policy, with a realization that with transparency comes close public scrutiny of company practices.

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Connecting **Sales Operations** WITH COMPLIANCE

The primary objective of a sales team is just that – to sell the product. Sales incentives, quotas and quarterly budgets weigh heavily in that regard. How a company marries its sales goals with its compliance responsibilities is critical. Clear, ongoing communications that begins at the earliest stages of planning will save time and money and help both teams achieve their goals.

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Connecting **Data Analytics** WITH COMPLIANCE

Collecting, analyzing and validating data is a huge trend in all kinds of businesses, including the life sciences. But what you do with the data, including how you apply it to business decision making, is where the connection to compliance takes on real importance. Intelligent data analytics should be used on both a tactical level and a strategic level to improve operations, streamline activities and of course, to assist with compliance in detecting abuse, reporting, auditing, monitoring and minimizing risk.

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Connecting **State Regulations** WITH COMPLIANCE

States, cities and regions are continually implementing new laws, rules and regulations that impact our Commercial Operations and Compliance. For a manufacturer to ensure compliance to these ever-evolving state requirements, the Compliance team has to be a part of reviewing the requirements, assessing the impact on the organization and implementing processes to ensure the company is not at risk. Depending on the requirements, there can be challenges for the business, legal and compliance teams to all align. State regulations can have an impact in ways far beyond the obvious.

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Connecting **Auditing & Monitoring** WITH COMPLIANCE

By establishing a strong auditing and monitoring program, an organization is demonstrating their commitment to compliant behaviors and ethical business practices. They are mitigating risk, which can lead to improved operations. Ongoing auditing and monitoring serves as a quality assurance test that helps an organization not only uphold a positive image, but build a bridge connecting a consumer's trust and belief in that organization. Trust leads to consumer loyalty, and customers are more likely to believe in and support an organization or service they identify as trustworthy. Today's organizations have an obligation to not only create a culture of compliance that promotes ethical and compliant behavioral standards, but they must maintain such standards in order to protect their customers and be perceived as a leader in their community.

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Connecting **Fulfillment & Logistics** WITH COMPLIANCE

Best practices in fulfillment and logistics are important in keeping operational activities on track, whether they are related to cold chain storage, product returns, direct to practitioner fulfillment or direct to patient logistics. But there's a regulatory aspect to these activities beyond operational efficiency, and making sure the two are aligned is paramount for compliance and cost effectiveness.

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Connecting **Legal & Ethics** WITH COMPLIANCE

An ethical business culture is more than elegantly written Codes of Conduct, Value Statements and Ethics Principles. It's the way things really work when a company conducts its day-to-day business. It's a workplace environment that makes it easy to do the right thing and difficult to do the wrong thing. To instill that culture in an organization, the message needs to emanate from the top down; be strongly rooted throughout the corporate structure; and most importantly, be continually guided by those with the Legal and Ethics responsibility. It is that business culture that allows ethical conduct to be embraced.

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Connecting **Free Goods & PAP** WITH COMPLIANCE

With more than 46 million uninsured Americans and millions more considered underinsured, Prescription Assistance Programs (PAP) and other free goods programs have emerged in an effort to help patients obtain the medications they need. For many pharmaceutical companies who offer these programs, the goal is to provide free or low cost prescription drugs to indigent patients who qualify with the hope that it helps patients comply with recommended drug therapies. With increased scrutiny of PAP and free goods programs by OIG, DOJ and even the IRS, both business and compliance stakeholders must ensure appropriate safeguards and oversight are in place to protect the pharmaceutical company from any potential violations of Anti-Kickback Act and False Claims Act.

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Connecting **Security & Investigations** WITH COMPLIANCE

The HHS OIG has identified basic elements of a pharma compliance program, which include “...policies and procedures for the investigation of identified instances of noncompliance or misconduct.” The FDA has codified required security and audit procedures including an investigatory requirement when a company has reason to believe drug sample documentation has been falsified, or product diverted; or when a company becomes aware of a significant loss or known theft of drug samples. PhRMA, within its Code on Interaction with Healthcare Professionals, reiterates that “All companies that interact with healthcare professionals about pharmaceuticals should adopt procedures to assure adherence to this Code.” An effective security program and investigative response to compliance concerns are critical to your corporate integrity.

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Connecting **Vendor Management** WITH COMPLIANCE

Selecting and managing vendors presents a unique set of challenges to life science companies. Most importantly, you must remember that while you may be outsourcing the work, you are not outsourcing the responsibility. As mandated by law, the manufacturer maintains final responsibility for compliance, meaning the relationship must be a true partnership. Therefore, the process for selecting a partner must have a compliance focus. Communication between parties must be clear and open, with nothing hidden on either side. Systems and practices must be initiated to ensure effective and compliant operations – there can be no vacuum.

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Connecting **Sample Distribution** WITH COMPLIANCE

The PDMA has many requirements which, if not followed, could result in both civil and criminal penalties. In some organizations, the Sample Management group may work somewhat independently of the compliance function. For optimal effectiveness, the two organizations should work closely together. This ensures consistency in the messaging of sample management across sales operations, human resources and legal. It precludes duplication of effort. It fosters agreement in the creation of Policies and Procedures that are implemented for both areas. It helps create a solid Violation Management Policy. And finally, if/when the FDA pays a visit to the organization, both groups are aware of the Policies and Procedures.

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Connecting

Credentialing WITH COMPLIANCE

Many privately and publicly owned companies have implemented procedures to increase security and ensure privacy, and hospitals are no exception. As such, it is vital to ensure your company is compliant with hospital policies for access to the practitioners who reside in these institutions. Credentialing involves many diverse internal and external business areas along with many complexities in the actual process. Regardless of where the credentialing responsibility resides within your company, it is important to note that establishing a comprehensive program is critical. Expanding this program to include an internal company core team to oversee each functional area, challenges in the process and alignment with best practices is imperative for maintaining compliant access to institutions.

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Connecting **Product Promotions** WITH COMPLIANCE

Product promotions, advertising, lunch and learns and other initiatives are an important part of the product marketing mix. Sometimes, whether intentional or not, these initiatives can be areas of concern if the promotion programs stray from approved messaging. Discussing “promotion”, by necessity, must always include the connection to compliance. Educating the brand and marketing teams on FDA and State laws, regulations, guidances and enforcement actions is a great way to ensure that marketing programs drive sales revenue and not compliance violations.

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Connecting **Speaker Programs** WITH COMPLIANCE

Speaker programs are an excellent tool to provide product, disease state or other legitimate business information to customers. But managing these events to ensure appropriate “messaging” and learning interactions is critical. Speaker training, monitoring of events, and responding to potential inappropriate activities is the compliance life cycle. It’s a life cycle that requires program coordination, and a firm understanding of compliance implications.

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Connecting **Regulatory Affairs** WITH COMPLIANCE

Inherent in the role of the regulatory professional is the need to keep track of changing legislation in the geographic regions and market segments in which their company competes. The Regulatory Affairs responsibility is to provide operational direction and support, while ensuring operations are compliant with regulations. The connection to compliance is in the practical application of that knowledge. Integrating the legal “do’s and don’ts” with our policies, systems and operations is an ongoing and ever-evolving task.

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