Rethinking Operating Models to Increase Regulatory Compliance

Terumo and Alcon redesigned their systems to build connections across departments and focus on regulatory compliance at every step of the product lifecycle.

As the industry transitioned to remote work, it became painfully obvious that working across silos is inefficient and difficult. Forward thinking companies are using MDR as the driver to modernize their global operations and centralize data with a single source of truth.

Terumo and Alcon looked to unify their systems with Veeva MedTech to increase data consistency and regulatory compliance. Company leaders shared their learnings on how a cross-departmental focus on compliance and risk management reduced versioning issues and increased efficiencies across the organization.

Reduced document version issues

Faster claim approvals

Quicker adjustment to MDR regulations

Rethinking Business to Integrate Technology

"MDR was one of the big drivers for us to break down silos," said Lori Holder, senior director of global regulatory operations at Alcon. Alcon realized that to meet MDR requirements and remain compliant, business processes would need to be connected across regulatory, quality, supply chain, and clinical operations.

This became especially evident with claims. Once a claim is in place, the organization needs a clear connection to the proof that the claim is in fact accurate and true. Holder explained that because of MDR regulations Alcon went back and reviewed their instructions for use. "We're in continual refinement of how we track claims, but I think we've come a long way," she concluded.

Establishing consistency across business units can also decrease approval time. Marie-Pierre Devez from Terumo Europe explained that if the clinical operations teams understand the requirements up-front, they can address them before sending for approval, thereby reducing approval time at the end of a study. “We need to understand what’s required to drive the business,” said Clinical Operations Director Devez.

Creating a Single Source of Truth Across Departments

Before their transformation, Alcon struggled with document version control that crossed departments, such as test reports. Even though a document was revised, the old versions were still in circulation, which caused extra work to ensure final versions. Even worse, this could cause submission issues. “As we put systems in place, we made the decision to have a single source of truth for our documents,” said Holder. And that system was the Vault MedTech Suite.

Terumo also shared the situation with version control noting that the version control issue affected consent forms and submissions within the eTMF. They plan to implement automated processes within Veeva Vault that will manage the protocols and be flexible enough to have country-specific clinical investigation plans. By managing all documents within a single repository, they are also creating a single place to track milestones, country-specific documents, and regulatory specifications which will speed submissions processes.

Integrating Risk Management into the Company Mindset

Holder and Dewez agree that the centralized system is only as good as the information being fed into it. This starts with a clear and concise change-management strategy throughout the company.

Both Alcon and Terumo are working to create ongoing training plans for their teams, including identifying champions within different departments to help communicate the benefits of the new system and answer user questions when they come up. “Risk management is a mindset that needs to be incorporated throughout clinical operations activities,” said Dewez.

Alcon is already replacing the notorious tracking spreadsheet with the automated reports within the Vault RIM Suite. And while getting users onboard can be tricky, once they see the value and the speed at which management can move based on data trends, it’s easier to get people to buy in.

Both companies are also working to outline processes ahead of time so they can take swift corrective and preventative action as needs arise. They need a system to ensure regulatory consistency, but also the flexibility to adjust to country-specific protocols. By incorporating risk-management into the company mindset, users across the world are focused on the same goals.

Cross-Functional Consistency Creates Efficiencies

As MedTech organizations continue to create more efficient ways of working cross-functionally, cloud solutions like Veeva Vault help them collect and distribute information globally. Holder pointed out that Alcon gained significant efficiencies because of having the same interface across the connected Vault systems.

At Terumo, they're looking forward to the possibilities of an interconnected system. Dewez understands that the system is only as powerful as the information that populates it, so she is focusing on user training to ensure Veeva Vault Suite will be used to its full potential. "And it's not a one-time thing, we will need to continue to optimize as we grow," she explained.

To learn more about how Veeva MedTech can transform regulatory oversight in your company, visit veeva.com/medtech.

Watch the entire roundtable discussion to dive into how Terumo and Alcon transformed their data systems using the Veeva MedTech Suite.