Digitalization, global expansion, and changing compliance requirements are driving medical device manufacturers to rethink their commercial models with a specific focus on content management. The industry’s move toward digital has caused a proliferation in content—marketing teams are churning out 10 times more assets today than just five years ago. Current processes and technologies are fragmented and no longer sufficient to manage content creation, approval, and distribution or enable collaboration with external partners, such as marketing agencies. In addition, as device companies expand geographically, sharing all of this content is cumbersome. Rather than improving speed and efficiency, digitizing commercial assets has resulted in the unintended consequence of slowing execution. Manufacturers operate without visibility into workflows or access to data to measure the effectiveness of
their campaigns and promotional materials.

Maintaining compliance in the face of new and changing global medical device regulations is another challenge. A revision to ISO 13485, for instance, increases quality requirements, and the mandated FDA 501(k) submission requirements specify more complex clearance processes involving content and format provisions for different medical device types and classifications to ensure their safety.¹

These issues are roadblocks to digital evolution in the medical device and diagnostics industry. To overcome them, companies are transforming how they manage commercial content and digital assets. Two medical device leaders, for instance, recently streamlined their processes across the global enterprise, significantly improving efficiency, visibility, and compliance while accelerating their digital evolutions.

Coloplast, a medical device company that develops ostomy, continence, urology, wound, and skin care products, set out to improve compliance with a new content management strategy. It needed to find a faster and easier way to match claims within promotional materials to supporting evidence. Its existing tool did not efficiently associate claims to promotional materials or provide a complete audit trail. Furthermore, Coloplast was still using unsecured email to send documents and other content.

While looking for a better solution for claims management, the company decided to go a step further and optimize its entire content management system. Multiple siloed systems and processes were limiting true collaboration and visibility
throughout the enterprise. “Our U.S. subsidiaries saw an opportunity to make sweeping improvements to our commercial content review and approval processes,” said Charlotte Sylvest, senior master data governance manager for Coloplast. “The hope was that the initial project would demonstrate the value of an end-to-end digital asset management platform to streamline the processes for creating, sharing, and reviewing content. A new modern system would address a range of inefficiencies stemming from disconnected, manual ways of doing business.”

Coloplast implemented an end-to-end content management system in the cloud to increase visibility and control, as well as quickly move content through the digital supply chain. Marketing can now tie each claim directly to supporting evidence and maintain everything in a central system.

Auditors no longer spend hours questioning multiple people to determine which part of a research study applies to a particular claim. Instead, audit trails show the workflow that produced the document to demonstrate the process meets regulatory demands. “Instead of taking a half day to evaluate what they need to review for one piece, auditors are done in about 15 minutes,” added Sylvest.

Coloplast now leverages a cloud-based content management application that combines content creation, review, approval, and distribution with digital asset management. Previously, individual product managers relied heavily on email while storing documents and videos on different hard drives. The new system provides a single source of truth for all approved content and assets. Now, brand and campaign teams can ensure the entire
organization is using the correct version of each piece of content to dramatically improve compliance and efficiency.

In addition to ensuring compliance, Coloplast decreased content review and approval times and increased reporting on trends to utilize content more effectively. Coloplast now operates with a more structured, process-driven methodology that provides greater control over worldwide content usage. The company expects to continue to reduce costs through greater content reuse and better asset management as they develop their overall content strategy.

Another medical devices firm with operations in 25 countries streamlined its commercial content development by automating manual tasks with a cloud-based technology solution. The global organization produces more than 6,000 promotional pieces annually. It previously relied on paper-based processes to create and review content, which limited access to approved materials, slowed execution, and duplicated marketing efforts.

The company also lost opportunities to collaborate on new campaigns. During production, team members would exchange handwritten edits on PDF documents via email, which was inefficient and risk-averse. There was no version control or reliable audit trail. Further, the company juggled between digital and manual processes, using folders to circulate documents and handwriting routing numbers, signatures, titles, and other important information.

To overcome these challenges, the company adopted an end-to-
end content management system and has since optimized the entire process from conception to dissemination. Team members now review commercial content in real time, on any device, and collaborate efficiently without reading long chains of emails or paging through paper documents. Additionally, internal teams and global affiliates have total visibility into the same information to create, share, edit, approve, and distribute commercial content to the field faster than before, despite ever-increasing content volume.

“Moving onto a cloud-based content management system allows us to plan better and drive greater efficiency in our commercial execution,” explained a corporate spokesperson. “Global teams can collaborate and easily access the right content to meet regulatory obligations and execute faster.”

The new solution combines content creation, review, and distribution with a digital asset management system that maintains an inventory of all content—important data for future planning and optimization of existing assets worldwide. Dashboards created for market sectors enable teams to review projects for the year and evaluate if they are producing too many or redundant promotional materials so they can quickly determine whether or not to advertise anymore during the year.

Looking ahead, the company will use its new solution to support additional functional areas, including regulatory and clinical, as well as its design team. “Initially, we implemented a content management system to provide easy access to content change requests and visibility into work approved for distribution without relying on emails,” added the spokesperson. “Now, we aim to
increase collaboration by connecting all groups with a single, cloud-based platform and suite of applications.”

The two medical device organizations have overcome many of today’s compliance and efficiency challenges of going digital by adopting end-to-end content and digital asset management solutions. In the cloud, these technologies eliminate system, site, and country siloes to streamline workflows. Instead of relying on email, all stakeholders work from one system for a single source of truth.

“By implementing a comprehensive, cloud-based solution, we can link promotional pieces to the claim document rather than spending hours to find evidence to prove our claims,” concluded Coloplast’s Sylvest. “All commercial content and data is available in one place so everyone can access it with a full audit trail. Greater data consistency optimizes quality control to ensure compliance. Solving this content management puzzle is a critical step for device companies making a digital transformation.”

Reference


Terri Howard

has more than 20 years of experience in life sciences, with the last decade focused on regulated content management technology for the medical device industry. She has worked with leadership teams to form and influence change in regulatory and
marketing business practices, most recently at CareFusion (now BD). Howard joined Veeva Systems in 2015 as director of commercial strategy to help medical device companies leverage cloud technology to more successfully engage with customers and bring products to market faster and more efficiently.