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Product Content Management in a Regulated Environment

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What are some challenges that medical device companies face when it comes to ensuring collateral quality, compliance and approval?

The Environment: Ultra-competitive marketplace

In today's environment of strict regulation and reduction in spending for healthcare, medical device companies are under pressure to reduce operational costs, increase efficiency and provide greater value to the system – all while meeting (and exceeding) the expectation to develop and distribute innovative and life-saving products in an ultra-competitive marketplace.

The Challenge: Commercialization

Given the ultra-competitive environment, intelligent marketing teams need to ensure they:

- ✓ Build the brand effectively.
- ✓ Develop an expert sales force to get the products into the hands of healthcare professionals.
- ✓ Create an impeccable regulatory group to ensure both of the above functions are always FDA compliant

It's easy to see that medical device companies are faced with quite the set of challenges.

This set of challenges includes ensuring the quality, compliance and approval methods for the collateral that supplements a company's product or device portfolio. Whether that collateral is a sales aid, a training presentation or a clinical case study, it must meet FDA standards.

With numerous product lines, multiple regions around the globe and countless methods for information sharing, guaranteeing quality and compliant product content can be more challenging than it sounds.

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How can companies overcome these challenges?

Cross functional collaboration is key!

One way companies overcome the challenges associated with developing and distributing compliant medical device content is to collaborate cross-functionally.

As the way in which the world receives and digests information about healthcare evolves, medical device companies have to evolve with it.

That might mean reaching physicians with an email campaign, creating interactive content in an app that teaches patients about their upcoming procedure or submitting clinical data to an internet database.

With this evolution comes more and more channels for information sharing. Consider how long a list of these channels might be for a medical device company—now consider how important it is to maintain each and every one of those channels for quality and compliance.

It's crucial that groups like Marketing, Regulatory and IT all work in tandem to understand how to best utilize, manage and maintain these various outlets.

This can be done by creating collaborative work groups, holding regular channel audits and habitually educating those in each function about the implications associated with compromising quality and compliant collateral.

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What complications arise from a lack of appropriate document and collateral tracking?

Complications that arise when distributing non-compliant product content vary.

Compliance

If the content is in clear violation of the FDA's promotional guidance, the company at fault may be subject to receiving an FDA warning letter. These letters can incur costs associated with process overhaul, employee dissatisfaction and damage control.

Credibility

Medical device companies that produce substandard collateral also face the possibility of losing the trust of their customers. For example, a physician might rely on a digital data sheet to inform their staff of device order numbers for a procedure. If the version that the physician is using has not been properly vetted by a regulatory or quality team and lists the wrong numbers, that will inevitably lead to a frustrating experience for the staff member who goes to place the order. This reflects poorly on the sales rep who provided the digital data sheet, and on the company as a whole.

Lack of Coordination

Another complication that medical device companies encounter by distributing inaccurate product content is a lack of trust between functional groups. In most instances, Marketing is tasked with creating product collateral, Regulatory is expected to fully vet that collateral and Sales then allocates that collateral to their customers. If any of these groups does not properly fulfill their responsibility, it can quickly widen the notorious gap between functions.

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How can companies avoid these complications?

Companies avoid these complications by eating, breathing and sleeping process. This is not an unfamiliar method for medical device companies, as process is involved in nearly every aspect of every day.

There's a process for how to successfully bring a product to market, how to properly manufacture that product and how sales reps are trained to sell that product. It only stands to reason there should also be a process for how to develop and distribute FDA compliant product content.

More important than the process itself is the company-wide adoption of it. For groups like Marketing, Sales and Regulatory to embrace the process, it must be:

- **Collaborative**
- **Comprehensive**
- **Consistent**

The process should involve all key stakeholders, have no shortcuts and be easily repeated.

By implementing an agreed-upon process, medical device companies are much less likely to encounter complications with the FDA or any internal and external trust issues.

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What best practices do you recommend medical device companies employ to ensure quality and regulatory compliance?

When considering best practices that medical device companies can employ to ensure quality and regulatory compliance, they can be summed up by:

Education

Ensure that any stakeholder involved in the process of developing product content is educated on the most current set of FDA promotion standards. By giving employees complete visibility into the damaging outcomes of distributing non-compliant content, it is far less likely for mistakes to be made.

Collaboration

Encourage those same stakeholders to engage collaboratively in the workplace—whether that be through the product collateral approval process or working together to conduct frequent content audits, any opportunity to work in tandem will only improve the quality of the content produced.

Adaptation

Expect change. The environment in which medical device companies produce and sell products is consistently evolving. Information is being shared in new ways, more often. Regulations are being challenged, and the pressure to reduce spending in healthcare is growing. Sales, Marketing and Regulatory groups must be willing to adapt to these changes in order to ensure the utmost quality and compliance of the product collateral they create.

Seismic is the leading end-to-end content automation solution for life sciences firms worldwide. Seismic's platform gives medical device, biotech, and pharmaceutical companies the ability to deliver content that is always compliant and on-brand, facilitating a world-class customer experience. With Seismic, marketing teams are automating the creation of customer-facing materials via Seismic's award-winning LiveDoc® technology, which are then automatically accessible to distribution teams at any time, on any device and fully compliant, allowing them to spend more time developing and nurturing customer relationships with full confidence in knowing the materials are up to date. Headquartered in San Diego and with 150 employees across the globe, Seismic is privately held by its founding executive team and investment firms General Atlantic, JMI Equity, and Jackson Square Ventures.

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