Accelerate regulatory submissions

with structured content

Technical documentation: The new bottleneck for regulatory submissions

As medical devices and their regulations evolve, technical files are becoming extremely complex. Manufacturers and regulators alike are being challenged to:

- create more technical content
- within the same time frame
- and within the same budget.

That's rapidly turning content authoring and management into a **major bottleneck for regulatory submissions** and, ultimately, **delaying product launches.**

What's slowing things down?

Veeva's 2022 Year-end Regulatory Benchmark Report[1] found that MedTech organizations are facing numerous technical documentation and regulatory submission challenges:

31% manage their submissions manually, using individual spreadsheets

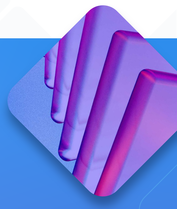
41% review, approve and publish submissions by emailing individual documents

37% still manage documents locally on laptops and file shares

Something needs to change. And the good news is, many MedTech organizations understand how they want the management of technical documentation to evolve:

62% want to develop a single source of truth for medical device documentation over the next 2 years

57% expect the industry to modernize to enable global content reuse across submissions and regions over the next 2 years



5 ways structured content authoring and management can help you create compliant documents faster

1. **Easy change propagation**
   Structured content management systems provide a single source of truth for all your documents – from clinical evaluation reports (CERs) to 510(k) premarket notifications. Simply edit the source once and every piece of your content is automatically updated.

2. **Rapid response to regulatory feedback**
   Using the system, regulators can securely access your documents online just as easily as your own teams. That enables them to provide feedback quickly and show you exactly what paragraph, data or image must change to achieve compliance.

3. **Data and content integration**
   From technical manufacturing specifications to lab results data, you can combine data and text dynamically to create reports that are always up-to-date and accurate – wherever they're published.

4. **Traceability by design**
   All changes made to your technical files are automatically recorded – making them easily traceable by anyone, and permanently audit-ready.

5. **Technical file automation**
   With componentized content, all teams – from R&D to marketing – can flow their technical documentation content directly into pre-designed templates, helping them publish faster without wasting time on formatting.

1 www.veeva.com/medtech/resources/2022-regulatory-benchmark-report/

Accelerate regulatory submissions and time-to-market with Tridion Docs

With the Tridion Docs structured content platform, your clinical trial, regulatory affairs, marketing and product teams can seamlessly collaborate on consistent documentation – accelerating both time-to-compliance and time-to-market for new medical devices and products.

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