



# Streamlining Regulatory Operations

## Industry Trends & Innovations



**Dominik RETERSKI**

Corporate Vice President,  
Quality Assurance/Regulatory Affairs



[themedtechforum.eu](https://themedtechforum.eu)



**Charlene BOUMARD**

Director, Regulatory Strategy,  
Europe



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# Regulatory Pulse Benchmark Study



**Focus on MedTech**

*Peer-to-peer MedTech comparison, current state & future needs.*

**Focus on Internal RA Organization**

*Direct influence on the performance of the internal organization (vs external indirect influence).*

# Regulatory Maturity in MedTech - Benchmark Output



**54%** Harmonized global processes across regulatory operations

Submission forecast, planning and tracking

**66%**

Individual or manual tracking spreadsheets.

Submission documents management

**>70%**

Local laptops, file shares, or regional document management systems.

Performance and KPI reports

**60%**

Creates reports manually.

Global registrations governance & tracking

**55%**

Uses a single system.

*\* Maturity regarding unified and connected technology adoption to drive top-line and bottom-line performance and reduce compliance risks*

# Implications of Disconnected (or absent) RA Supporting Systems



in cooperation with  Irish Medtech

## Top Line Revenue

- The faster the submission compilation, the higher the speed to market, the faster revenue comes in.
- Missing revenue due to expired registrations
- Not gaining full potential from M&A portfolio increase

## Knowledge Vulnerability

- When people leave, knowledge leaves.
- Employee retention rate: highly educated RA staff executing admin tasks
- Talent Attraction

**89%**  
of surveyed  
MedTech **don't**  
have a global RIM  
system in place

## Bottom Line Efficiency

- Wasted efforts searching, duplicating, verifying (cross-functional) data and version control.
- Wasting time on reporting based on weak data.
- M&A bottom line impact of contractors etc. to revise unscalable processes.

## Compliance Risks

- Unannounced audits pose significant risks
- Data inconsistency leading to overlooked signals or trends
- Data driven decision making based on weak data
- Mismatched claims across regions

# A clear framework is needed to transform Regulatory Operations



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