MasterControl™

Regulatory:New Digital Pathways

Capitalizing on Growth

According to KPMG's analysis, the medical device industry is poised for steady growth, with global sales forecast to rise by over five percent per year and reach nearly US$800 billion by 2030.[1]

Good news, right? That depends on your organization's ability to capitalize on the trends underlying these projections, like increasing demand for innovative new devices (wearables) and services (health data), a highly expanding competitive ecosystem, new digital value chains, and the huge potential in global markets.

The truth is, there has never been more opportunity for growth, but capitalizing on those opportunities won't be easy – particularly for organizations that are slow to modernize their approach to new product introduction.

Pressure to operate more efficiently on a global scale is driving companies to focus on implementing technology solutions to accelerate their ability to harmonize processes, improve data quality, and adopt shared global systems.[2]

More Data, More Harmonization: A surge of change is underway in regulatory information management (RIM) as life sciences companies re-evaluate their global operating capabilities.

Less Time, Less Margin for Error: New product introduction has always been a tenuous balance between speed, cost and quality. First to market typically wins, but a race to the finish line that ends with failure to gain market access, or worse – a product that makes it to market only to be recalled – can cost your company everything.

- First movers average 40 percent market share 10 years after launch[3]
- Yet 44 percent of new product introductions fail to meet quality or commercial success metrics[4]

Complexity, Convergence and Change: As medical devices become more complex – mixing both device and drug delivery and/or integrating software, applications or connected sensors – the regulatory environment is becoming more challenging. According to Deloitte, the current landscape of regulatory pressures and internal challenges often leads to poor decision-making, integration and execution. Modernizing compliance using technology, with a focus on efficiency and value creation, can shape the future compliance landscape and transform how the compliance function is viewed.[5]

As a result, companies must strategically invest in a strong interoperable digital infrastructure, and harness data to expand their business models and position themselves to compete in a transformed environment.

New Digital Pathways

In Deloitte's 2022 predictions for life sciences, they pose a future state in which leading companies have automated up to 95 percent of regulatory filings, saving nearly 12 months in the launch cycle time. This prediction is aligned with the evolving maturity of digital platforms for accelerating new product development and introduction.

Digital Accelerates New Product Introduction:

- New product introduction success rates improve with quality and compliance process and system integrations.[6]
  - 21.2 percent higher success rate with cross-functional processes to share compliance
  - 21.2 percent higher success rate with EQMS/MOM integration
  - 19.7 percent higher success rate with EQMS/ERP integration

Regulatory Departments Overhaul Systems:

- According to a recent study, 86 percent of life science companies are looking to update one or more of their regulatory systems.[7]
  - 65 percent plan to change submissions planning systems
  - 41 percent plan to change submissions content management systems
  - 73 percent are changing systems for managing health authority interactions

Life Science Embraces a Platform Approach:

- Tata Consulting's perspective on platform adoption provides a clear view of how digital platforms are opening up new pathways to connect and accelerate product lifecycle development:
  - "Life science digital transformation can be led by a purpose-built, scalable platform which, in a structured manner, provides personalized clinical data to stakeholders across a product lifecycle – through intelligent search and analytics-led insights. Insights gleaned from patient and trial outcome data can be used to establish program-specific key risk indicators (KRIs), which can be tracked through a risk-based monitoring (RBM) platform. Researchers can thereby improve quality oversight by discovering and predicting adverse events, such as protocol deviations. Artificial Intelligence-based pharmacovigilance is bringing in advancements in medical assessment and complaint handling."[8]

Insight to Action

Digitize: MasterControl Regulatory Information Management (RIM) software provides an integrated digital solution to centralize and harmonize design, study and compliance data and processes across stakeholders and provides a single tool for regulatory program planning, global dossier compilation, submission/registration management and agency communications.

Converge: The MasterControl Platform ensures organizations can automate processes, connect data and optimize performance across Regulatory and Quality departments, so you can use data-driven, risk-based models to drive new levels of operational excellence and remove barriers to innovation.

Accelerate: Ultimately, our mission is your mission – to bring life-changing products to market faster. By removing process barriers, connecting data and harmonizing processes, MasterControl can help you achieve new levels of digital regulatory excellence that improves your ability to gain and sustain market access faster.

To learn more about MasterControl's innovative approach to regulatory excellence and our solutions for Regulatory Information Management, please contact us at 1 866 747 8767 or visit www.mastercontrol.com.

1. "Medical Devices 2030," KPMG International Cooperative, 2018, https://assets.kpmg.com/content/dam/kpmg/xx/pdf/2017/12/medical-devices-2030.pdf
2. "Pursuing World Class Regulatory Information Management (RIM)," Gens and Associates, Annual RIM White Paper, 2016, http://gens-associates.com/wordpress/wp-content/uploads/2016/09/Executive_World_Class_RIM_Whitepaper_Summer_2016_Edition.pdf
3. "Sustainable Growth Via Profitable, High-Quality NPI," LNS Research, 2018, https://newiso9001.files.wordpress.com/2018/04/ic-qualty-2018-apr-npi-ebook.pdf
4. "Sustainable Growth Via Profitable, High-Quality NPI," LNS Research, 2018, https://newiso9001.files.wordpress.com/2018/04/ic-qualty-2018-apr-npi-ebook.pdf
5. "2018 Life Sciences Regulatory Outlook: Trends in life sciences and health care regulations," Analysis, Deloitte, 2018, https://www2.deloitte.com/content/dam/Deloitte/us/Documents/regulatory/us-regulatory-2018-life-sciences-industry-outlook.pdf
6. "Sustainable Growth Via Profitable, High-Quality NPI," LNS Research, 2018, https://newiso9001.files.wordpress.com/2018/04/ic-qualty-2018-apr-npi-ebook.pdf
7. "Pursuing World Class Regulatory Information Management (RIM)," Gens and Associates, Annual RIM White Paper, 2016, http://gens-associates.com/wordpress/wp-content/uploads/2016/09/Executive_World_Class_RIM_Whitepaper_Summer_2016_Edition.pdf
8. "Digital Reimagination," TATA Consulting Services, May 28, 2018.

About MasterControl

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.

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