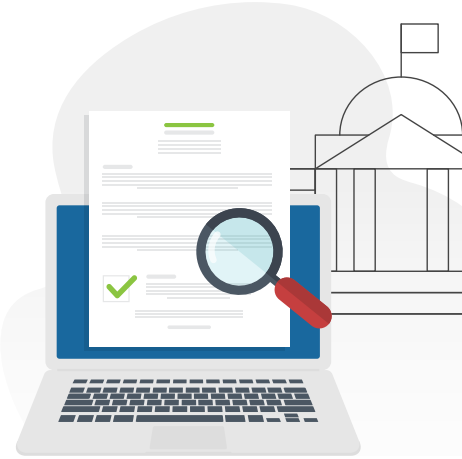
Solving Pharma's Regulatory Jigsaw Puzzle

Piecing together European regulation

The global regulatory agenda is dense, dynamic, and will intensify the data collection and management challenge for biopharma companies. With several new and complex regulations due to be introduced in parallel over the coming years **[Figure 1]**, sponsors run the risk of getting entangled in continuous and costly change management efforts.



In Europe, the Extended EudraVigilance Medicinal Product Dictionary (xEVMPD)[1] has been mandatory since 2012[2] and will continue until at least 2024. Not only do sponsors need to complete submissions in a structured database form, but they also face considerable pressure to adapt their submissions within 30 days of requesting changes to marketing authorizations. Companies of all sizes are struggling to process hundreds, if not thousands, of changes each year within the prescribed timeframe.

An Intense Data Management Challenge for Sponsors

50–60%

more data involved in IDMP than xEVMPD

Meanwhile, the European Medicines Agency's (EMA) Identification for Medicinal Products (IDMP)[3] looms large on the horizon and will become mandatory for all centralized approved products in Europe by the end of 2023. Initially intended to replace xEVMPD, the two regulations are now set to run in parallel until at least early 2025. With an estimated increase of up to 60% more data involved than in xEVMPD, IDMP poses an even greater challenge to sponsors' data management and processing efforts.

At a recent Veeva roundtable, customers described the difficulty of tackling data standards, governance, and quality foundations for the first time. Stakeholder alignment is a prerequisite and yet many cross-functional teams are not accustomed to collaborating.

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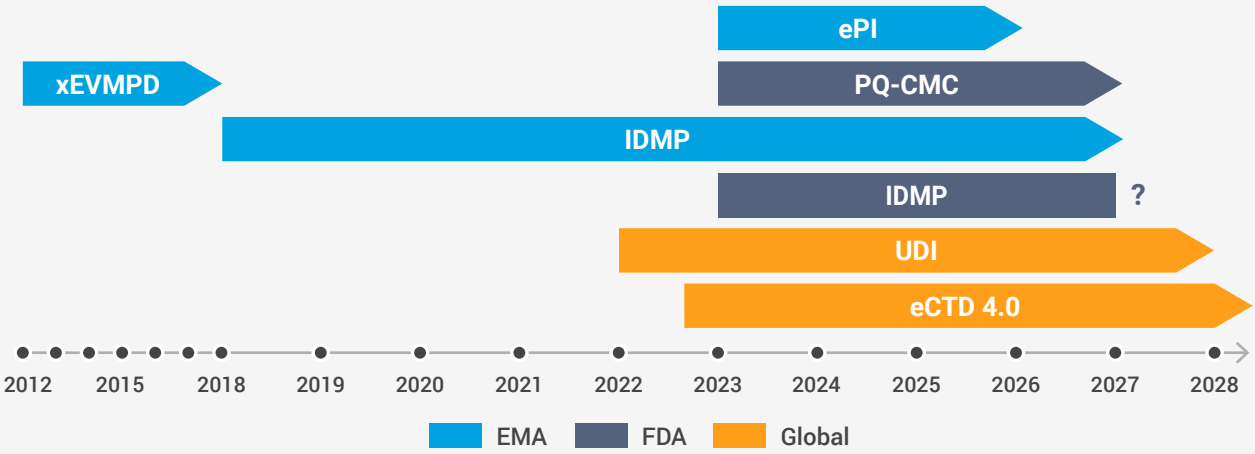
1 European Medicines Agency, Human Regulatory, Post-authorisation, Extended EudraVigilance medicinal product dictionary (XEVMPD) training
2 European Medicines Agency, Human Regulatory, Post-authorisation, Data submission on authorised medicines (Article 57)
3 European Medicines Agency, Human Regulatory, Data on medicines (ISO IDMP Standards): Overview

FIGURE 1: A DENSE REGULATORY AGENDA FOR SPONSORS



Although companies will feel IDMP's impact differently depending on their size, there is no alternative to compliance. The new requirements will be particularly daunting for emerging biotechs that need to register a centrally authorized product, given that these small companies are not well set up to navigate a complex regulatory environment.

Medium-sized companies with an established product portfolio must also prepare but are less immediately exposed to the impact of the regulation: as yet, there are no set deadlines for the decentralized procedure (DCP) for mutually recognized products (MRP) or national product authorizations. However, as a result of their legacy portfolio, these companies must comb through (and cleanse) data from different sources, and will need to establish data governance to keep up.

Enterprise sponsors will struggle the most to be agile, as they must coordinate between functions on an appropriate data governance structure, redeploy resources effectively, and require extensive system support.

The biopharma sector also faces a dynamic regulatory context outside of the EU. Sponsors selling products in the U.S. must prepare for the new electronic data standard introduced by the Food and Drug Administration (FDA) for Pharmaceutical Quality/Chemistry, Manufacturing & Controls (PQ/CMC).[4] This may introduce integration issues with other source systems due to the additional product manufacturing information that sponsors need to manage.

On the process side, the Electronic Common Technical Document (eCTD v4.0)[5] is transforming the way companies build submissions for approval to global authorities — with a significant impact likely on business processes.

Combined with a series of rolling EU deadlines (e.g., IDMP will mean two to three years of evolving requirements for different levels of authorizations), pharma companies are facing complex and continuous change management for several years.

[4] U.S. Food & Drug Administration, FDA Data Standards Advisory Board, Pharmaceutical Quality/ Chemistry, Manufacturing & Controls

[5] U.S. Food & Drug Administration, Development & Approvals Process | Drugs, Forms & Submission Requirements, Electronic Common Technical Document (eCTD v4.0)

Point solutions don't fit

Sponsors have been down similar roads before. The traditional response is to introduce distinct information management systems for each new regulation coming in. But piecing together point solutions won't work this time, given the volume of data, documents, and content covered by the rules.

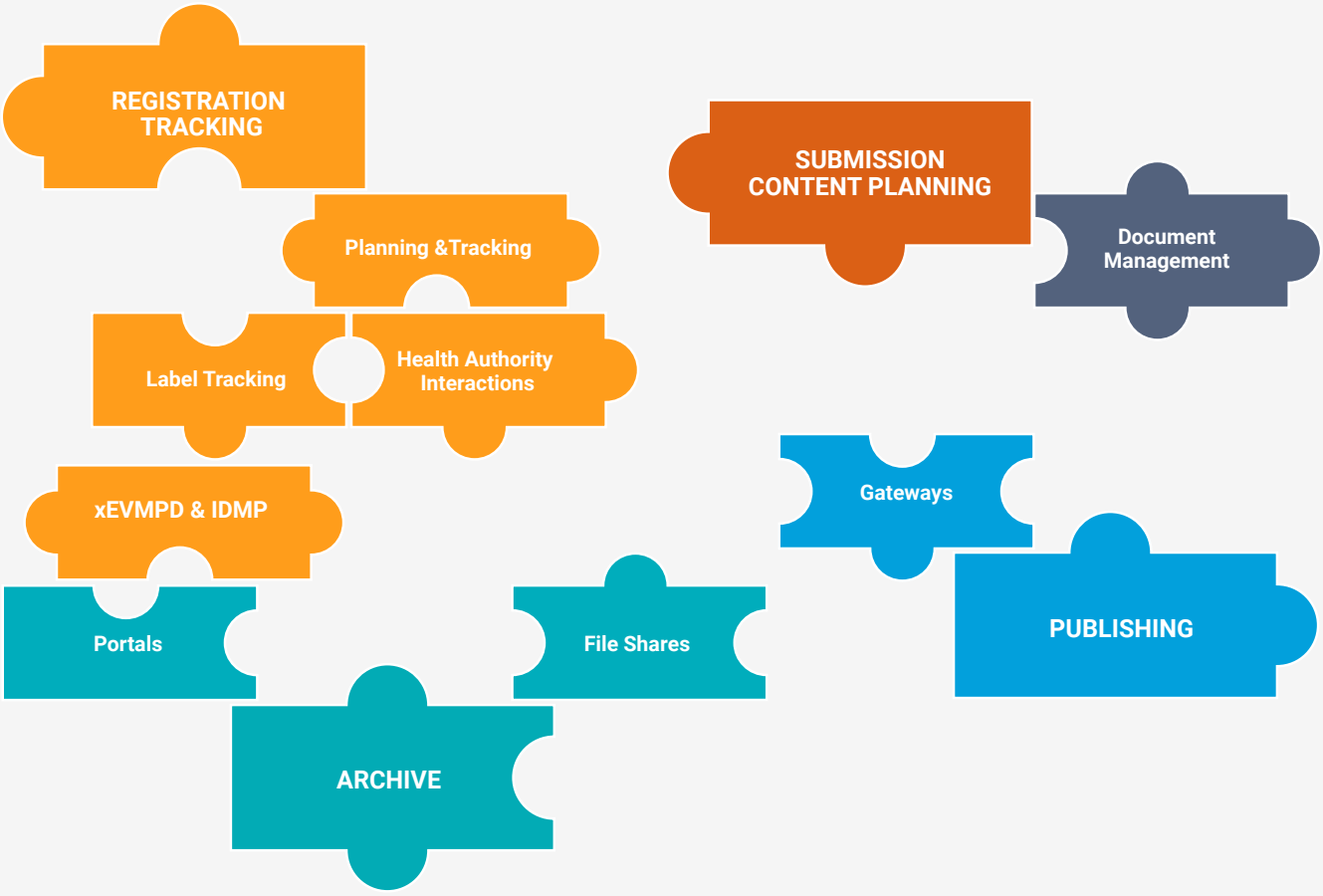
Pharma companies that try to respond to each of the upcoming regulations in isolation will become overwhelmed and struggle to solve the jigsaw puzzle **[Figure 2]**. Instead, the sector should take a holistic approach to the challenge, which means determining processes, systems, and skills that could govern all regulatory outputs.

A Series of Rolling Regulatory Deadlines

2–3 Years

of evolving requirements for authorizations at different levels

FIGURE 2: POINT SOLUTIONS WON'T UNLOCK THE PUZZLE THIS TIME



New rulebook for navigating change

There will be winners and losers from the new regulatory agenda. To navigate the required change management, companies need to assess their digital maturity **[Figure 3]**. Typical signs that an early-stage company will struggle include limited C-level interest or vision for digital transformation and a compliance-based approach to technology adoption that focuses on solving specific tasks (left-hand side of the framework).

Those that succeed — on the right-hand side of the model — tend to be:

- **Maturing organizations.** Companies of all sizes can be on the right-hand side of the framework but enterprise sponsors tend to feature heavily in this category.
- **Free of legacy systems.** Smaller companies are often on the left-hand side (early-stage) but able to move right quickly because their technology landscape is greenfield.
- **Focused in their portfolio.** Conversely, those that combine a broad portfolio (over-the-counter drugs, cosmetics) and legacy systems tend to have the most challenging journey.

The most digitally mature companies take a platform approach across R&D, bringing data and documents together in one unified suite for full oversight and compliance. This enables leaders to manage regulatory information from anywhere, eliminate non-value-adding tasks, and focus on what really matters to end-to-end drug development.

FIGURE 3: DIGITAL MATURITY FRAMEWORK FOR PHARMA

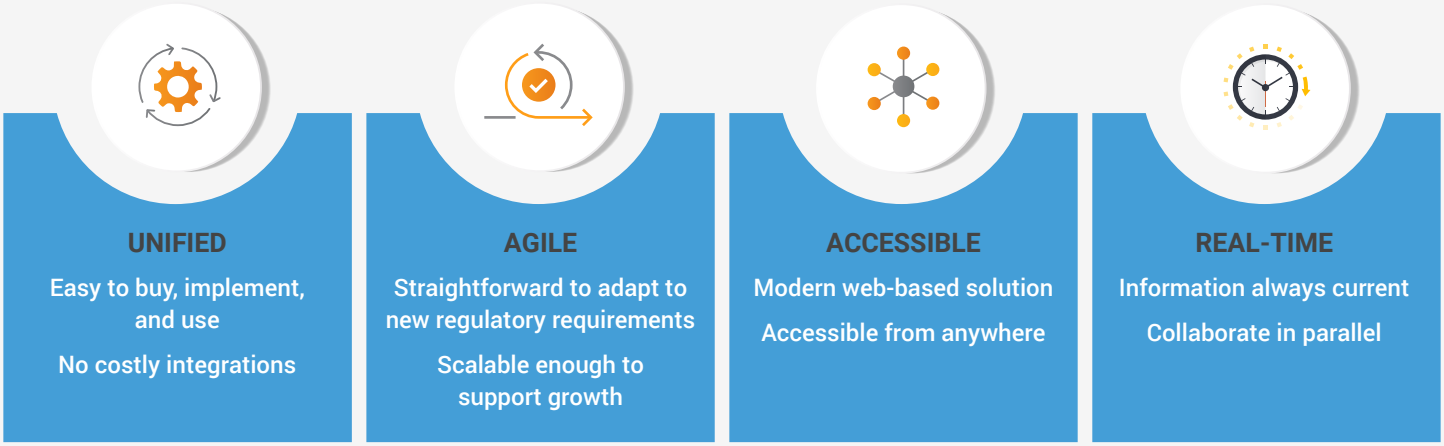
	●○○ EARLY STAGE	●●○ DEVELOPING	●●● MATURE
Corporate Vision	No clear vision on digitalization	Focused on process efficiencies and cost improvements	Understands how digitalization can transform the business
C-level Involvement	No C-level involvement or interest	Limited involvement, indirectly present at key touchpoints	Fully engaged with frequent direct touchpoints
Drivers	Compliance, ease of use, ability to solve specific tasks	Streamlining processes, driving measurable value	Transforming end-to-end operations with a unified suite
IT Solution	Point solutions	Connected systems	Platform approach across R&D

Source: Veeva Systems

Completing the jigsaw puzzle

Point solutions simply aren't scalable enough to address the new regulatory agenda, so won't provide an effective launchpad for digital transformation. Instead, companies need to take a unified approach to regulatory information management if they want to advance toward their goals of meeting patient needs, quickly and compliantly **[Figure 4]**.

FIGURE 4: FOUR SUCCESS FACTORS FOR REGULATORY INFORMATION MANAGEMENT



Technology is one component but insufficient to solve the regulatory puzzle. To sustain successful change management, regulatory leaders need to acknowledge the complexity of the challenge and build cross-functional teams that can manage people, processes, and data holistically.

When data management and governance are not standardized, it becomes challenging to know whether a given document version or data point is the right one. But once data is structured and compliant, it can be reliably shared cross-functionally, and create a data foundation. Putting in place standards, aligning correctly to the right reference material, and having a good governance process will also make it easier to adopt future standards **[Figure 5]**. Carried through effectively, the value of these changes will be undeniable to the wider organization.

FIGURE 5: ARE YOU READY? PHARMA'S REGULATORY CHECKLIST

Understand technology and procedural landscape

- ☐ Take inventory of existing systems and procedures that are unable to meet the regulatory requirements
- ☐ Identify data silos and repositories that need to be updated and connected

Evaluate data readiness and perform remediation

- ☐ Establish consistent nomenclature and data definitions
- ☐ Plan and execute data remediation projects
- ☐ Craft a sustainment plan to ensure that future data meets regulatory requirements

Establish data ownership and accountability

- ☐ Develop documentation on data handling for consistency and compliance
- ☐ Tie data ownership to functional areas
- ☐ Establish a culture of compliance with proper training and accountability for data integrity

Modernize regulatory operations

- ☐ Identify and implement a scalable RIM solution
- ☐ Ensure data repositories are properly linked across the organization
- ☐ Digitize RegOps and shift away from manual information repositories and spreadsheets

A game-changing approach

Structured data will smooth the health information exchange between EMA and the FDA, providing regulatory authorities with better visibility for pharmacovigilance and safety than possible with documents alone.

With immediate and comprehensive access to regulatory information, EMA and the FDA will be better placed to run analytics and share product knowledge across jurisdictions. For example, it will become easier to set up an early-warning safety system to flag any emerging issues with specific substances in products. It will also facilitate drug supply tracking, helping national health authorities to avoid shortages of critical supplies, as they experienced during the pandemic.

Better analytics, tracking, and data will lead to smoother trade, making situations of parallel imports — where each country determines pricing for doses and medications — less likely. Most important of all, patients will reap the benefits of access to innovative products at a lower cost.

Solving this complex regulatory puzzle will require a mindset shift — but the prize of a more competitive European sector that delivers better patient outcomes is certainly worth pursuing.

Find out how to prepare for the new regulatory agenda using Veeva Vault RIM.

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