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Right First Time: What The Medical Device Sector Can Learn From Pharma's Structured Data Challenges

As medical device suppliers respond to rising regulatory scrutiny, they can expedite their preparations by looking at the lessons learned in pharma around product data and associated content management. Here, Celegence's Sonia Veluchamy distils some best practices.

Life sciences Regulatory Affairs teams and their colleagues in Quality and Safety face already overwhelming workloads, which are compounded each year by evolving health authority (HA) expectations around detailed product information capture, monitoring and reporting. While the pharma industry is steeped in experience of this now, the medical device sector is playing catchup.

In pharma, a steady progression of HA requirements has triggered extensive investment over the last two decades – in IT systems, data standards and data governance preparations, and optimised data and content management. Most recently this has been towards adherence with ISO IDMP, the international framework designed to describe medicinal products using agreed vocabularies.

The wider goal for companies as they adapt to regulators' evolving needs is to achieve this in an affordable and futureproof way with benefits to their own operational efficiency. In pharma, this has prompted a series of strategic technology investments to streamline regulatory processes and ensure that patients can continue to access the drugs they need.

Growing Controls in a Booming Market

The global medical device market, worth an estimated $518.46 billion in 2023, is set to reach a value of $886.80 billion by 2032.[1] As ever more sophisticated devices – from surgical robots to implantable defibrillators and smart diabetes monitors – come to play an increasingly prominent and critical role in everyday patient care, regulators are steadily introducing new rules to ensure their safety. (The global drug device combination products market alone, which includes wearable devices, was worth $138.47 billion in 2023 and is set to grow at a CAGR of 9.0% over the next six years.[2])

As device suppliers strive to fulfil growing regulatory expectations, including those set out under the EU's trailblazing Medical Device Regulations (EU MDR),[3] there is an opportunity for these companies to learn from the challenges pharma has strived to overcome. These include overcoming information silos, harnessing unstructured data, and streamlining regulatory information management.

Responding to Rising Regulatory Expectations When Resources are Lacking

Since many rising stars in the medical device industry lack sizeable Regulatory functions, it is particularly important that they maximise their resources.

New research among Regulatory Affairs (RA) professionals across pharma and medical devices[4] confirms that time and bandwidth are the entire industry's primary challenge, followed by costs and budgetary pressures – concerns that are particularly acute for device suppliers. While just over half (57%) of pharma RA teams feel under-resourced to meet their 2024 priorities, this rises to more than three-quarters (77%) of medical device RA teams.

Among the best practices being established in pharma is a steady distancing from the traditional document-centric, case-by-case approach to dossier creation; extracting, collating and preparing the right

information each time – a highly repetitive and labour-intensive process that carries a risk of omission or incorrect insertions, and adds little value beyond the immediate purpose.

Modern regulatory information management (RIM) and enterprise information management (EIM) strategies, and supporting systems and processes, help tackle these inefficiencies – first by breaking down silos so that Regulatory, Safety and Quality teams can more readily share data and materials. This means they can avoid creating new content from scratch for each respective set of submission or reporting requirements. Ideally, they will now submit the exact information that is required in each given scenario too – no more, no less.

Minimising Repetitive Tasks

With proportionally fewer Regulatory professionals to defer to compared to pharma, medical device manufacturers can benefit from technology adoption and digitalisation in a number of ways.

A proactive approach to establishing systems and processes for content management and information exchange, for instance, will help companies keep pace as health authorities move forward with plans around electronic information exchange (*e.g.* under the FDA's eSTAR; the EU's EUDAMED; and STED, supported by many countries globally).

More strategically, companies also have an opportunity to leverage content prepared for one country for other markets. They could save a lot of time by reusing existing content components to submit to another countries, supported by appropriate technology. (That potential increases further if they harness niche tools geared to regulatory innovation, such as Generative AI – GenAI – capabilities as an aid in content creation, verification, formatting and change management, as discussed below.)

Identified Priorities For Investment

Medical device companies' appetite to invest in supporting technology is tangible. In the 2024 survey of Regulatory professionals' priorities and concerns, the top three targets for planned investment specifically by medical device companies were system capabilities to cope with MDR compliance and MDR maintenance, as well as improvements to regulatory intelligence – to keep track of respective market requirements.

Currently a large proportion of device companies track regulatory developments manually, and respond to changes reactively. This is despite the survey finding that almost half of medical device suppliers indicated 'knowledge of changing global regulatory landscapes' as among their top three most critical compliance skillsets for the next 2–3 years.

Digitalisation and cross-enterprise connection rank highest on device suppliers' wish-lists from RIM systems or platforms, meanwhile, as these companies look to implement something more formal and advanced in this area.

Content Re-use: The Practical Advantages of Structured Data Management

In pharma, where RIM capabilities are more advanced, change management came out as a higher priority in the survey, signalling a capability medical device suppliers are likely to need in future too. All of this places an emphasis on being able to pinpoint where various data and content assets are, and where any cascading interdependencies exist between them.

Many pharma companies are now seeing the benefit of transforming narrative/text-based content from existing documents into data-driven structured/tabular information. Turning flowing text into data or content extracts makes it possible for content to be reliably re-used. This can be achieved via software featuring smart automation – to populate each new template, and fulfil the given set of regulatory submission or publishing requirements – adding just what is needed, and no more. It can also support more efficient change management across the product lifecycle, as part of compliance maintenance.

Taking a more structured approach to content creation also supports 'lean authoring', a more direct and to-the-point way of writing that focuses documents on key data – resulting in streamlined documents that are easier to digest; reduced review and quality control time; and increased quality.[5] For regulatory dossiers in the life sciences industry, lean authoring involves maximising the scope for reuse of sections of approved content (content modules or building blocks), while keeping the emphasis on what each respective HA ultimately wants. Preparing a new HA submission, report, or compliant labelling/instructions for use, then involves building on content that has already been approved, using technology to help automate the associated cross-checking and content retrieval.

In the survey more than half of pharma RA professionals highlighted increased consistency across submissions, and reduced time and effort as the two main benefits of automated submission preparation/reuse of content extracts. This was in the context of eCTD 4.0-formatted drug submissions (those adhering to the latest ICH standard, a format that will ultimately also apply to medical device submissions).

Laying The Foundations For AI Use

As pharma's plans advance for smarter information and content repurposing, the opportunity to harness artificial intelligence (including GenAI) is now coming into focus, again signalling where medical device Regulatory professionals may want to lay foundations now.

Key targets for AI-based task optimisation included automated data extraction from documents and other sources; information summarisation from different sources; submission planning and tracking; document management (including document discovery); and compliance gap analysis. Survey respondents from medical device suppliers identified similar opportunities, but with information summarisation topping the list.

One of the overriding challenges the pharma industry has faced in its RA obligations over the years has been the diversity of approaches, processes, systems and formats in use across global organisations and markets. Bringing visibility, order and consistency to all of this has arguably been the greatest struggle of all.

This is among the strongest reasons for the medical device sector to move forward decisively in its approach both to capturing, managing and sharing its information, and to using this to build, submit and publish regulated content – from HA submissions and safety reports to labelling and instructions for use. If medical device suppliers can capture information from the outset in a form that will be easily retrievable and reuseable in different forms for different purposes, it follows that they will be setting themselves up for maximum process efficiency in future.

Setting Expectations

While exact standards for regulatory content management in the medical device industry

are still being set down and harmonised across the major regions of the world, the pharma industry's progress – with everything from eCTD dossier compliance to AI-supported structured content authoring – maps out a route that the medical device sector is very likely to travel down. So why not prepare for the journey now?

The convergence of the pharma and medical device sectors – driven by drug-device combinations as well as the growing interest of pharma in its sister sector's projected market growth – is reason enough for regulatory pathways to dovetail. Since the medical device sector is much more diverse and complex in its product definitions (and, by its own admission, already overwhelmed in fulfilling its existing obligations), it is all the more important that it introduces order, efficiency and sustainability to the way its product and manufacture data and content is managed.

A final recommendation for medical device companies is to cultivate the right mindset internally – towards data and content sharing, re-use, and building resources in a granular and structured way that serves multiple purposes across the product lifecycle – in contrast to the siloed mentality that has hampered technology-driven process transformation for so long in so many industries.

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Sonia A. Veluchamy

Sonia A. Veluchamy is the CEO and co-founder of Celegence, a company dedicated to improving patient outcomes through intelligent regulatory compliance. Previously Managing Director and a Board Member at ArisGlobal, and with 1.5 decades of industry experience, Sonia founded Celegence in 2017 with COO Punya Abbhi, to support life sciences companies by building technology and solutions to streamline strategic and operational compliance activities and make business more efficient.

Email: sveluchamy@celegence.com
Web: www.celegence.com