WEBINAR SUMMARY

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Pink Sheet
Pharma Intelligence

Real World Pharmaceutical Labeling Management: From Change Trigger to Implementation

Julian Backhouse, Associate Director, Regulatory Technology, IQVIA
Hilmar Rauhe, Product Owner, Pharma Artwork, IQVIA
Jane Z. Reed, PhD, Director, Life Science, IQVIA
Cham Williams, Associate Director, Business Systems, IQVIA

Jason Berning, Associate Business Development Director (EMEA Region), Regulatory Technology Solutions, IQVIA (Moderator)

KEY TAKEAWAYS

- Pharmaceutical companies recognize the need for improvements to the drug labeling process.
- Focusing on change management is key to improving labeling workflows.
- Transparent component management can facilitate the submission process.
- Labeling may turn out to be the initial use case for structured content authoring (SCA) and structured component management (SCM) in life sciences.

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OVERVIEW

Drug labeling is a dynamic and taxing workflow with many moving parts and hundreds of new or updated labels published weekly across regions. Labeling teams often spend an inordinate amount of time and effort sifting through multiple drug label sources and languages for relevant data and insights.

Pharmaceutical companies can benefit greatly from simplifying the process of finding and extracting drug label information. IQVIA's label management solutions provide a way of doing just that by enabling setup of custom label searches, rapid capture of relevant labeling documents from diverse sources, and optimization of label writing and analytics.

CONTEXT

The panelists discussed how IQVIA's end-to-end solution for label life cycle management can support pharma companies in simplifying the labeling activity process.

KEY TAKEAWAYS

Pharmaceutical companies recognize the need for improvements to the drug labeling process.

With increasingly complex pharmaceutical products coming to the marketplace, the requirements for labeling those products are also growing in complexity. Changing regulations related to new identification of medicinal products (IDMP) standards, which aim to harmonize how such products are described across data sources, are adding another layer of complexity.

> "Because there hasn't been a defined solution for labeling, companies have found themselves putting together ad-hoc technological responses with varying degrees of effectiveness and high cost of maintenance."
>
> *Cham Williams, IQVIA*

Ad-hoc technological solutions notwithstanding, most labeling processes are still too document-driven and characterized by time-consuming, manual, repetitive search and feature-extraction work, added Jane Reed. "There's a lot of potential for digital transformation, automation, and human-in-the-loop augmented intelligence."

Problems with data quality and consistency in the labeling information are additional challenges, as are error-prone, inefficient processes at the artworking stage that take the focus away from the real goal. "It's about bringing back the art to artworking because in the end artworking is what makes [labels] useful for the patients," said Hilmar Rauhe.

Focusing on change management is key to improving labeling workflows.

The evident weaknesses in the drug labeling process are causing companies to consider how re-orchestrating the way it is managed may help them bring new products to market more efficiently.

Managing access to information	The overarching objective of change management should be to enable an enterprise-level view of labeling, such that all teams have access to labeling information and a shared understanding of the labeling process not only within their company, but also across competitors and regions. "It's critical to be able to find and compare drug label information both from your core labels and your national labels, but also from your labels to other labels and against the guidelines," Reed said. She explained that labeling intelligence solutions that incorporate natural language processing technologies can go a long way toward helping pharma companies capture such nuanced information.
Managing label variations	The next step is to change the way people think about editing documents so as to "move away from thinking entire documents and start thinking small pieces that are put together where needed," Williams noted. He pointed out that when a change is made in a labeling document somewhere, people ought to consider what other documents use that piece of information, so that the change can be reflected in them, too, thus streamlining the entire workflow. Changes to label documents are often driven by **label variations** across different markets. Managing label variations, in turn, requires robust **component management**, which entails breaking down the labeling workflow into discrete chunks of information. *"Once your labels are being managed as elements, components and assemblies . . . [you can] tag a particular component that needs to be changed and [it will] propagate down to all instances of that component, whether it's been reused or repurposed in some way, shape, or form."* – Julian Backhouse, IQVIA
Managing artwork	At the end of the line of the labeling workflow is the artwork. Artwork in the pharma industry generally refers to packaging (e.g., folding boxes, leaflets) and web-based product representation. *"There are two perspectives here. The first is making things as efficient as possible for those who are creating artworks, meaning minimize errors and efforts and bring order into complexity; here is where we can make use of the components-driven approach. But there's also the patient perspective; here it means making things accessible and easy to understand; this is [about] bringing back the art to artwork."* – Hilmar Rauhe, IQVIA

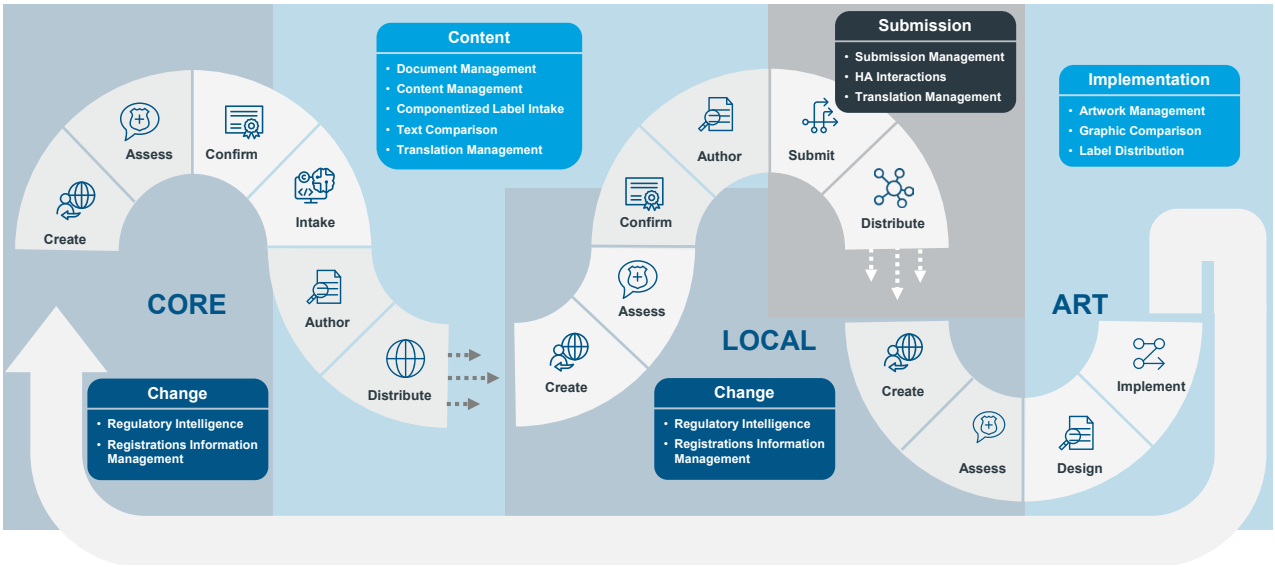
Transparent component management can facilitate the submission process.

Component management is an effective and efficient methodology not only for streamlining the management of label variations and the internal document editing process, but also for accelerating the entire new drug submission workflow.

As a data-centric approach to label management, rather than a docu-centric approach, component management can be used to pull together regulatory intelligence and visualize where regulatory changes impact labeling from a document perspective, Williams explained. "[Component management enables companies] to compile submissions not as a document but as different pieces needed to create that document [and] to create the next version of the submission."

> "With component management, there's no manually walking something back and forth. That component is traveling through the process from start to end and the accuracy remains confident."
>
> *Cham Williams, IQVIA*

Figure 1. Smart labeling: Using component management to achieve labeling compliance



Labeling may turn out to be the initial use case for structured content authoring (SCA) and structured component management (SCM) in life sciences.

Because local labels are structured at source, the labeling process lends itself to being a great starting point for implementing SCA in the regulatory and life science environments. Components can be infused with RIM core data elements, auto drafting, and error reduce features, while validated content can be reused in downstream destinations such as art/packaging, ePI portals, and commercial and aRMM materials.

What is important to keep in mind when building a SCA-based labeling solution, though, is how the process used to create that solution can be applied to other functions in the enterprise value chain. "You need to look at the bigger picture and not just focus in and say, 'We're going to build this all-encompassing labeling solution and forget about everywhere else,'" said Julian Backhouse. "That's never helpful; you'll regret doing that down the line."

Digitalizing and *componentizing* source documents to foster their reusability and facilitate the generation of downstream label dossiers can be viewed as a building block to realizing SCM in labeling, Reed added. Rauhe offered a perspective that illustrated why labeling may be only the start for the application of SCM: "SCM is terribly efficient, in particular if you want to be ahead of the chaos that comes with the growth of information. Having structured data-defined components is in fact the prerequisite for any digitalization or automation."

Granted, digitalizing document-centric processes and components can be excruciatingly onerous to do manually. That's where automating software, such as IQVIA's labeling intelligence platform, comes in.

CONCLUSION

Improving the labeling process can have significant and tangible commercial benefits for pharma companies wrestling with ever-changing regulatory, submission, content, quality, and CMC (chemical, manufacturing, and controls) requirements. With nearly half of pharmaceutical recalls due to errors in product labeling and packaging artwork—essentially, due to human error—it is easy to see how a robust, structured management process of labeling workflows can prevent many of those errors.

Williams summed up the return on investment of labeling intelligence solutions such as IQVIA's: "For a company, the return on investment is avoiding the issue that doesn't become apparent until the end of the process." Backhouse agreed: "It's engineering out the problems before they happen rather than trying to catch them at the back end."

BIOGRAPHIES

Julian Backhouse
Associate Director, Regulatory Technology, IQVIA

Julian Backhouse is an Associate Director – Regulatory Technology, leading the team responsible for labeling solutions at IQVIA. He has over 25 years of experience in component content management, automation, and global change control. Leveraging insights from CPG, FMCG, and Life Science, within which he specializes in labeling and packaging artwork management, localization, and automation, he has held positions in product strategy, technology delivery, and consulting services.

Hilmar Rauhe
Product Owner, Pharma Artwork, IQVIA

Hilmar Rauhe is an experienced professional with over 20 years of software development in various programming languages and has a background in the healthcare industry and printing and packaging industry. He joined IQVIA in 2022 and is product owner of ArtworkPlus®, a software for the automatic creation of artworks for pharmaceutical packagings (such as folding boxes, leaflets etc.).

Some of his accomplishments include inventing DNA cryptography in 1998, and publishing articles, patent applications, and press reports on topics such as DNA cryptography and anti-counterfeiting. In addition, he has been awarded multiple accolades for his work, including the 1st Rank of Cologne's Award of Innovation for "Molecular data memory" and funding from the State of North Rhine-Westphalia. He graduated in biology and computer science and holds a diploma from the University of Cologne.

Jane Z. Reed
PhD, Director, Life Science, IQVIA

Jane Reed is Director of Life Science at Linguamatics, an IQVIA company. She is responsible for leading the strategic vision for the Linguamatics product portfolio and business development for the pharma and biotech market, with a focus on development, safety, and regulatory. Reed has 20+ years' experience in vendor companies supplying data products, data integration and analysis, and consultancy to pharma and biotech—with roles at Instem, BioWisdom, Incyte, and Hexagen. Before moving into the life science industry, she worked in academia with post-docs in genetics and genomics. Reed holds a MA from Cambridge University and a PhD from Birmingham University.

Cham Williams
Associate Director, Business Systems, IQVIA

Cham Williams has more than 20 years' experience in the life sciences industry working globally for pharmaceutical, consulting, and technology solutions companies. His expertise includes managing regulatory technology, business process optimization, and systems planning and implementation. As a principal consultant, Cham advised clients on regulatory strategy and process development. He started his career as part of a pioneering submissions team recognized for submitting electronic CRFs, which later led to the development of electronic NDAs. Now at IQVIA, Williams is bridging the technology and business worlds, designing products that help shape the next generation of RIM solutions. Williams holds a BS in Economics from the University of the West Indies and a MS in Project Management from Drexel University.

Jason Berning
Associate Business Development Director Regulatory Technology Solutions, IQVIA (Moderator)

Jason Berning has more than 10 years of experience in Regulatory Technologies in various roles that include: consulting, product management, and sales. As an Associate Director of Business Development at IQVIA, Berning focuses on bringing transformational Regulatory Technology and Consulting solutions to his customers. He has worked with a wide variety of pharma companies of various sizes and is passionately optimistic about the digitalization of regulatory affairs.