Insight Brief

21ST CENTURY REGULATORY PUBLISHING

How AI will significantly cut turnaround in the regulatory publishing workflow

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TABLE OF CONTENTS

INTRODUCTION

For decades, regulatory publishing has been dominated by manual tasks. Publishers spend hours formatting documents, generating agency-compliant PDF documents, performing quality checks, compiling documents for submissions and troubleshooting issues to ensure that all submission requirements have been resolved and deadlines met.

These tasks are laborious and exacting, requiring the efforts of professionals with advanced science and medical knowledge to ensure accuracy and integrity of the components and compilation of the submission. For example, on a 200-page summary document in a New Drug Application dossier, a team may spend hundreds of hours to author, review, create summary document links to pages in other documents, and corroborate every statement. This translates to an expensive and time-consuming set of activities that require laser-sharp focus from the people ensuring basic data searching and verification tasks.

But imagine if many of those tasks were automated.

In the not-too-distant future, authors' and publishers' jobs will be transformed by artificial intelligence (AI) and machine learning (ML), with algorithms custom-built to manage all the routine work, freeing up skilled professionals to focus on the high-value tasks that leverage their scientific expertise.

We aren't there yet, but innovations in this space are moving rapidly in that direction.

AUTOMATION: THE FIRST STEP

One of the early innovations in this space occurred when medical writers began color-coding text to make it easier to see what statements needed to be linked back to other documents in the dossier. This drove efficiencies in the publishing workflow saving time and adding clarity to the process. However, the color-coding system didn't automate any of the work; it merely made it easier for publishers to complete the workflows.

In the near-future, vendors will employ machine learning algorithms to automate these steps. ML algorithms will be taught to add tags (citations) during the authoring process—even when the target document is not available—and to auto-generate links during the publishing process, eliminating the need for human intervention.

These algorithms will be trained using a company's specific publishing style and formatting preferences so they will recognize specific phrases (citations) that require additional references. This will be an important aspect of publishing automation because every company has its own language. For example, where one team might use the phrase "as shown in table two," another might write "see table 2." This application of automation can cut a significant number of hours from the submission process, and free up resources to focus on more value-driven and rewarding tasks.

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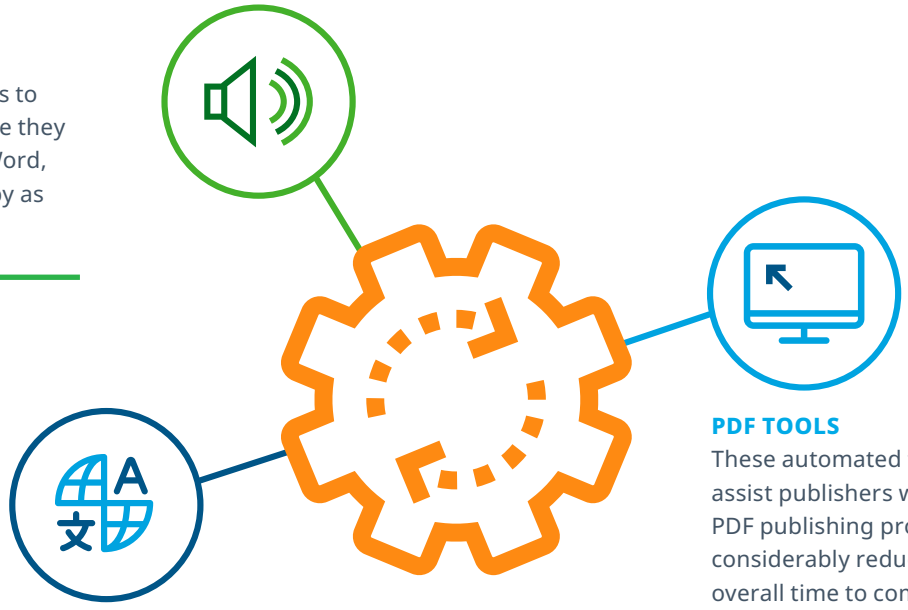
IQVIA is already deploying regulatory workflow automation tools in its RIM Smart solution and delivering impressive results. For example, a global pharma company has leveraged a series of IQVIA's automated publishing tools to eliminate hundreds of hours of manual labor from every submission process.

These include:

CITATION ASSIST
This add-on tool enables authors to insert pre-defined citations while they are creating documents in MS Word, reducing task completion time by as much as 40 percent.

SMART CITATION
This feature, available in RIM Smart, automates the PDF linking and bookmarking process for the citations present in the documents, reducing activity completion time from roughly 100's of hours per submission to less than 30 minutes.



PDF TOOLS
These automated tools assist publishers with the PDF publishing process, considerably reducing the overall time to complete these tasks as well.

TOTAL AUTOMATION: A VISION FOR THE FUTURE

Regulatory publishing innovations will continue to evolve. In the near-future, algorithms will be able to read and reuse text, interpret language, and eventually assemble whole documents using smart text elements and knowledge gleaned from existing databases. These documents will then be verified by the publishing team and as they are readied for submission.

Eventually, we may get to a point where publishers will come to work each day and receive a report from a bot alerting them to data that has been compiled for their approval — such as updates to labels based on manufacturing changes approved by an agency, new requests from health authorities that need to be addressed and reminders of queries and citations that require their review. When new requests come in, or tasks are automatically completed, the bots will notify the publishing staff in real time, ensuring that workflow moves quickly and smoothly and complex submission documents are delivered promptly and correctly to avoid costly delays.

We can also employ bots to do routine keyboard tasks that will drive efficiency in completing regular, repetitive publishing tasks.

If biopharma and MedTech companies want to leverage these publishing innovations, they must be willing to rethink their publishing processes. Automation tools can't be just tacked on to the end of processes or deployed as off-the-shelf solutions. They need to be integrated into the Regulatory Information Management (RIM) system so they can access all of the databases, standards, regulations and most current information necessary when creating or editing documents.

Then the algorithms then need to be trained to perform tasks in ways that are relevant to the team and add efficiencies to the process. That training will take time and it will require collaboration between the internal publishing and IT teams, and the AI solutions vendor to break down every step in the workflow and train the algorithms to recognize patterns and respond appropriately. This process can take months, however once the algorithms are trained, they will transform the publishing process and potentially cut thousands of hours from the team's workload. And with every document they will become even more reliable and efficient.

If biopharma and MedTech companies want to leverage these publishing innovations, they must be willing to rethink their publishing processes.

CONCLUSION

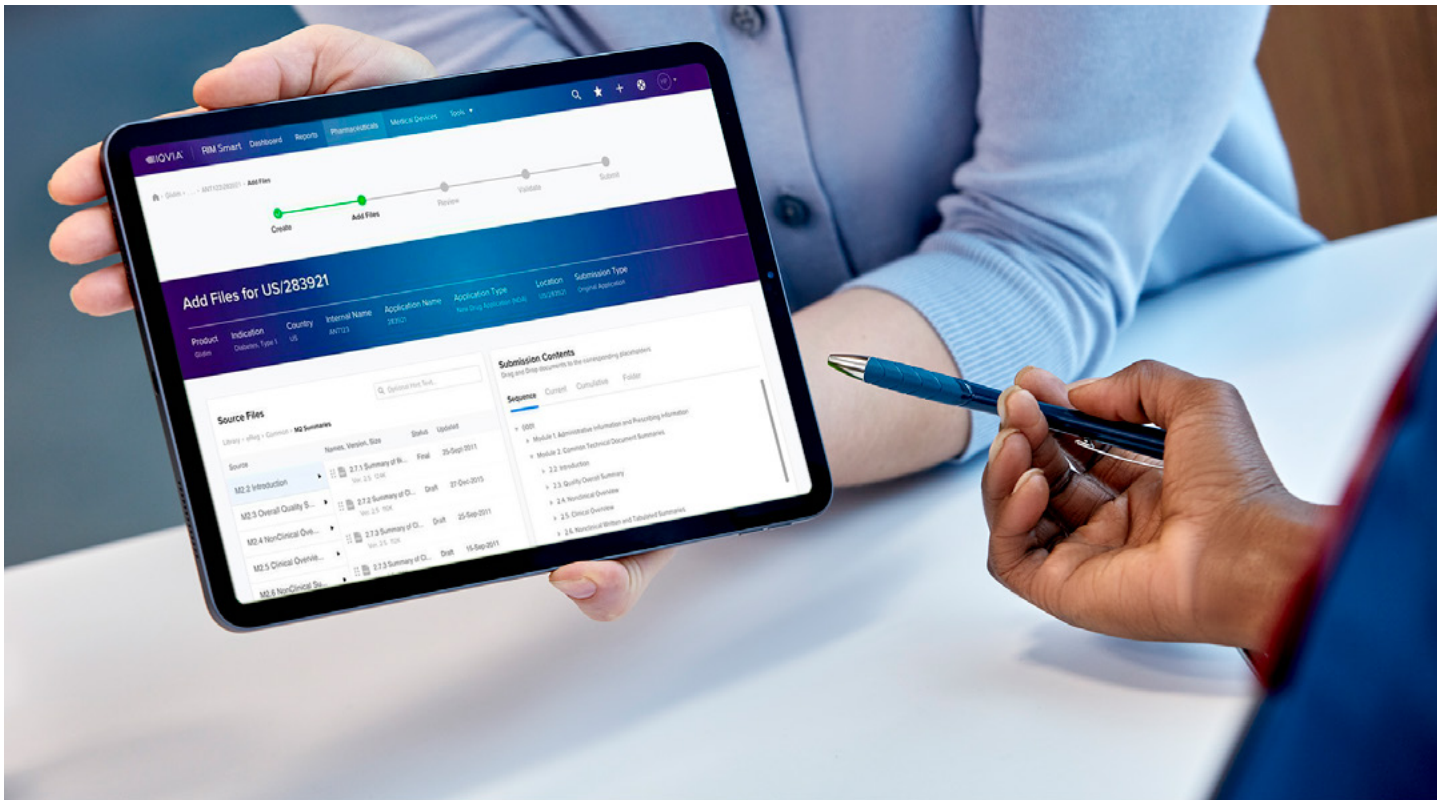
THE JOURNEY HAS BEGUN

While these solutions will never completely replace human experts in the process, they will make their jobs more rewarding and value-driven.

The heavy load of publishing is already being lightened through automation using IQVIA RIM Smart, which has eliminated many of the paper-based tasks over which publishers once labored. In the near-future, integrated RIM systems will feature real time updates, ensuring efficiency, productivity, speed and the ability to provide real-time information for health authorities.

These automated AI-driven tools will not only eliminate time from the regulatory publishing workflow. They will free-up skilled regulatory professionals to focus on the conclusions regarding patient safety and new treatments, making the future publishing environment more productive and accurate.

To learn more about how IQVIA can assist your company with regulatory publishing, contact us at: iqvia.com/rimsmart



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As Director and Head of Global Regulatory Affairs for IQVIA in India/APAC, Devjani Ghosh Dasgupta is responsible for managing the delivery of GRA services to global clients that range from large pharma to niche bio-pharma companies.

She also heads the Publishing CoE that provides flexible, agile, speedy and timely publishing services to global clients using a "follow the sun" approach. Devjani Ghosh Dasgupta focuses on managing the strategic growth of tech-enabled GRA and Publishing services ensuring optimal efficiencies, productivity and resourcing for delivery.

Her experience exceeds fifteen years providing global organizations with strategic leadership in Medical Writing and Regulatory Submissions.

Devjani Ghosh Dasgupta is Lean/Six Sigma certified and a champion for process improvements within GRA. She earned a PhD in Chemistry from Jodhpur University.

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As Associate Director, Offering Management for the Technology Solutions business unit at IQVIA, Joel Finkle is responsible for leading the integration of Product Labeling, Medical Devices, and the ISO IDMP standards for IQVIA™ RIM Smart.

He focuses on regulatory innovation and strategy, as well as leading the integration of emerging standards into the specifications and requirements of RIM Smart. Finkle is also responsible for IQVIA's Regulatory Templates Solution.

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LEARN MORE

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