



White Paper

The Impact of Generative AI in Quality Management

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Introduction

Life sciences companies recognize that their quality management (QM) and regulatory affairs (RA) teams are struggling to keep pace with increasing volumes of work and ever shorter deadlines. Generative AI, and large language model (LLMs), have the potential to revolutionize how QM and RA tasks are done. By integrating generative AI-powered solutions into workflows, organizations can generate quality management system (QMS) and regulatory content, support users with bot assistants, and automatically classify and tag regulatory and quality information.

IQVIA is committed to developing AI-based tools that provide a great user experience, while improving the efficiency of QM and RA teams.



Key takeaways

QM and RA leaders are grappling with globalization, complexity, and resource constraints

In today's global business world, harmonization is a goal for many regulatory bodies. However, most countries still have specific requirements when it comes to QM and RA. Complexity is on the rise in many life sciences organizations due to the volume of regulatory work, as well as the volume and velocity of workflows.

The time spent on compliance is increasing, but regulators are shortening the amount of time in which organizations have to report. Given these conditions, many life sciences companies are less confident that they can maintain compliance and keep pace with the volume of data and work. With the human resource pool shrinking, technological solutions will be needed to manage these challenges.

“There are over 101,000 global regulations and reference documents. Each year, over 8,000 new regulations and reference documents are published. That means there's a new or changed regulation or reference document published somewhere in the world every 13 minutes.”
- Kari Miller, IQVIA

“Each year, over 8,000 new regulations and reference documents are published.”¹

— Kari Miller, IQVIA

Generative AI is powering massive productivity gains across industries

Experts agree that generative AI tools will touch every industry, thanks to their ability to create images and video, software code, new compounds for drug discovery, and more. According to McKinsey, generative AI will add \$4.4 trillion per year to the global economy. Organizations like Harvard, MIT, and Boston Consulting estimate that productivity gains from generative AI may be up to 60%.

These productivity increases are due to the convergence of natural language and generativity. Natural language capabilities mean that the complexity inherent in tasks and interfaces can be hidden. As a result, users can communicate with computers more effectively. At the same time, generativity creates new content via deep learning models, whether that's in language, code, images, or video.

Figure 1: Generative AI Will Touch Every Industry



1. IQVIA Regulatory Intelligence data – October 2022



Large language models will have a significant impact on quality and regulatory work

Large language models are a form of generative AI that powers textual analysis and knowledge work. These deep learning models have been trained on large text-based datasets. Brewer shared the following insights about LLMs:

- *LLMs are highly accurate prediction engines.* These models learn the structure of the data and how to predict the next word. This gives them the ability to create content, perform sentiment analysis, transform one type of content into another, summarize content, and more. LLMs also have emergent behaviors; with natural language, users can coax and prompt models to do things that they weren't explicitly trained to do in the beginning.
- *Over the last three to five years, there has been rapid advancement in LLM capabilities.* This has occurred for multiple reasons. The underlying architecture of models has changed, processing power has improved, and much more training data is available. Large language models offer building blocks of capability which include conversing, generating content, summarizing, recognizing, classifying, and transforming.

Figure 2: Six Building Blocks for LLM-Powered Natural Language Processing Applications



Converse

- Communicate in natural language to the LLM and to other tools
- Understand intent and meaning
- Chatbots
- Q & A
- Query in natural language



Generate

- Generate content
- Text
- Code



Summarize

- Synthesize summaries, ideas and suggestions from different types of content



Recognize

- Entity identification
- Identifying the names, places, objects in content



Classify

- Sentiment
- Context-aware
- Other classification



Transform

- One type of content into another
- Language translations
- Tone and style
- Reading level

Figure 3: Promising Applications for Generative AI in Quality and Regulatory Software

<p>1 CHATBOTS AND CO-PILOTS</p>	<ul style="list-style-type: none"> • Q&A bots • Assistive help • Training/support bots
<p>2 RESEARCH TOOLS</p>	<ul style="list-style-type: none"> • Search • Synthesis • Summarization
<p>3 CONTENT CREATION</p>	<ul style="list-style-type: none"> • General • Domain-specific — e.g., pharma labels, quality and regulatory content
<p>4 CODE CREATION</p>	<ul style="list-style-type: none"> • Support for entry level • Support for advanced
<p>5 GENERAL PRODUCTIVITY</p>	<ul style="list-style-type: none"> • Synthesis, summarization • Recommendation
<p>6 TICKETING</p>	<ul style="list-style-type: none"> • Helpdesk • Feature request
<p>7 PERSONALIZATION</p>	<ul style="list-style-type: none"> • Persona-driven experiences • Sentiment-driven • Context-aware
<p>8 TRANSLATIONS</p>	<ul style="list-style-type: none"> • Global languages • Technical data to lay language • Reading levels











- *Large language models are changing the user experience.* Historically, users operated in a command-based paradigm. In quality management, if a user wanted to determine if any processes were out of control at a manufacturing plant, they might pull up a table of data, filter it, and apply knowledge about quality management processes. Today, users can query systems using natural language, providing instructions about the outcome or benefit they want to receive. In the field of quality management, for example, an LLM can be combined with other intelligent tools to provide immediately useful output — such as a graph about manufacturing processes and identification of quality trends.
- *Generative AI-powered features can be applied to a wide range of quality and regulatory work, including user training and support, research, content and code creation, personalization, translations, and more.*

IQVIA’s product design process overcomes AI model challenges and delivers a great user experience

The integration of generative AI into users’ workflows is a growing trend. Creating these generative AI-powered solutions, however, poses challenges for product designers. On the one hand, there are human factors to consider when interfacing with LLMs. On the other hand, the LLMs have inherent challenges to overcome, such as hallucination, data limitations, privacy and protection, memory limits, performance and more.

Design and human factors challenges can be overcome through a robust product design and testing process and emerging UX design principles and patterns for generative AI. The IQVIA Design System (IDS) leverages design kits, patterns and code libraries to provide a consistent best-in-class user experience and is being adapted and expanded to support generative AI use cases.

Figure 4: UX Design Principles for Generative AI-Powered Products

 <p>Keep humans in the loop</p> <p>The future is human-machine collaborative</p>	 <p>Communicate capacities</p> <p>Help users understand gen-AI abilities and weaknesses</p>	 <p>Support users</p> <p>Support users of all abilities and experience to get optimal results</p>	 <p>Avoid harm</p> <p>Avoid data leakage, cybersecurity risk, bias, misinformation, other harms</p>	 <p>Embrace variance</p> <p>Variability is a feature not a bug for some use cases</p>
 <p>Deliver the promise</p> <p>Connect to data/ecosystem providing real value and deliver high quality outputs</p>	 <p>Enable rich interactions</p> <p>Expect and leverage multimodality in inputs and outputs</p>	 <p>Be transparent and trustworthy</p> <p>Be transparent about AI actions and sources</p>	 <p>User control and memory</p> <p>Give user a way to manage AI, track history, customize, and protect data</p>	 <p>Contextualize and personalize</p> <p>Rich trove of data to be mined for ever-improving experiences</p>

From a security and privacy perspective, using proprietary and company data in LLMs also presents challenges. Retrieval augmented generation (RAG) is one approach that addresses these concerns. RAG transiently provides proprietary and company information to an LLM for use when generating an answer. As a result, the data flows through the model and isn't stored in a persistent way.

“At IQVIA, we have a design system that we use to push a really great user experience throughout all of our products. As we move into this generative AI future, we are keeping up with that in our design system and adapting new components to support the user experience.”

— Melanie Bennett Brewer, Ph.D., IQVIA Technologies



Quality and regulatory teams can use generative AI to improve efficiency and performance

Life sciences organizations see four key benefits of using generative AI to support quality and regulatory work:

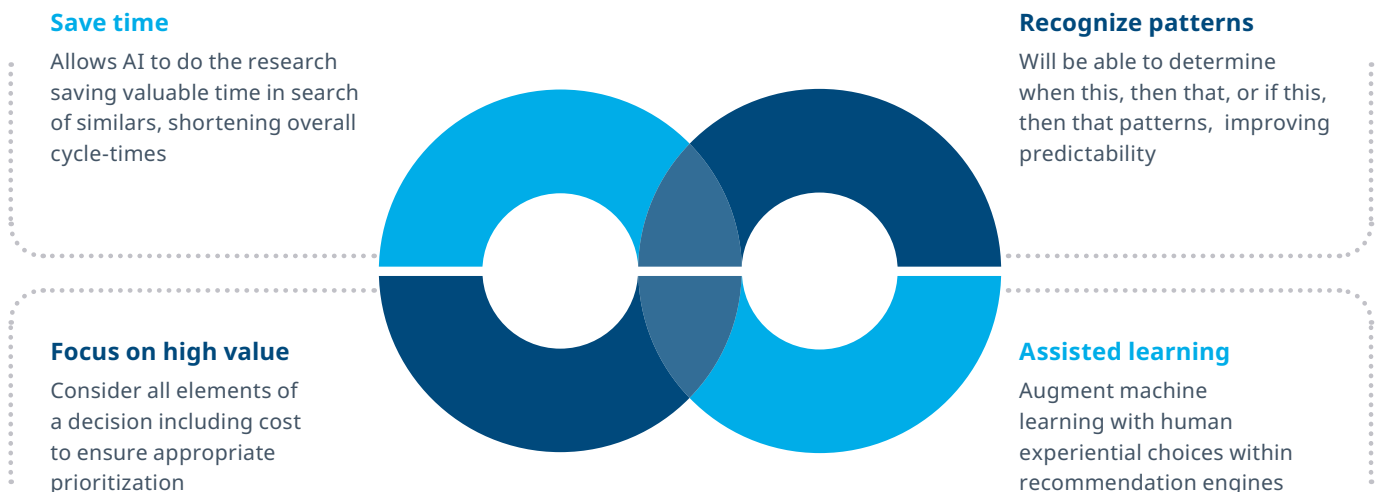
<p>IMPROVED OPERATIONAL EFFICIENCIES</p>	<p>Generative AI can decrease time and costs of executing robust quality management processes. The technology provides efficiencies when implementing and revising quality processes</p>
<p>FASTER TIME TO MARKET</p>	<p>By minimizing manual processes, generative AI minimizes unnecessary delays.</p>
<p>BETTER QUALITY CONTROL</p>	<p>Generative AI can contribute to continuous quality improvement through enhanced workforce training as well as assessment and implementation of changes to quality processes.</p>
<p>DECREASED CYCLE TIMES</p>	<p>By leveraging and connecting regulatory information more efficiently and increasing productivity through generative AI, cycle times decrease.</p>

AI tools handle tedious, repetitive tasks, and humans make the final decisions based on experiential knowledge



AI interactions that are augmented by human knowledge can be powerful in the quality and regulatory space. In these cases, the AI tools handle tedious, repetitive tasks, and humans make the final decisions based on experiential knowledge. Augmented human-AI interactions can be used with all types of AI, not just generative AI.

Figure 5: The Benefits of Augmented Human-AI Interactions



Generative AI tools are a good fit for many QMS and regulatory use cases

Miller discussed four categories of QA/RA work where generative AI tools deliver significant value:

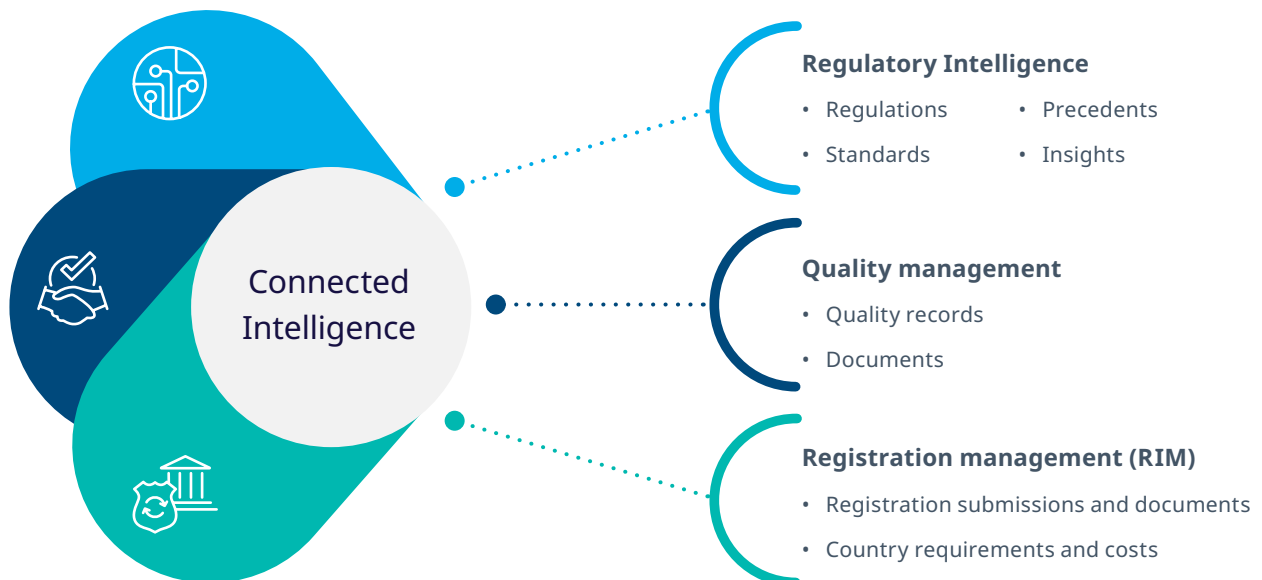
QMS CONTENT GENERATION	Generative AI can assist with content associated with audits, design control meetings and review sessions, training content, documents, and translations.
REGULATORY CONTENT GENERATION	Promising applications of generative AI include submission document content, label authoring, and generation of consistent responses to regulatory bodies.
BOT ASSISTANTS	These tools can support eSOPs and work instructions, how-to guides, summarized instructions for power users, and user support.
AUTO CLASSIFICATION AND TAGGING OF REGULATORY AND QMS INFORMATION	Generative AI can read and summarize lengthy regulatory documents, auto-suggest metadata and tags, and leverage existing ontologies and taxonomies.

IQVIA Connected Intelligence supports regulatory intelligence, quality management, and registration management

IQVIA Connected Intelligence powered by generative AI enables teams to take content from multiple sources, automatically assess and categorize it, and create new content that intelligently connects different QA and RA disciplines. By keeping all areas of QA and RA synchronized, rework is eliminated, efficiency increases, and audit results are improved.



Figure 6: IQVIA Connected Intelligence™ – Powered by Generative AI



Getting started with generative AI is all about balance

As life sciences organizations begin their generative AI journey, it's a good idea to focus on three areas:



Starting in the right place

Identify the problem that needs to be solved. Consider what data is available, since data is paramount to successful AI. Review the technology options.



Ensuring the problem is worth solving

Will the value delivered by AI exceed the cost? Organizations must never deploy technology for technology's sake.



Finding fit-for-purpose solutions

Verify that the technology is fit for the purposes that you have. Ensure that there is the right data, structure, content, governance, and security. It's also important to do a financial viability check.

Conclusion

As life sciences organizations seek to improve their operational efficiencies and reduce their time to market, many are exploring how generative AI can be applied to QM and RA functions. The opportunities are numerous, but not all AI-based solutions are created equally. Successful tools provide a user-friendly experience, while protecting sensitive data.

IQVIA is committed to delivering AI-based solutions to life sciences QM and RA teams, such as IQVIA Connected Intelligence, which keep humans in the loop, avoid harm, and are transparent and trustworthy.

About the authors



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Melanie is a human factors and information design expert with more than 20 years working in life sciences, healthcare, clinical trials and product research & design. She currently leads the User Research group of the Product Experience Design (PXD) team, delivering research, strategy and design innovation across a diverse portfolio of products in the Digital Products Organization (DPO).



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As the Sr Director of Product Management for IQVIA's SmartSolve, Kari Miller is responsible for driving the strategic product roadmap, and delivery of industry best practices and regulatory compliance solutions for quality management. Kari has more than 25+ years of experience delivering software solutions for life sciences. She brings that knowledge to her current team as they focus specifically on translating market and industry requirements into industry-leading enterprise quality management solutions that meet the needs of the heavily regulated life sciences QMS market. Kari earned a Bachelor of Science in Business Administration and a Bachelor of Science in Psychology from Marian College of Fond-du-lac, Wisconsin.

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