White Paper

2024 Safety and Regulatory Compliance Trends and Predictions for Pharma and Biotech

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Table of contents

Executive summary

Rapidly evolving technologies like artificial intelligence (AI), machine learning (ML), and natural language processing (NLP) are becoming the way forward for navigating pharmacovigilance (PV), safety, and regulatory needs. Staying ahead of the curve with innovative technology and safety partnerships is critical. In a recent panel discussion, IQVIA leaders, Archana Hegde, Senior Director of Integrated PV Solutions; Michelle Gyzen, Senior Director of Regulatory Affairs and Drug Development Solutions; Alisa Hummings, Senior Director and Head of Medical Information and Local AE Intake Services; Michel Denarié, Principal of Regulatory Affairs and Drug Development Solutions; and Simon Johns, Director of Medical Information and Marketed Product Safety, provided their insights into the safety and regulatory compliance trends on the horizon.

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— Alisa Hummings

Looking back at 2023, what safety and compliance trends surprised you?

Hummings: Despite ongoing cost pressures across the economy, there is still a bit of reluctance to think outside the box when it comes to technology solutions. We've been thinking of creative ways to maintain a low-cost solution for our customers while maintaining the status quo. In 2024, I think technology solutions will be more welcome, especially as the economy evolves.

Denarié: This year, we've seen a drying up of funding from venture capitalists and private equity funds. There are still funds, but they are a lot more discerning. On the scientific side, cell and gene therapies are the growth engine of the industry. Many companies are coming out with in vivo CAR T cell therapies, which is quite an incredible feat.

Hegde: When new technology comes into the world, it typically gets engineers, software professionals, and technologists excited. With ChatGPT, the buzz is not restricted to the technology community. Everyone is using it to enhance how they operate. This was such a pleasant surprise in 2023.

Johns: Coming out of the pandemic, people became very familiar with digital channels. You would've thought there'd be a big uptick in technology use as a result. However, there is a lot of uncertainty around ChatGPT that we must address to follow a customer-centric approach. For example, as we support medical information inquiries from healthcare professionals and patients, we must maintain compliance while using technology to the best effects.

Gyzen: Regulatory is sometimes hesitant to take on new technologies or step into the unknown, but we have come to a crossroads between 2022 and 2023 and reached a new understanding of what's achievable. This has ignited optimization campaigns for businesses. From last patient in, we're looking at anywhere from six to eight weeks to submission in the regulatory operations space. This is a major trend moving into 2024.

> *"Many companies are coming out with in vivo CAR T cell therapies, which is quite an incredible feat."*
>
> *— Michel Denarié*

Generative AI (GenAI) has created quite a stir this past year. Where do you see this technology advancing in the next year and what will be the major impact for your areas of focus?

Johns: Adoption of GenAI is a crucial factor. The industry is going to become more familiar and adapt to having GenAI support. It's going to drive efficiency both operationally and financially. However, it has been very disruptive in terms of individual pharmaceutical companies and their technology road maps. Companies need to consider what AI means for them.

Hegde: We have to nurture GenAI to see its full potential. There are rough edges, including data privacy issues, inconsistencies, and inaccuracies. GenAI must acquire the training to provide the correct outputs over time. We will see GenAI tools being built into the workflow rather than being stand-alone aids. We'll also see models trained by SMEs to help them grow more consistent and accurate, including literature reviews, case narratives, report summaries, and predictive analytics.

Gyzen: In regulatory, we're looking at furthering automated AI content generation for all different types of regulatory data and documents. The goal is to do regulatory intelligence better and use GenAI to be more proactive.

"We have to nurture GenAI to see its full potential."

— Simon Johns

Hummings: For certain aspects of PV, it's critical to get ahead of information about regulations and changes in the industry. On a case-processing level, it's making sure that the system is going to work for us. AI is learning from our experts to help reduce the efforts and be an assistive tool. There are some low-hanging fruits that we look forward to being able to leverage AI for, including mailbox management.

Denarié: I see AI becoming more important in selecting how to prioritize indications. Most of the new drugs are platforms that can be used in many different therapy areas. You can cast the net very wide, and AI and ML will come in handy.

What 2024 trends do you see for intake tools that handle structured, semi-structured, and unstructured adverse event (AE) data as well as built tools for follow-up automation and reconciliation?

Hegde: When we talk about intake, I would broadly classify it into four different applications. One would be optical character recognition where we are getting inbound forms digitized. We are eliminating the need for the initial case entry of the activity with the ability to parse multiple inbound forms and automatically separate them out and identify the auto redaction needed. The second is neural machine translation (NMT). With any kind of global case processing, we need to have the ability to auto translate across languages and dialects, which would also make things quicker and save translation costs. The third category is rule-based automation, like duplicate searches, case compare, or merge and auto triage cases. The fourth would be around NLP, i.e., literature being extracted and processed for case-related information.

From a regulatory perspective, what do you foresee emerging in the next three years? How should pharma companies begin preparing to effectively address these challenges?

Gyzen: The desire for more rapid adoption of intelligent automation technology in pace with its availability is going to be one of the major challenges. Honestly, I don't believe that the industry is quite ready to take on that Pandora's box. We need clean data, accuracy in AI-generated intelligence, and to safeguard our information. These all pose considerable risks to adoption and could create regulatory pitfalls and compliance challenges. I'd like to see companies taking thoughtful, phased approaches to adoption where teams take time to retrain and repurpose staff. We need to remember that people are still our greatest asset in this journey.

Denarié: The implementation of Project Optimus by the FDA's Oncology Center of Excellence requires companies to find a dose that's optimal, therapeutically. Dose optimizations require more work, time, and money. If this continues to work well in oncology, I could see the trend moving into other therapy areas.

"We need clean data, accuracy in AI-generated intelligence, and to safeguard our information. ...I'd like to see companies taking thoughtful, phased approaches to adoption."

— Michelle Gyzen

Earlier this year, the FDA rolled out diversity plans. Can you describe these plans and how you see them affecting trial design in 2024?

Denarié: It's been an ongoing initiative. The first guidance came in 2016 and was reinforced in 2020. In April 2022, it was established that you must present a diversity plan no later than your Phase 2 meeting. The idea is that U.S. FDA trials should reflect a representative population. We've developed a methodology that looks at the prevalence of race and ethnicity for each indication to meet this demand.

As companies determine how to comply with different countries' regulatory landscapes, what do you predict will be the biggest challenges and what steps should companies start taking to address them?

Hummings: The biggest challenge that we've seen is divergent expectations coming out of local inspections. Local legislation might say one thing and then, in an inspection, we may get feedback that they're expecting something much stricter. It's important to have local contacts in your countries to understand the expectations of the local authorities. You need to have an effective documentation, tracking, and communication process for local legislation changes so that they can be administered across the PV workflow. Changes could impact aggregate reports, regulatory reporting submissions, and risk management plans.

Are there any new country regulations you're watching for in 2024?

Gyzen: I'm focused on technology enablement and the post-marketed and regulatory operations space. As we start to build out new systems and automations, global health authorities are going to respond. We may see greater collaboration and consolidation in how health authorities are accepting submissions. I suspect that we may see the reinvention of the electronic common technical document (eCTD).

Denarié: The MHRA and the EMA were joined at the hip before Brexit. For two years, they have respected each other's guidance, but I think they're going to part ways. We also see agencies trying to get guidance on cell and gene therapy. Anvisa in Brazil is making a big push in that area to be at the forefront of drug development.

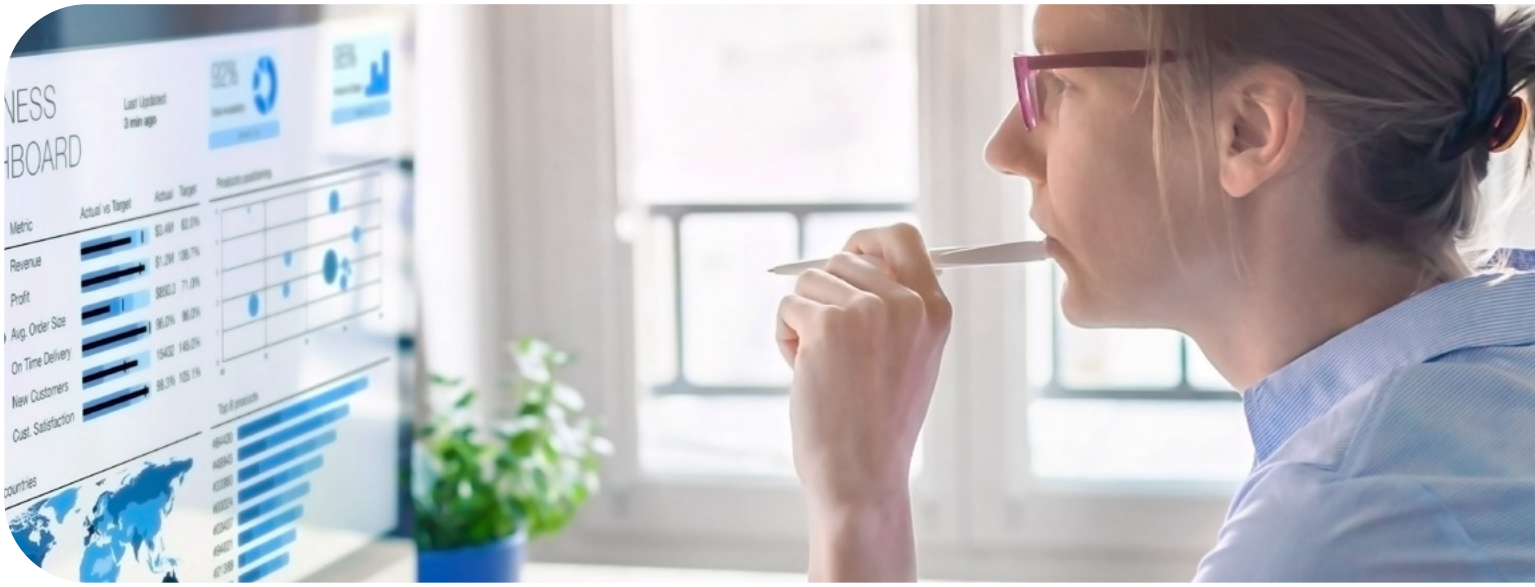
"There are very few companies in a position like IQVIA to provide tech and service together."

— Archana Hegde

It seems like the industry is shifting towards safety services and technology integration to stay compliant. Where should companies start when it comes to implementing combined services?

Hegde: Typically, pharma and med device companies deal with multiple vendors who provide technology while services come onboard after, or vice versa. They often work with two or more vendors, which ends up being inefficient, especially because they become a go-between. There are very few companies in a position like IQVIA to provide tech and service together.

A single vendor providing technology and PV services brings synergy, cost savings, and efficiency. If they're trying to build their PV organization from the ground up, they should go with a technology and service vendor to get started in the right direction. If they have existing tech or service partners with contractual agreements, it doesn't need to be something they switch to immediately. It can be a transitional process.



Many are wondering whether AI chatbots will replace humans in the pharma industry over the coming years. What's your perspective on this and how can companies prepare?

Johns: It's a very important question. Pharmaceutical companies must have suitable channels to facilitate customer engagement. They must provide a channel for healthcare professionals and patients to contact their pharmaceutical company with PV or medical information questions.

I view the chatbot solution as an agent assist rather than an agent replacement. If it's a very busy time for a call center, offer an AI agent as a backup followed by a warm transfer to a human agent. Ensure that the content to support inquiries is approved by your medical affairs department and drives compliance requirements. Consider the suitability of an organization to adopt said technology, identify initial key areas that could be optimized, and then phase them in.

What other uses of AI and machine learning are you seeing augment PV services?

Hegde: Conversational AI for medical information. It's an intelligent decision assistant that offers medical literature parsing and extraction, and auto translation. Giving intelligence to the data is a big part of what AI does. The auto causality can be captured based on previous events or patient information by giving recommendations for a cause and delegating the right SME to choose it. For regulatory reports, there is potential to prepare the draft for the safety expert to review. Efficiency is important, but that doesn't trump patient safety and compliance.

"I view the chatbot solution as an agent assist rather than an agent replacement."

— Simon Johns

How do you see AI being used in indication prioritization next year?

Denarié: This is one of our most popular deliverables. Often, companies have indications in mind and ask us to prioritize based on scientific rationale, market attractiveness, and operational feasibility. Sometimes a company provides data on the asset and asks for indications. For a company that wanted us to consider anything related to HLA appetite, we used NLP to come up with hundreds of different literature pieces. We identified 15 indications. Afterwards, one of our experts spent weeks determining which ones had merit. AI and ML could come in to save time and money for customers.

How will AI, ML, and LLM be introduced in eCTD preparation, submission, and query management?

Gyzen: It's already been introduced through simple automation document comparison. In the future, we'll be seeing automated content creation using AI, ML, and LLM in a more sophisticated way. We're looking at end-to-end automation of eCTD development — from authoring compilation to validation and submission. AI, ML, and LLM will aid in deciphering and managing communication from health authorities. We can also combine our organization's intelligence to answer health authority queries efficiently and deliver expected outcomes.

What trend excites you the most for 2024?

Gyzen: I'm excited to see how people will adapt. We're quite resilient and I think we're going to find folks learning things that they may have never thought they would learn.

About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry. IQVIA creates intelligent connections to deliver powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients. With approximately 86,000 employees, IQVIA conducts operations in more than 100 countries. Learn more at www.iqvia.com.

About the authors

MICHEL DENARIÉ
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Michel Denarié is a Senior Principal with IQVIA's Regulatory Affairs and Drug Development Solutions, a group that helps emerging biotech sponsors around the world with their early clinical development strategy and regulatory process. Denarié's experience in the pharmaceutical industry spans over three decades and encompasses roles in consulting, sales, marketing, market research, and offering development, both on the pharma and vendor side of the industry. A frequent author and speaker, Denarié's work has appeared in several trade publications. Denarié earned an MBA from the Darden School of Business at the University of Virginia and holds a BS in finance from the American University in Washington, DC.

MICHELLE GYZEN
Senior Director, Regulatory Affairs and Drug Development Solutions (RADDS), IQVIA

Michelle Gyzen is a Senior Director with IQVIA's Regulatory Affairs and Drug Development organization, designing strategic solutions for regulatory, focused on operational efficiency, scalability, and technology. She has over 20 years of experience in pharmaceuticals, biotech, and medical devices with expertise in designing large-scale regulatory outsourcing programs, offshore resource modeling, and regulatory tech integration and automation. She serves on industry panels and consortiums, providing expertise on Future-Fit Regulatory. Gyzen studied Business and Industrial Organization at both North Carolina State University and Southern New Hampshire University.

ARCHANA HEGDE
Senior Director,
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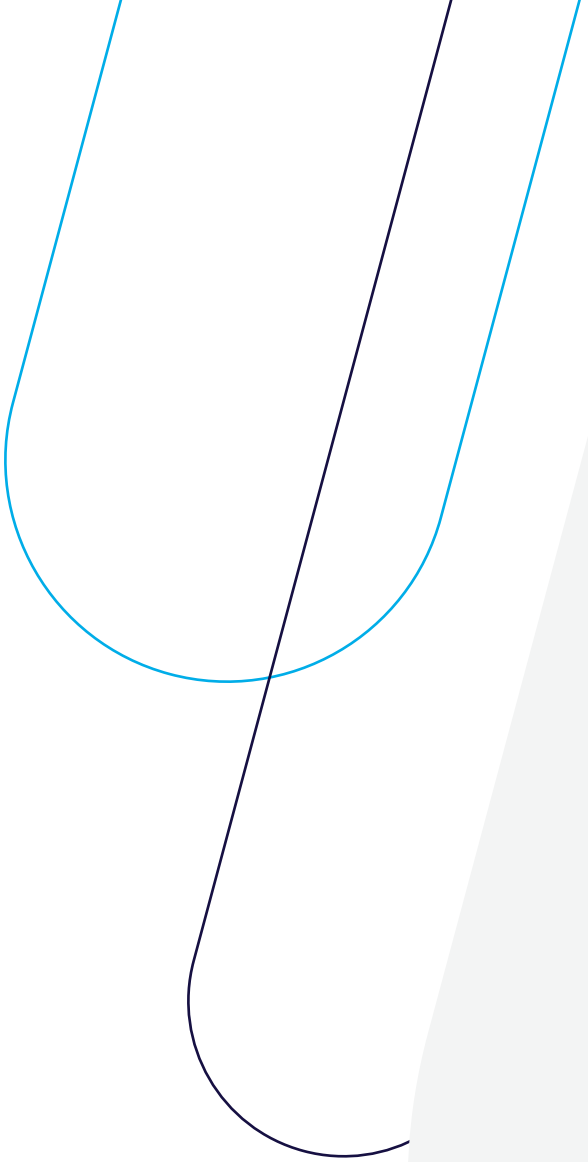
Archana Hegde joined IQVIA in 2015 and has been in various leadership roles implementing technology solutions to support critical business processes. In her current role, she provides senior leadership and oversight to the Safety Tech-Service Integrated Offering delivery combining IQVIA's expertise both from a technology and service perspective focusing on accuracy, efficiency, compliance, standardization and automation.

ALISA HUMMINGS
Senior Director and Head of Medical Information and Local AE Intake Services, IQVIA

Alisa Hummings joined IQVIA in 2010 and provides global leadership of the Medical Information and Local AE Intake Department. Hummings is responsible for global oversight and strategic leadership, and ensures proper governance is in place for all programs with Medical Information and AE Intake scopes.Located in RTP, North Carolina, Hummings has over 24 years of management experience and 17 years of CRO, pharmacovigilance, and medical affairs expertise.

SIMON JOHNS
Director, Medical Information and Marketed Product Safety, IQVIA

Simon Johns manages global MI projects focused on process optimization and technology enablement to drive enhanced efficiency and customer engagement. Johns is a member of the European DIA Medical Information and Communications Training Team, advising pharmaceutical companies on best industry practices, innovation and automation. He speaks regularly on topics ranging from combined human and AI conversational agent models for MI to the benefits and increased value of integrating MI and pharmacovigilance. Located in England, Johns has over 25 years of experience supporting global pharmaceutical customer projects.



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