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The State of Generative AI in Life Sciences

THE GOOD, THE BAD AND THE UGLY

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Introduction

Generative AI (GEN AI) has the potential to revolutionize various aspects of the life sciences industry from product development through commercialization and clinical trials through post market surveillance. GEN AI refers to the ability of AI systems to generate new data based on the existing datasets used to train it. The rapid advancements in AI and machine learning techniques have opened new possibilities for leveraging GEN AI models in Life Sciences. In this context, GEN AI could aid in optimizing research, development, and the manufacturing processes of medical products. However, our research shows the industry is not yet ready. Contributing to the lack of readiness are regulatory compliance and data security concerns, and workforce knowledge, indicating that navigating legal frameworks, protecting sensitive information, and upskilling employees are pivotal concerns.

In the dynamic landscape of the life sciences industry, GEN AI has emerged as a double-edged sword, embodying the promise of revolutionary advancements alongside significant challenges.

The Good:

Life science professionals surveyed for this report recognizes the potential of GEN AI to transform various facets, including:

– drug discovery

– medical device research and development (R&D)

– manufacturing

– supply chain optimization

– laboratory operations

– post-market surveillance

heralding a new era of innovation and efficiency.

The Bad:

Optimism for GEN AI is tempered by the realization of a prevailing lack of readiness in terms of infrastructure, expertise, and regulatory frameworks necessary to support the seamless integration of GEN AI technologies.

The Ugly:

An ugly truth about the current state of GEN AI in life sciences becomes apparent through organizations' admissions of their inability to adequately address the data management and privacy concerns associated with training large language models, casting a shadow over the full realization of GEN AI's potential in the life sciences industry.

Recognizing the transformative power of AI in healthcare, the FDA is proactively seeking to harness this potential responsibly and effectively.

"As part of our AI strategy, the Agency is collaborating with public/private partners to develop a framework for assessing the potential risks and benefits of healthcare AI—this issue is too large to be contained within the FDA. We're also developing guidelines for the responsible deployment and ongoing monitoring of AI-driven health care solutions, including those using both adaptive and GEN AI methods. The aim is to adapt general AI regulation and standards where needed to the unique characteristics of the health care sector. For instance, general AI regulations often stress the importance of accountability and transparency, which are also crucial in the health care domain due to the sensitive nature of health-related data." This strategic initiative underscores the FDA's commitment to ensuring that AI technologies in healthcare are deployed in a manner that is safe, effective, and aligned with the best interests of patients and the public[1]"

Robert M. Califf, M.D.
Commissioner, US FDA

Research Approach

To investigate the current state of adoption, as well as the practical use of GEN AI in life sciences, Axendia conducted a market research study and surveyed over 200 life science industry professionals and technology/software providers. This study explores the current landscape, opportunities, challenges, and use cases for Gen AI applications in life sciences.

Axendia thanks the following executives for their insights in this research report:

Rex VanHorn
SR AD, IT Technical Architect
Boehringer Ingelheim USA

Sarath Moses
Consultant – Digital Innovation
Bristol Myers Squibb

QUICKLINKS

In this report we share market research data specifically related to:

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1 The Industry's Current Knowledge of and Comfort Level with GEN AI

To begin, we explore the level of familiarity of life science industry professionals with the concept of GEN AI.

36% of industry professionals report being very familiar with the concept of GEN AI (Fig. 1) with an equivalent proportion describing themselves as being only somewhat familiar. 27% of respondents are still in the learning phase, leaving a significant opportunity for educational initiatives and strategic partnerships to bridge the knowledge gap. This distribution of familiarity levels reflects the current state of GEN AI adoption but also suggests the potential for rapid market expansion as awareness and understanding continue to grow.

There is a telling disparity in self-reported familiarity with the concept of GEN AI across various levels of responsibility within the life sciences industry (Fig. 2)

C-level executives lead with confidence, with 82% feeling very familiar with the concept, which may reflect their strategic oversight and need to stay ahead of emerging technologies. In contrast, individual contributors report a 31% rate of being very familiar, suggesting a more hands-on but perhaps narrower exposure to GEN AI.

Understanding a concept like GEN AI can range from recognizing its potential impact on the industry and across the product lifecycle, to grasping the intricacies of its mechanisms. It's one thing to understand GEN AI's benefits and strategic importance; it's another to understand the data requirements, model training, and validation processes necessary to implement GEN AI in GxP environments.

Rex VanHorn, Sr. AD, IT Technical Architect at Boehringer-Ingelheim, USA expressed his belief that many executives are familiar with the concept of AI

but not necessarily with its technology, application, or implications, suggesting that they are now working to understand where GEN AI can help their business processes, and the best way to bring GEN AI'S abilities to existing and future applications.

While there is some degree of awareness across all roles, there are noticeable differences in the depth of familiarity with the concept of GEN AI (Fig 3).

The data suggests that those in R&D roles have the highest self-reported familiarity with GEN AI, followed by personnel in Management and Digital

How familiar are you with the concept of Gen AI? (Select one)

- ■ Very familiar
- ■ Somewhat familiar
- ■ Learning

All survey respondents: 36% Very familiar, 36% Somewhat familiar, 27% Learning

Figure 1

C-Level Executive: 82% / 9% / 9%
VP/General Mgr.: 62% / 24% / 14%
Individual Contributor: 31% / 54% / 15%
Dep. Head/Director: 23% / 43% / 34%
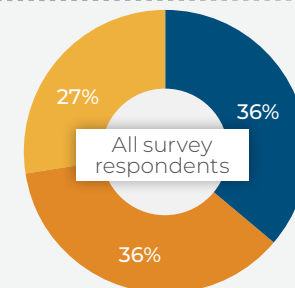
Figure 2: By levels of responsibility

R&D: 57% / 29% / 14%
Mgmt.: 55% / 18% / 27%
DX: 53% / 40% / 7%
IT: 43% / 36% / 21%
Quality: 38% / 51% / 11%
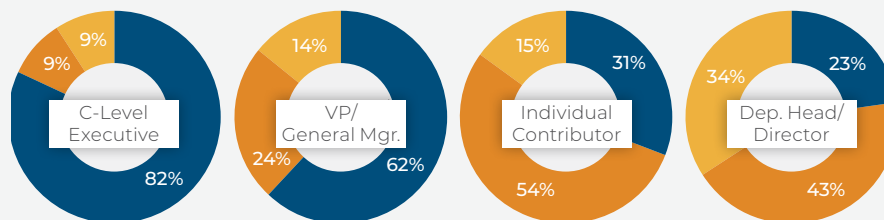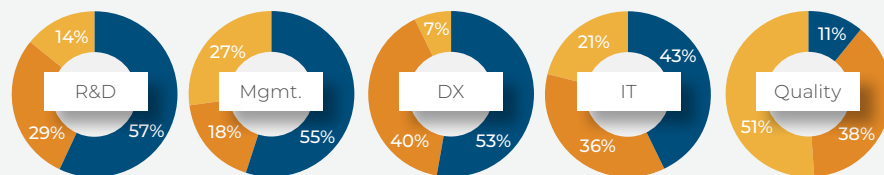
Figure 3: By role

Transformation. Individuals in Quality roles report less familiarity, with a significant number still in the learning phase. Personnel in IT report the closest balance between being very or somewhat familiar.

"AI technology is not new, but the ability to implement it at scale in the life science industry is. It's not necessarily that personnel in varying roles across organizations aren't currently familiar with GEN AI but rather they need the chance to learn it"

Rex VanHorn
SR AD, IT Technical Architect
Boehringer Ingelheim USA

Given these insights, it may be beneficial for the organization to invest in targeted educational programs to raise the overall understanding of GEN AI. This could include specialized training for those in Quality roles and collaborative learning opportunities that leverage the knowledge from R&D, Management and Digital Transformation departments to bridge the familiarity gap.

Today, the outlook for GEN AI in the life sciences industry in terms of infrastructure, expertise and regulatory considerations is bleak. Only 4% of survey respondents indicated the industry is very ready (Fig 4).

The varying perceptions of readiness for embracing GEN AI within the life sciences industry, segmented by different organizational roles is consistent with the consensus (Fig 5). The biggest takeaway from this data is that 9 out of 10 from each functional area selected not/somewhat ready. The highest level of readiness came from IT professionals, with 8% selecting very ready.

Technology and software providers who also completed the market research survey surprisingly have similar opinions (Fig 6). Six out of 10 vendors associated with QMS, MES and ERP solutions are of the opinion the industry is not ready. Those associated with LIMS and PLM present a more optimistic view.

60% of LIMS and 56% of PLM vendors are of the opinion that industry is very or somewhat ready.

The integration of GEN AI poses specific challenges for core systems such as QMS, MES, PLM, LIMS and ERP but there are opportunities as well. GEN AI can drive efficiencies, such as predictive maintenance in MES, enhanced forecasting in ERP systems, improved anomaly detection in QMS, advanced analytics for LIMS, and more accurate modeling in PLM. It can also facilitate innovation in drug development, personalized medicine, and clinical trials by harnessing the predictive power of AI to analyze vast datasets.

In light of these factors, Life Sciences organizations may need to conduct thorough assessments of their

In your opinion, how ready is the life sciences industry in terms of infrastructure, expertise, and regulatory considerations to effectively leverage Gen AI technologies? (Select one)

■ Very ready
■ Somewhat ready
■ Not ready

All survey respondents

4%
45%
51%

Figure 4

IT: 8% / 46% / 46%
R&D: 7% / 50% / 43%
Mgmt.: 5% / 41% / 55%
Quality: 4% / 38% / 58%
DX: 33% / 67%
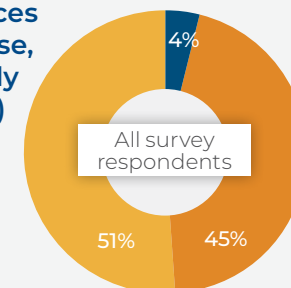
Figure 5: By organizational roles

ERP: 8% / 33% / 58%
LIMS: 7% / 40% / 53%
PLM: 6% / 50% / 44%
MES: 5% / 38% / 57%
QMS: 3% / 38% / 59%
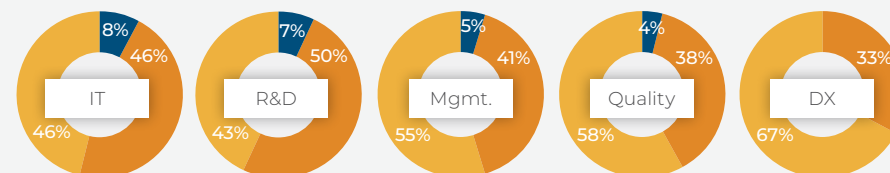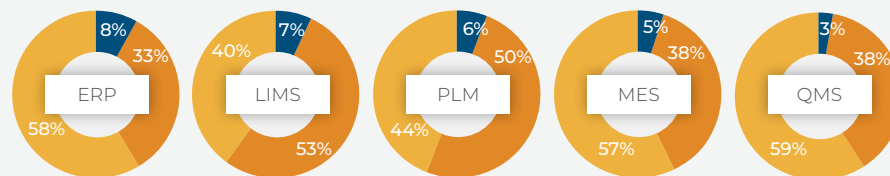
Figure 6: By technology providers

systems, invest in training or hire talent with the appropriate expertise, and engage with regulatory bodies to define the appropriate levels of assurance needed to support compliance when adopting GEN AI technologies.

"The response from IT professionals is likely due to their closer involvement with the technology itself. A more unified approach to AI readiness is necessary, which should include cross-departmental education, including how AI developers and data scientists can work with solution architects and application developers, investment in infrastructure, and a clearer path to the adoption of GEN AI applications in life sciences," said VanHorn and added, "there is a tectonic shift in the way that applications are being developed in order to implement AI. Now we're seeing the predictable but uncomfortable marriage between data scientists and applications developers; data scientists are being pushed towards classic solution architecture so that their models can be accessible to large swaths of business users, and application developers are being asked to integrate new models, techniques, and technologies into their solution designs. Successful integration requires deeper understanding in both directions. More interesting, perhaps, is the regulatory and validation aspects of AI. Clear guidance would be tremendously helpful, but first Quality groups need to better understand how the AI works in order to even approach its validation. But as AI shifts application development from deterministic to probabilistic, Quality groups now must find the delicate balance between deploying a model that is beneficial, though it may not be perfect."

Recapping the data up until this point, we learned familiarization is high and readiness is low. What about the impact of GEN AI on your own job within the next two to three years? According to our research, it's business as usual with seven out of 10 respondents indicating they are not concerned (Fig 7).

The majority of survey participants indicated it will take two to three years for GEN AI to become mainstream

in their respective job/functional area (Fig 8). The data suggests that while there is some anticipation for the swift adoption of GEN AI, the consensus leans towards a gradual mainstreaming of this technology. The most substantial portion of respondents (47%) foresee GEN AI becoming prevalent in their respective fields in a timeframe extending beyond four years.

There are varied expectations for the adoption of GEN AI across different technology vendors, Notably, within the QMS vendor community, 14% of respondents project that GEN AI will achieve mainstream status within the forthcoming year (Fig 9). Respondents in the LIMS and ERP categories believe it will take more than four years to have an impact on their job/functional areas.

How concerned are you about the effect of GEN AI on your own job in the next two to three years? (Select one)

- Not concerned
- Somewhat concerned
- Very concerned
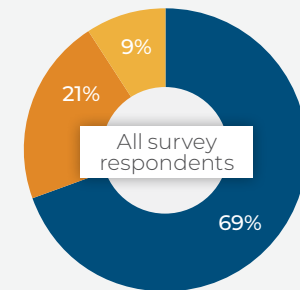

All survey respondents

9% 21% 69%

Figure 7

How soon do you think GEN AI will become mainstream in your job/functional area? (Select one)
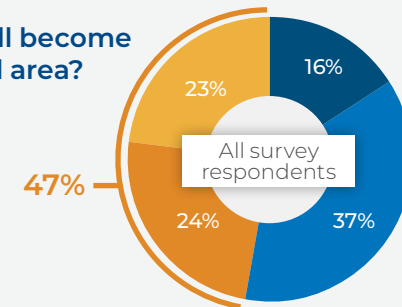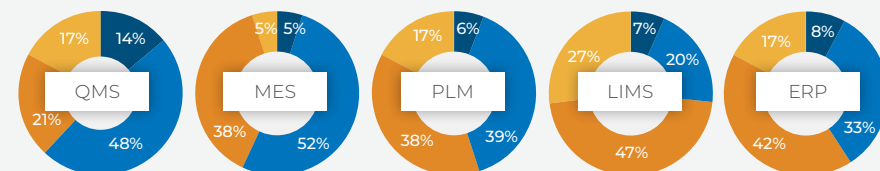
- 1 year
- 2-3 years
- 4-5 years
- 5+ years

All survey respondents

16% 37% 24% 23% **47%**

Figure 8

QMS: 14% 48% 21% 17%
MES: 5% 52% 38% 5%
PLM: 6% 39% 38% 17%
LIMS: 20% 47% 27% 7%
ERP: 8% 33% 42% 17%

Figure 9: By technology providers

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GEN AI in Drug Discovery

78% of respondents believe GEN AI has the potential to revolutionize drug discovery, in terms of efficiency and success rates. However, eight out of 10 respondents indicated they are not currently using GEN AI in drug discovery.
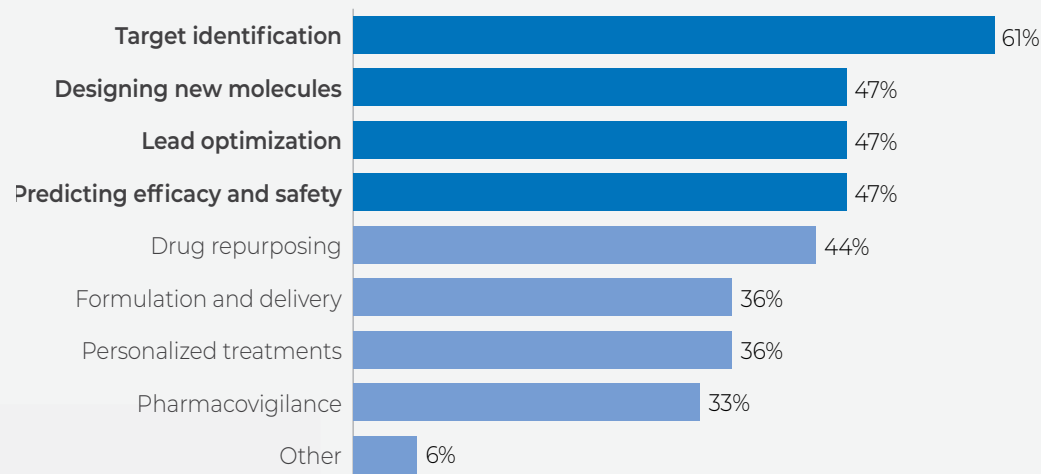
The most anticipated impact of GEN AI in drug discovery will be in target Identification, with over half of the respondents (61%) affirming this (Fig 10). Designing new molecules, lead optimization, and predicting efficacy and safety are equally regarded as significant areas, with 47% of participants acknowledging its impact. There is a moderate expectation for the role of GEN AI in drug repurposing, formulation and delivery, and personalized treatments, while pharmacovigilance and other (optimizing protocol design and data analysis) are seen as less impacted.

There is a strong inclination towards predictive modeling for drug efficacy and safety as the leading application of GEN AI in clinical drug trials, with over half of the respondents favoring this area (Fig 11). This suggests a strong belief in AI's potential to revolutionize the forecasting of outcomes and side effects in the drug development process.

👍 **BENEFITS**

What specific areas of drug discovery do you believe GEN AI could have the most significant impact? (Select all that apply) Figure 10

Area	Percentage
Target identification	61%
Designing new molecules	47%
Lead optimization	47%
Predicting efficacy and safety	47%
Drug repurposing	44%
Formulation and delivery	36%
Personalized treatments	36%
Pharmacovigilance	33%
Other	6%

"While optimism flourishes regarding the transformative potential of GEN AI in drug development, the gap between ambition and application reveals a cautious and risk-averse approach. This hesitancy underscores the need for clearer frameworks and pathways to implementation, ensuring that the promise of AI can be fully realized in the quest for medical breakthroughs."

Sarath Moses
Consultant, Digital Innovation
Bristol Myers Squibb

Real-time data analysis for monitoring patient reactions is viewed as the next most valuable application, with nearly a third of respondents endorsing it. This indicates recognition of the importance of AI in enhancing the monitoring and management of patient data during trials.
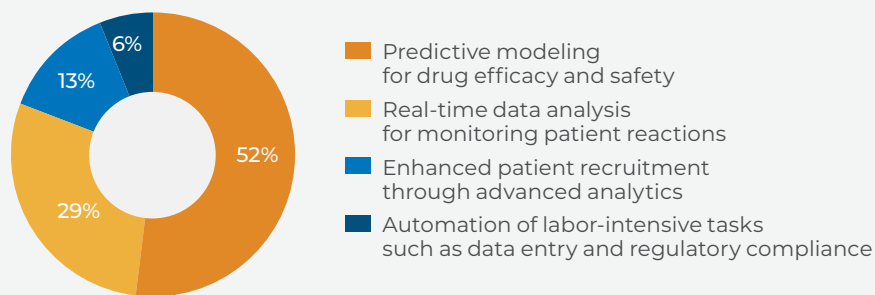
Enhanced patient recruitment through advanced analytics is identified by some respondents as a key use case, reflecting the potential for GEN AI to target and optimize the selection of trial participants.

A smaller percentage of respondents believe that automating labor-intensive tasks such as data entry and regulatory compliance is a promising use case for GEN AI in clinical trials. This suggests that while there is some acknowledgment of the value in streamlining administrative processes, it is not viewed as the primary benefit of AI in this context.

When it comes to the top three barriers and challenges with implementing GEN AI in drug discovery, bias and ethical concerns top the list (Fig 12), reflecting apprehension about the fairness and moral implications of GEN AI decisions. Close behind are regulatory compliance concerns, indicating anxiety about meeting legal standards in highly regulated industries. Data accuracy is the third most cited challenge, suggesting that the reliability of data used by GEN AI is critical for the credibility of drug discovery processes. These challenges underscore the need for careful consideration of ethical frameworks, compliance strategies, and robust data management and governance practices in the integration of GEN AI into the drug discovery process.

In your opinion, what is the most promising use case for the implementation of GEN AI in clinical drug trials? (Select one)
Figure 11

- Predictive modeling for drug efficacy and safety — 52%
- Real-time data analysis for monitoring patient reactions — 29%
- Enhanced patient recruitment through advanced analytics — 13%
- Automation of labor-intensive tasks such as data entry and regulatory compliance — 6%

BARRIERS

In your opinion, what are the top three challenges and barriers to implementing GEN AI in drug discovery? (Select three) Figure 12

Challenge	%
Bias, ethical concerns	56%
Reg. compliance concerns	53%
Data accuracy	41%
Data security	35%
Unclear/undefined use cases	29%
Competing priorities	26%
Workforce skillset	24%
Lack of management support	15%
Cultural inertia	9%
Low ROI	9%
Other	3%

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GEN AI In Drug Manufacturing

79% of respondents believe GEN AI has the potential to revolutionize drug manufacturing, in terms of efficiency and quality. However, only 5% of respondents indicated they are currently using GEN AI.

Within the drug manufacturing sector, professionals see the most significant potential for GEN AI in process modeling and simulation (Fig 13). This is followed by its use in optimizing processes and aiding in drug synthesis and formulation. Real-time quality monitoring and planning and scheduling are also recognized as areas where GEN AI could be advantageous. Meanwhile, equipment maintenance, quality control, and supply chain optimization are acknowledged to a lesser extent. Other aspects such as scaling up production, reducing bottlenecks, resource allocation, and technology transfer appear to have minimal expectation for benefit from GEN AI. Notably, there is no anticipation for GEN AI to benefit training within the sector.

The top three challenges to implementing GEN AI in drug manufacturing are regulatory compliance, data security, and workforce knowledge, indicating that navigating legal frameworks, protecting sensitive information, and upskilling employees are pivotal concerns (Fig 14). While other issues such as unclear AI use cases, intellectual property rights, and ethical considerations also represent notable barriers, they are secondary to the critical trio. The lesser concerns about ROI, cultural resistance, and management support suggest these areas are not seen as immediate obstacles to AI adoption in the industry.

👍 **BENEFITS**

In which areas of drug manufacturing do you believe GEN AI can be most beneficial? (Select one) Figure 13

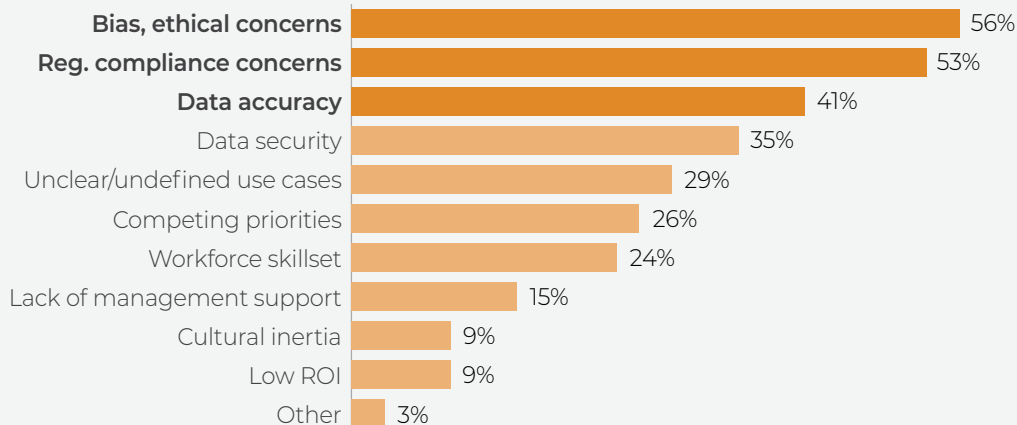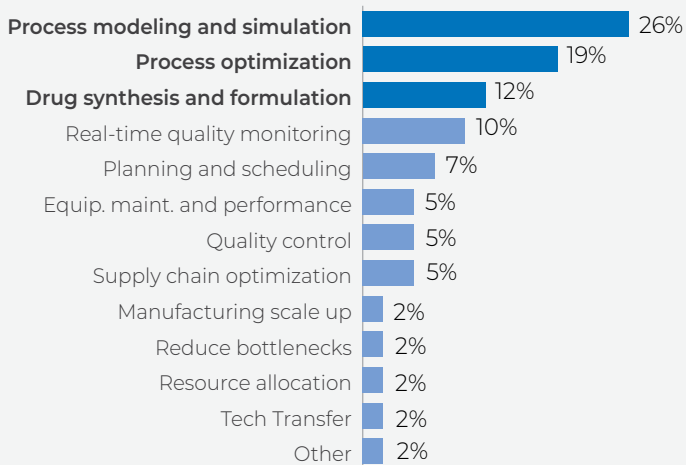|	
Process modeling and simulation	26%
Process optimization	19%
Drug synthesis and formulation	12%
Real-time quality monitoring	10%
Planning and scheduling	7%
Equip. maint. and performance	5%
Quality control	5%
Supply chain optimization	5%
Manufacturing scale up	2%
Reduce bottlenecks	2%
Resource allocation	2%
Tech Transfer	2%
Other	2%

👎 **BARRIERS**

In your opinion, what are the top three challenges and barriers to implementing GEN AI in drug manufacturing? (Select three) Figure 14

Reg. compliance concerns	69%
Data security	36%
Workforce knowledge	36%
Unclear or undefined use cases	33%
Intellectual property concerns	29%
Bias, ethical concerns	24%
Competing priorities	19%
Low ROI	19%
Cultural inertia	17%
Lack of management support	14%
Other	5%

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4 GEN AI in Medical Device R&D

67% of respondents believe GEN AI has the potential to revolutionize medical device R&D. However, none of the survey respondents indicated they are currently using GEN AI.

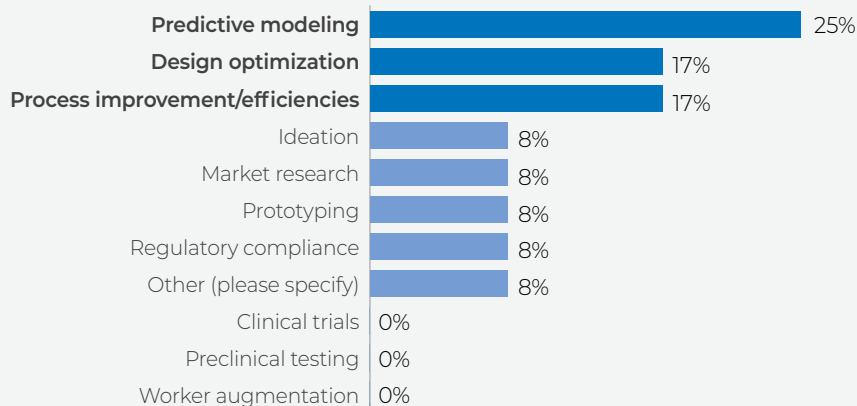Predictive modeling is highlighted as the primary area in medical device R&D where GEN AI is expected to have the most significant impact (Fig 15). Additionally, design optimization and process improvement or efficiencies are equally recognized as beneficial areas for the application of AI. Other stages like ideation, market research, prototyping, and regulatory compliance are also perceived to have potential for GEN AI, albeit to a lesser extent. This is surprising since these activities happen earlier in the product lifecycle. Responses categorized under "other," consisted of "all of the above." It is important to note that clinical trials, preclinical testing, and worker augmentation were not identified by respondents as areas where GEN AI is expected to have an impact.

Regulatory compliance concerns are the most prominent barrier, signaling the industry's focus on navigating the complex regulatory landscape that governs medical device development (Fig 16). Data security is again the next significant challenge, underscoring the critical importance of protecting sensitive research data in a highly digitalized environment. Workforce knowledge matches data security in perceived importance, highlighting a need for skilled professionals who can effectively integrate and leverage GEN AI technologies in R&D processes.

These challenges reflect a cautious approach to GEN AI adoption, emphasizing the need for robust regulatory strategies, data protection measures, and workforce development.
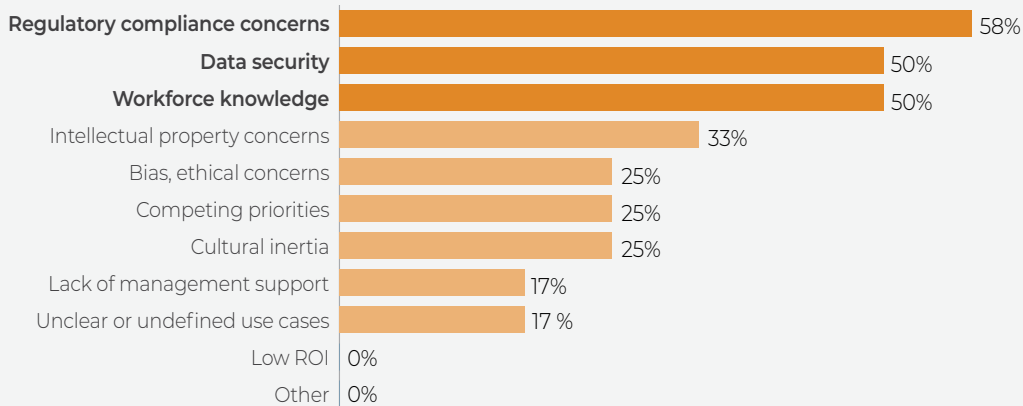
👍 **BENEFITS**

In which stages of medical device R&D do you see the most promising applications for GEN AI? (Select one) Figure 15

Stage	%
Predictive modeling	25%
Design optimization	17%
Process improvement/efficiencies	17%
Ideation	8%
Market research	8%
Prototyping	8%
Regulatory compliance	8%
Other (please specify)	8%
Clinical trials	0%
Preclinical testing	0%
Worker augmentation	0%

👎 **BARRIERS**

In your opinion, what are the top three challenges and barriers to implementing GEN AI in medical device R&D? (Select three) Figure 16

Challenge	%
Regulatory compliance concerns	58%
Data security	50%
Workforce knowledge	50%
Intellectual property concerns	33%
Bias, ethical concerns	25%
Competing priorities	25%
Cultural inertia	25%
Lack of management support	17%
Unclear or undefined use cases	17 %
Low ROI	0%
Other	0%

5   GEN AI in Medical Device Manufacturing

71% of respondents believe GEN AI has the potential to revolutionize medical device manufacturing. However, only 13% of survey respondents indicated they are currently using GEN AI in manufacturing.
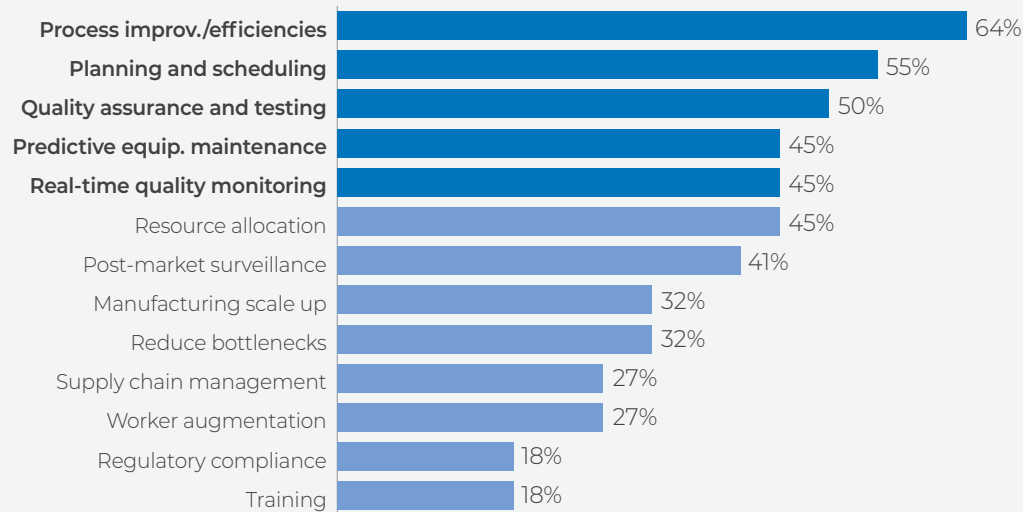
GEN AI could have the most significant impact on process improvement/efficiencies as indicated by the majority of the respondents (Fig 17). Other key areas where the technology is expected to make a considerable impact include planning and scheduling, quality assurance and testing, predictive equipment maintenance, and real-time quality monitoring.

These top five areas are prioritized by respondents, suggesting a strong belief that GEN AI can significantly enhance operational aspects of medical device manufacturing. Areas like resource allocation, post-market surveillance, and manufacturing scale-up are also noted, albeit with a lesser degree of impact expected. Conversely, regulatory compliance, worker augmentation, and training are seen as less influenced by GEN AI since they received the least acknowledgment from the respondents.

BENEFITS

In which top five areas of medical device manufacturing do you believe GEN AI could have the most significant impact? (Select five)
Figure 17

Area	%
Process improv./efficiencies	64%
Planning and scheduling	55%
Quality assurance and testing	50%
Predictive equip. maintenance	45%
Real-time quality monitoring	45%
Resource allocation	45%
Post-market surveillance	41%
Manufacturing scale up	32%
Reduce bottlenecks	32%
Supply chain management	27%
Worker augmentation	27%
Regulatory compliance	18%
Training	18%

The most prominent concerns when implementing Gen AI in medical device manufacturing are data integrity/governance, regulatory compliance, and data security, each cited by a significant portion of respondents (Fig 18).
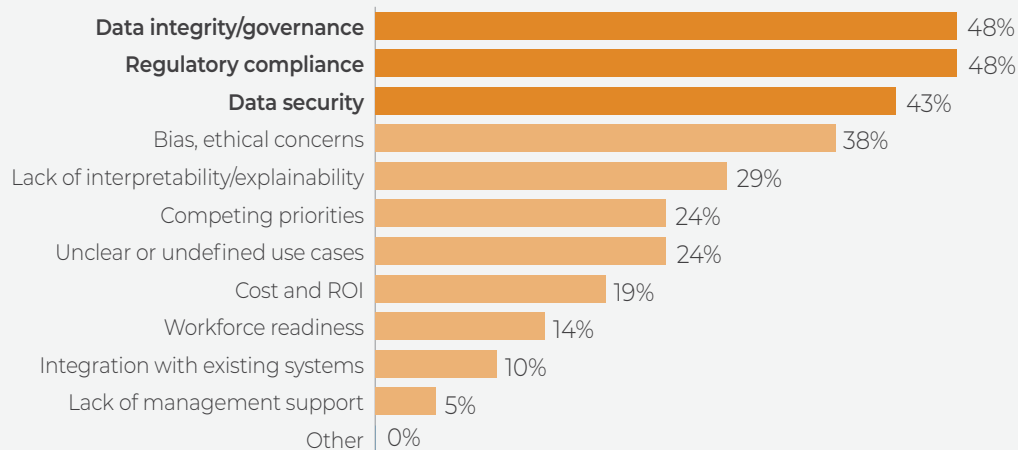
These top three issues highlight the critical importance of managing data responsibly, adhering to stringent regulatory standards, and protecting sensitive information in the medical device industry.

Other concerns like bias and ethical issues, and lack of interpretability/explainability, are also notable, indicating there are some worries about the fairness and understandability of AI decisions. Competing priorities and unclear or undefined use cases are identified by a quarter of respondents, suggesting some uncertainty about how best to integrate AI into existing workflows. Lesser concerns include cost and ROI, workforce readiness, and integration with existing systems, while lack of management support appears to be the least pressing issue.

The data indicates that while there is awareness of the potential benefits of GEN AI, medical device manufacturers must carefully navigate a complex landscape of ethical, operational, and regulatory challenges to successfully implement this technology.

👎 **BARRIERS**

What are the top three potential challenges or barriers you foresee in implementing GEN AI in medical device manufacturing? (Select three) Figure 18

Barrier	%
Data integrity/governance	48%
Regulatory compliance	48%
Data security	43%
Bias, ethical concerns	38%
Lack of interpretability/explainability	29%
Competing priorities	24%
Unclear or undefined use cases	24%
Cost and ROI	19%
Workforce readiness	14%
Integration with existing systems	10%
Lack of management support	5%
Other	0%

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6 GEN AI in Supply Chain

33% of respondents equally selected **demand forecasting, predictive analytics,** and **inventory management and optimization** as the most promising applications for GEN AI. This consensus highlights the optimism surrounding GEN AI's potential to significantly enhance supply chain resilience.

Supplier network optimization also received a notable number of responses, while risk assessment and mitigation strategies, along with real-time monitoring and adaptive response mechanisms, were considered less impactful.

Supply chain professionals have a high degree of confidence in GEN AI's ability to enhance the efficiency and resilience of supply chain management (Fig 19). Overall, the data suggests a leaning towards trust in GEN AI for improving supply chain operations, with a combined 56% of respondents falling in the confident range. However, 77% of respondents indicated they are not currently using AI-driven technologies or analytical tools to manage supply chain resilience.

How confident are you that GEN AI can enhance the efficiency and resilience of supply chain management? Figure 19
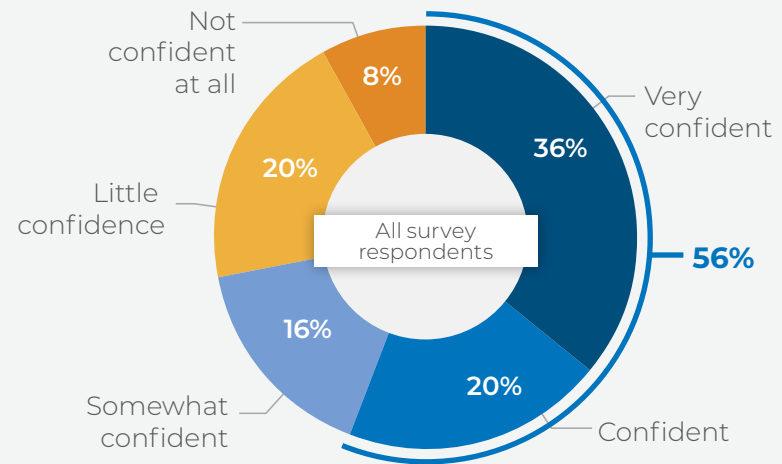
77% While 77% of respondents indicated they are not currently using AI-driven technologies or analytical tools to manage supply chains, a combined 56% of respondents have a high degree of confidence in GEN AI's ability to improve supply chain efficiency and resilience.

The foremost challenge of integrating GEN AI solutions into supply chain management process to enhance resilience, identified by 63% of respondents, is data quality and availability, emphasizing the need for high-quality data across multiple stakeholders and systems (Fig 20). Bias and ethical concerns, along with the ability of GEN AI to adapt to constant changes and unforeseen events, both tie as the second most significant challenges. This reflects apprehension about the fairness and moral implications of GEN AI, as well as its agility in responding to dynamic supply chain environments. Costs and ROI, also at 42%, indicate the importance placed on the financial viability of integrating such advanced technologies.

These challenges highlight the complexity of implementing GEN AI in supply chain management, balancing technical, ethical, and financial considerations.

👎 **BARRIERS**

What are the top three challenges you foresee in integrating GEN AI solutions into supply chain management practices to enhance resilience? (Select three) Figure 20

Data quality and availability: ensuring the availability of high-quality data across the supply chain can be a challenge, when dealing with multiple stakeholders, different data formats, and varying levels of data transparency.	**63%**
Regulatory compliance concerns: adopting generative AI solutions may raise concerns about data privacy, security, and ethical considerations.	**42%**
Dynamic and uncertain environments: supply chains are subject to constant changes, uncertainties, and disruptions. Generative AI models might struggle to adapt quickly to unforeseen events or novel scenarios.	**42%**
Costs and ROI: calculating the return on investment (ROI) and justifying the expenses associated with these technologies may require careful analysis.	**42%**
Expertise and talent gap: finding and retaining qualified data scientists, machine learning engineers, and AI experts with knowledge of generative AI.	**38%**
Integration with existing systems: Ensuring smooth integration and compatibility with existing workflows is crucial to avoid disruptions during the implementation process.	**33%**
Model interpretability and trust: for critical supply chain decisions, it is crucial to have transparent and interpretable models to build trust and gain insights into model outputs.	**25%**
Computational resources: training and deploying generative AI models can be computationally expensive, requiring substantial computational power and storage infrastructure.	**17%**
Other	**0%**

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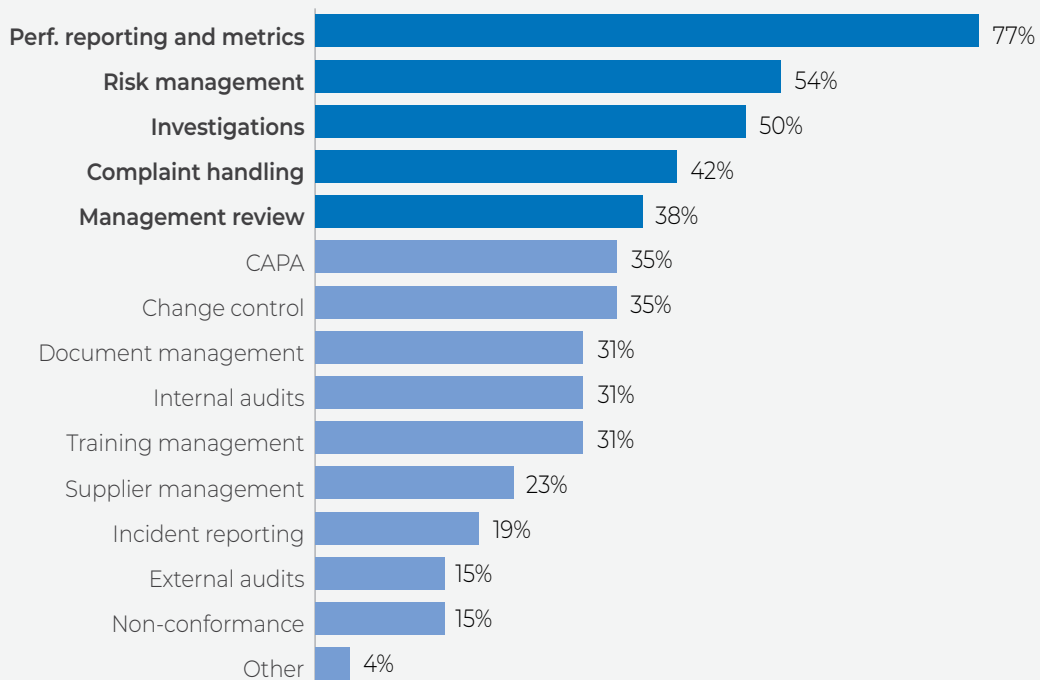# GEN AI in Post Market Surveillance and Quality Systems

92% **of respondents (an overwhelming majority) believe GEN AI has the potential to revolutionize post market surveillance processes in terms of efficiency and quality. However, only 12% of survey respondents indicated they are currently using GEN AI or data analytics tools to support those activities.**

The implication is clear. There is a robust belief in GEN AI's capacity to transform proactive risk strategies and investigative efficiencies. Performance reporting and metrics is identified as the paramount area where GEN AI is expected to drive significant value, with an overwhelming majority of respondents underscoring its potential (Fig. 21). This suggests a strong confidence in GEN AI's ability to enhance data analytics and performance insights, which are crucial for informed decision-making.

Risk management and investigations are also highly regarded, with more than half of the respondents recognizing the substantial advantages that GEN AI could bring in forecasting and problem-solving within these complex areas.

Other functional areas such as complaint handling, management review, and CAPA are acknowledged as important, yet they do not quite match the top-tier expectations set for a GEN AI application. Document management, internal audits, and training management display a balanced view, suggesting these are areas where GEN AI is seen to support and streamline, but perhaps not revolutionize, existing processes.

In which aspects of the quality management system (QMS) do you see the most valuable application of GEN AI in your organization? (Select five) Figure 21

Perf. reporting and metrics	77%
Risk management	54%
Investigations	50%
Complaint handling	42%
Management review	38%
CAPA	35%
Change control	35%
Document management	31%
Internal audits	31%
Training management	31%
Supplier management	23%
Incident reporting	19%
External audits	15%
Non-conformance	15%
Other	4%

Areas such as supplier management, incident reporting, and external audits appear to be lower in priority for AI application, which could reflect contentment with current methodologies or a wait-and-see approach towards the maturity of GEN AI capabilities in these areas.

The standout benefit of integrating GEN AI into existing Quality Management Systems (QMS), as identified by a significant margin, is advanced risk management and mitigation, where 58% of respondents foresee GEN AI as a transformative tool (Fig. 22). This aligns with a strategic emphasis on AI's predictive capabilities and real-time risk analysis.

Quality Trends Forecasting is another area where GEN AI is expected to deliver substantial impact, with half of the respondents acknowledging its potential. This suggests a forward-looking approach to quality management, where predictive insights can shape future strategies.
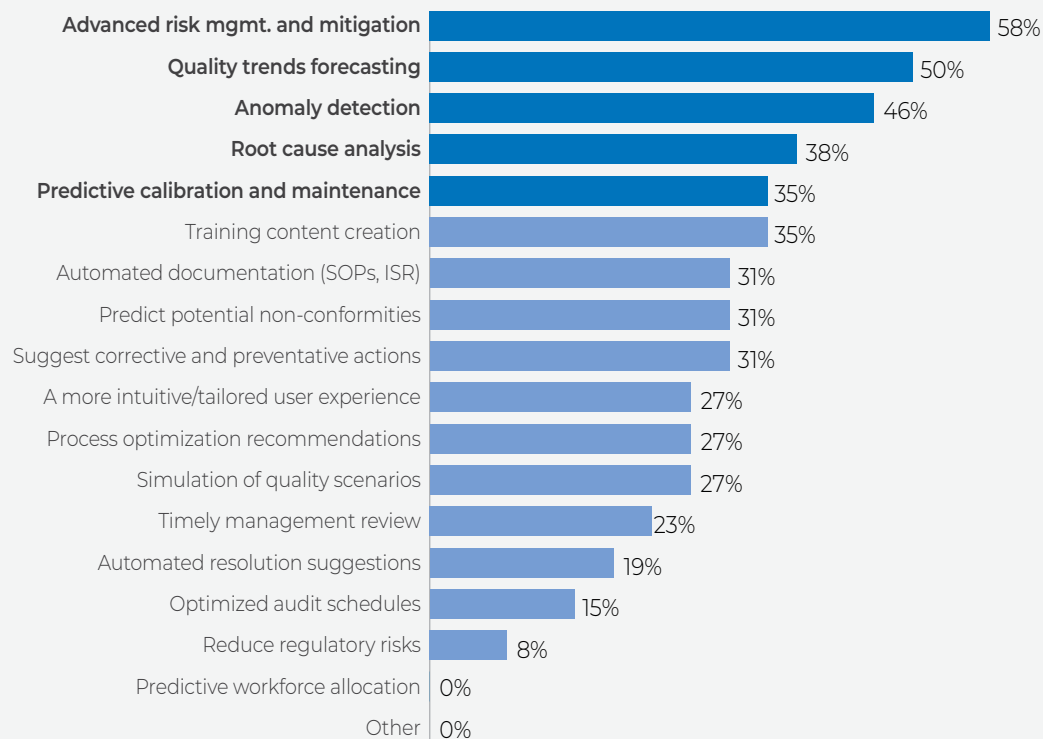
Anomaly Detection and Root Cause Analysis are recognized by a considerable number of respondents, highlighting AI's role in identifying and addressing the underlying issues in quality-related processes. Other areas such as Predictive Calibration and Maintenance, along with Training Content Creation, are also expected to benefit from GEN AI, as indicated by over a third of the respondents. This reflects an appreciation for GEN AI's capacity to enhance operational efficiency and workforce development.

Notably, functions like Automated Documentation, Predicting Potential Non-conformities, and Suggesting Corrective and Preventative Actions are seen as important, but they rank slightly lower, suggesting a balanced view of GEN AI as a tool for both strategic and operational improvements.

The data reflects a professional consensus on the value addition of GEN AI across diverse aspects of QMS, with a clear focus on leveraging the technology for risk management and predictive analysis to drive quality enhancements.
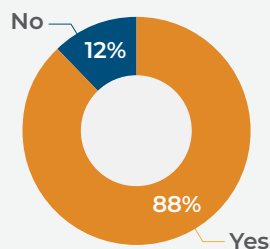
👍 **BENEFITS**

In your opinion, what are the top five benefits of adding GEN AI functionality to your current QMS? (Select five) Figure 22

Benefit	Percentage
Advanced risk mgmt. and mitigation	58%
Quality trends forecasting	50%
Anomaly detection	46%
Root cause analysis	38%
Predictive calibration and maintenance	35%
Training content creation	35%
Automated documentation (SOPs, ISR)	31%
Predict potential non-conformities	31%
Suggest corrective and preventative actions	31%
A more intuitive/tailored user experience	27%
Process optimization recommendations	27%
Simulation of quality scenarios	27%
Timely management review	23%
Automated resolution suggestions	19%
Optimized audit schedules	15%
Reduce regulatory risks	8%
Predictive workforce allocation	0%
Other	0%

58% The standout benefit of integrating GEN AI into existing Quality Management Systems (QMS), as identified by a significant margin, is advanced risk management and mitigation, where 58% of respondents foresee GEN AI as a transformative tool

Do you think GEN AI could introduce potential quality risks?
Figure 23

No 12%

88% Yes

Nine out of 10 respondents are concerned with GEN AI introducing potential quality risks (Fig. 23). This data suggests a widespread recognition that while GEN AI offers numerous benefits; it also comes with its own set of challenges and uncertainties that could impact quality.

This concern may stem from various high-level factors such as the complexity of GEN AI systems, which can make them difficult to understand and predict. Additionally, the dependency on data quality and the potential for bias in AI algorithms could lead to quality risks if not managed carefully. **"If there is inherent bias to the data, then yes the quality is compromised,"** noted Sarath Moses, Consultant, Digital Innovation, Bristol Myers Squibb.

There is also the aspect of GEN AI's adaptability and the need for continuous monitoring to ensure its performance aligns with quality standards. Only 12% of respondents do not see GEN AI as a source of potential quality risks, which could indicate a belief in robust GEN AI systems' design and governance to mitigate such risks effectively.

The top three barriers for implementing GEN AI for post market surveillance are data integrity/governance, data security, and regulatory compliance concerns (Fig. 24). Data integrity/governance is the most cited challenge, indicating that ensuring the accuracy and proper management of data is a primary concern. Data security and regulatory compliance are equally ranked as the second most significant barriers, reflecting concerns over protecting patient data and meeting the stringent regulations that govern medical post-market activities.

Bias and ethical concerns are also significant, pointing to worries about maintaining fairness and ethical standards when deploying GEN AI in such a sensitive area. Integration with existing systems is seen as a challenge by a smaller proportion of respondents, suggesting some concerns about how well new AI technologies will work with current infrastructures. Workforce readiness is acknowledged by a few respondents, indicating a recognition that employee preparedness to work with GEN AI is necessary.

Competing priorities, cost and ROI, and lack of interpretability/explainability are seen as moderate barriers, which suggests a balance of strategic, financial, and technical concerns regarding the implementation of GEN AI.

Lack of management support and unclear or undefined use cases are the least cited challenges, potentially indicating either a strong management buy-in or a clear vision for GEN AI's role in post-market surveillance within the respondents' organizations.

👎 **BARRIERS:**

What are the top three potential challenges or barriers you foresee in implementing GEN AI for post market surveillance? (Select three)
Figure 24

Data integrity/governance	56%
Data security	44%
Regulatory compliance	44%
Bias, ethical concerns	36%
Integration with existing systems	28%
Workforce readiness	20%
Competing priorities	16%
Cost and ROI	16%
Lack of interpretability/explainability	16%
Lack of management support	12%
Unclear or undefined use cases	12%
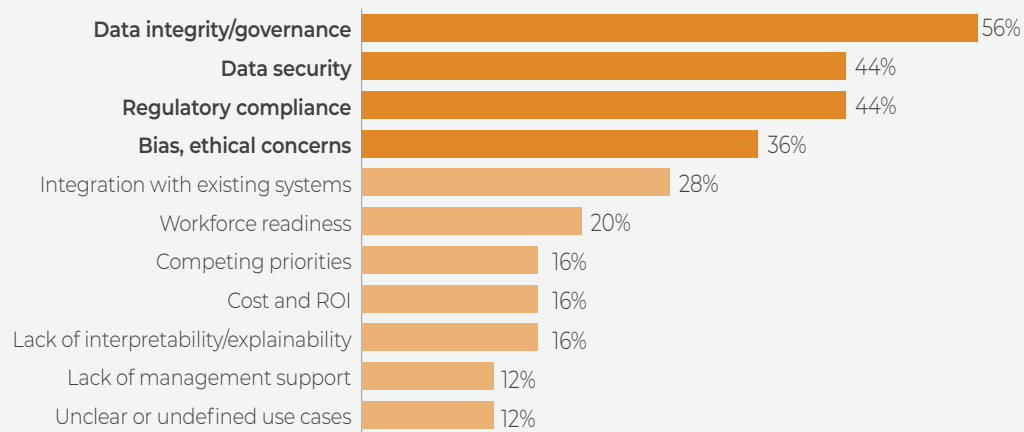
8 GEN AI In Laboratory Operations

7 out of 10 respondents believe GEN AI holds the potential to revolutionize laboratory processes in terms of efficiency and quality. However, only 21% of respondents indicated they are currently using GEN AI technologies to support data analysis in the laboratory.
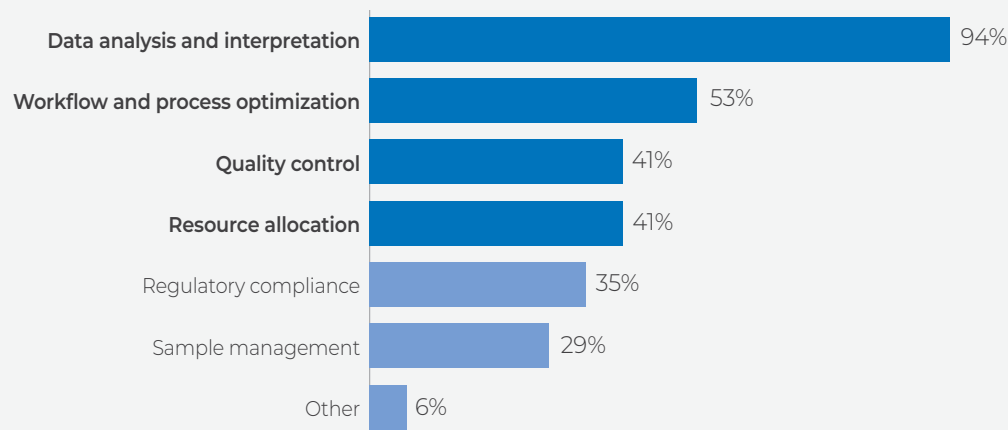
Data analysis and interpretation are at the forefront of anticipated benefits at 94% (Fig. 25). The next tier of benefits, which includes workflow and process optimization, quality control, and resource allocation, illustrates an expectation that GEN AI will significantly improve operational efficiency and resource management. Regulatory compliance and sample management are also recognized as areas that stand to gain from GEN AI, albeit to a lesser extent. A small fraction of respondents suggested additional benefits not listed, indicating that while the main areas of impact are covered, there may be more niche applications of AI in laboratory settings yet to be fully recognized.

The data reflects a strong belief in GEN AI's capacity to enhance both the analytical and practical aspects of laboratory work.
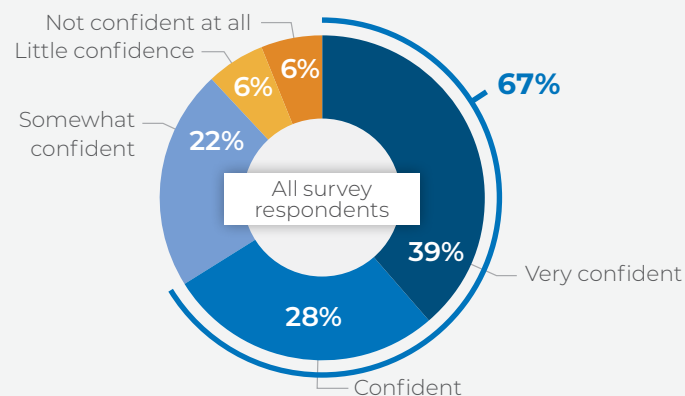
The confidence in GEN AI's ability to improve data analysis in laboratories is very strong (Fig. 26). A small fraction of respondents exhibit skepticism, with the lowest confidence levels garnering minimal support. In contrast, there's a pronounced lean toward optimism, with a majority indicating high confidence, including a substantial portion expressing the highest level of confidence. This optimism likely stems from GEN AI's capabilities in handling large datasets,

BENEFITS

Which areas of laboratory operations do you think would benefit the most from the implementation of GEN AI? (Select three) Figure 25

Area	Percentage
Data analysis and interpretation	94%
Workflow and process optimization	53%
Quality control	41%
Resource allocation	41%
Regulatory compliance	35%
Sample management	29%
Other	6%

How would you rate the potential impact of GEN AI on improving data analysis in laboratory settings? Figure 26

All survey respondents

- Not confident at all — 6%
- Little confidence — 6%
- Somewhat confident — 22%
- Very confident — 67%
- Confident — 28%
- Very confident — 39%

providing advanced analytics, and potentially automating complex analysis tasks that are critical in laboratory environments.
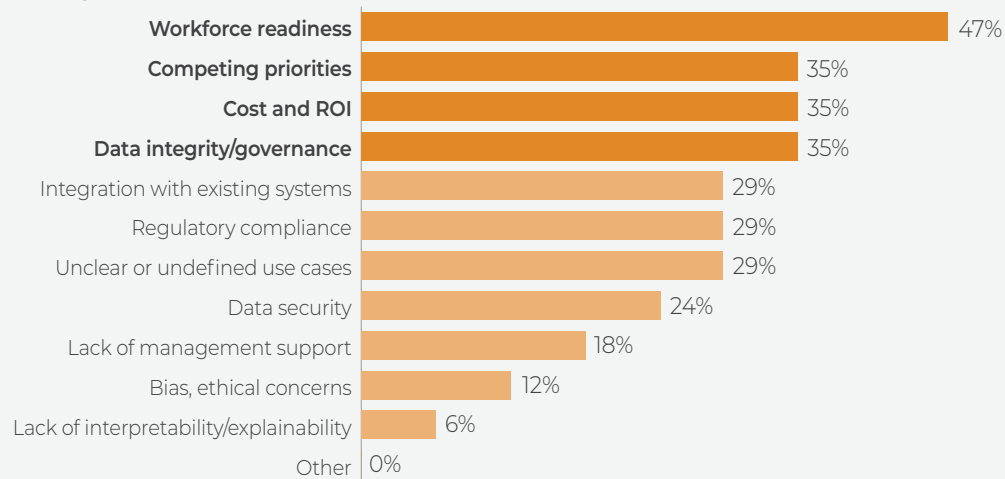
The trend suggests a broad expectation that GEN AI will significantly advance the precision, speed, and efficiency of lab data analysis.

Workforce readiness is the most cited challenge, with 47% of respondents indicating that preparing the workforce for GEN AI integration is a significant hurdle (Fig. 27). This suggests a perceived need for more skilled personnel or training in GEN AI technologies. Competing priorities and cost and ROI are each identified by 35% of respondents, indicating that aligning GEN AI projects with other business initiatives and demonstrating their financial viability are also key concerns.

The data suggests that the successful implemen-tation of GEN AI in laboratories will require addressing the readiness of the workforce, understanding financial implications, and aligning AI adoption with other organizational priorities, while also ensuring that data governance and regulatory compliance are managed effectively.

BARRIERS:

What are the top three potential challenges or barriers you foresee in implementing GEN AI in your laboratory? (Select three) Figure 27

Category	Percentage
Workforce readiness	47%
Competing priorities	35%
Cost and ROI	35%
Data integrity/governance	35%
Integration with existing systems	29%
Regulatory compliance	29%
Unclear or undefined use cases	29%
Data security	24%
Lack of management support	18%
Bias, ethical concerns	12%
Lack of interpretability/explainability	6%
Other	0%

47% Workforce readiness is the most cited challenge, with 47% of respondents indicating that preparing the workforce for GEN AI integration is a significant hurdle

9 Data Management And Privacy Concerns

The majority of survey respondents indicate their organizations are only somewhat prepared to manage potential data privacy issues associated with the use of GEN AI (Fig. 28). While there is a general awareness of data privacy issues surrounding GEN AI, many organizations may still be in the process of developing or strengthening their data privacy and protection protocols to fully address the nuances introduced by AI technologies. The relatively small percentage of organizations that feel 'Very Prepared' suggests that there is room for growth and improvement in data privacy practices in the context of GEN AI.

There are varying degrees of perceived readiness to manage potential data privacy issues associated with the use of GEN AI based on levels of responsibility (Fig. 29) The data shows that Individual Contributors report the highest level of being 'very prepared,' (20%) followed by C-Level Executives, Department Heads/Directors, and Vice Presidents/General Managers.

The "somewhat prepared" majority across all roles indicates an awareness of data privacy issues but also reflects a general sense of uncertainty about whether current measures are sufficient to handle the complexities introduced by GEN AI. The relatively low percentage of respondents feeling "very prepared" suggests room for improvement in data privacy preparedness across the board.

Organizations should consider a strategic approach to fortify the data privacy frameworks in the context of GEN AI utilization. This entails initiating comprehensive training programs aimed at equipping AI teams with the necessary expertise to address GEN AI's distinctive data privacy considerations. Concurrently, it is imperative to establish data governance structures to adeptly navigate the intricacies of GEN AI integration. Cultivating a corporate ethos that prioritizes data privacy across all operational levels is essential, ensuring that each employee is cognizant of their role in data protection.

The level of preparedness of technology and software providers to manage data privacy issues associated with GEN AI across their own organizations is also low (Fig. 30). The highest number of respondents who offer ERP systems feel only 'somewhat prepared', with 75% indicating this level of readiness.

How prepared is your organization to manage potential data privacy issues associated with the use of Gen AI? (Select one)
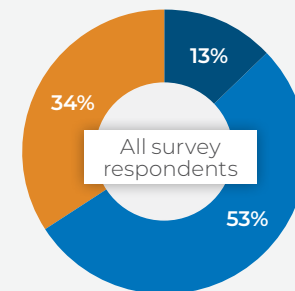
- ■ Very prepared
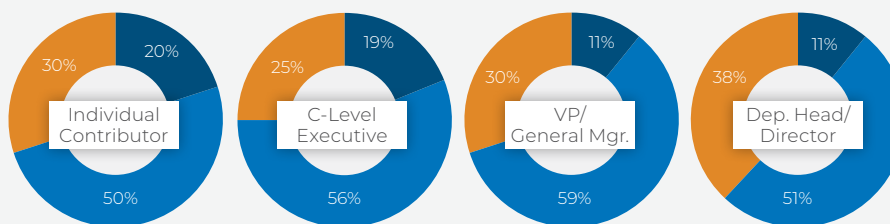- ■ Somewhat prepared
- ■ Not prepared

All survey respondents: 13% Very prepared, 53% Somewhat prepared, 34% Not prepared

Figure 28

Individual Contributor: 20%, 50%, 30%
C-Level Executive: 19%, 56%, 25%
VP/General Mgr.: 11%, 59%, 30%
Dep. Head/Director: 11%, 51%, 38%

Figure 29: By levels of responsibility

PLM: 22%, 67%, 11%
QMS: 21%, 62%, 17%
LIMS: 20%, 67%, 13%
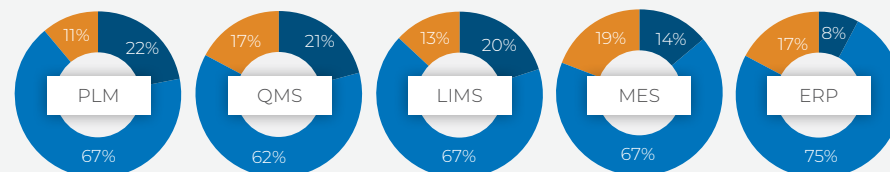MES: 14%, 67%, 19%
ERP: 8%, 75%, 17%

Figure 30: By technology providers

Providers of LIMS, MES, PLM, and QMS follow a similar trend, with the majority feeling only 'somewhat prepared', ranging from 62% to 67%. Notably, a significant proportion of users in each category do not feel 'very prepared', indicating potential gaps in readiness that could be addressed with targeted data privacy strategies tailored to each software system's specific requirements and vulnerabilities.

This data points to a need for enhanced measures and specialized approaches to ensure data privacy within the context of GEN AI applications across different software solutions – and/or platforms.

A sizable portion of the respondents rate their organizations' current capacity to handle the data management and privacy concerned associated with training large language models as merely moderately adequate (Fig. 31). This indicates they possess some level of preparedness but acknowledge room for improvement. Another significant segment of respondents feel that their capacity is not adequate, reflecting a lack of confidence or a need for substantial enhancement in their current practices. Meanwhile, a smaller group believes their organization's capacity to be very adequate, showing strong confidence in their data management and privacy measures for GEN AI initiatives.

The variation in opinions among life science companies regarding their capacity to handle data management and privacy concerns with large language models could be attributed to several factors:

1. **Budget Allocation:** Companies may have differing levels of investment in technologies and systems that ensure data privacy, leading to varied confidence levels.

2. **Regulatory Environment:** Those with more experience navigating a changing regulatory environment may feel more prepared, while others

How would you rate your organization's current capacity to handle the data management and privacy concerns associated with training large language models? (Select one)

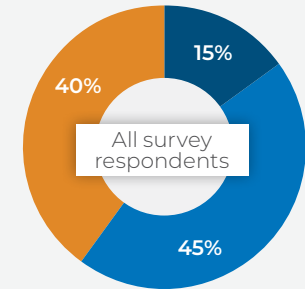- ■ Very adequate
- ■ Moderately adequate
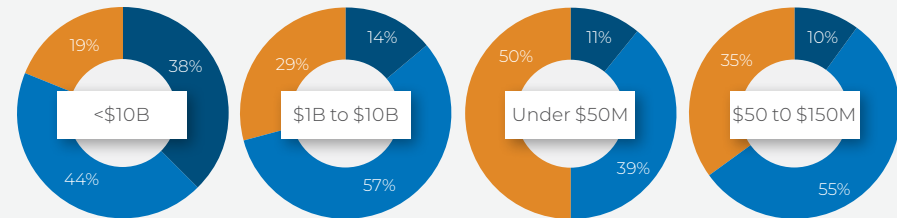- ■ Not adequate

Figure 31
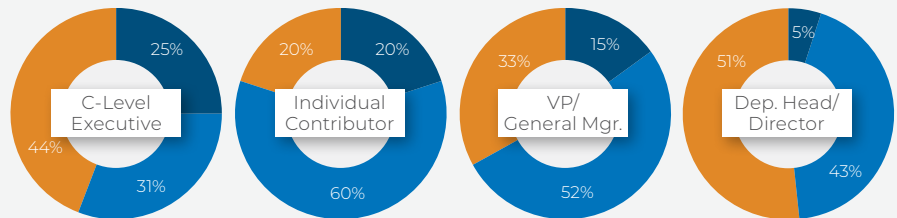

Figure 32: By revenue size
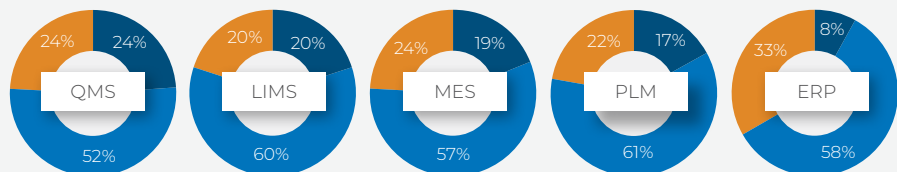

Figure 33: By level of responsibility

Figure 34: By technology providers

(i.e., in start-up mode) who are still adapting to these regulations may feel less so. On the other hand, larger organizations often need to overcome regulatory inertia to adopt a new technology.

3. **Data Management Maturity:** Organizations vary in their stage of data management maturity. Companies with advanced data governance strategies identify as more prepared.

4. **Risk Perception:** The perceived risks associated with GEN AI in, a highly regulated industry, such as life sciences, can influence how prepared an organization feels, with more risk-averse companies potentially feeling less prepared.

These factors often collectively contribute to the spectrum of preparedness levels when it comes to managing data privacy issues.

A closer look at the data shows how life sciences companies of varying revenue sizes rate their capacity to handle data management and privacy concerns when training large language models (Fig. 32). Companies with smaller revenues (under $50M) have the highest proportion of respondents indicating they are not adequately prepared.

As company revenue increases, there is a trend toward a higher perception of moderate preparedness, with the largest companies (over $10B) having the highest percentage of respondents feeling very prepared.

Conclusion

The current state of GEN AI in the Life Sciences industry reveals a broad spectrum of familiarity with the concept of the technology. While there is an overall perception across life sciences that GEN AI will revolutionize processes including discovery, R&D, manufacturing, post market surveillance, etc., it is important to note AI is a tool, not a strategy.

The potential of GEN AI to revolutionize industry processes and product lifecycles is widely acknowledged. This recognition underscores the importance of bridging the gap between understanding its benefits and acquiring the technical expertise necessary for successful implementation within GxP-regulated environments.

Vendors offering core systems including QMS, MES, PLM, LIMS, and ERP face particular challenges with the integration of GEN AI, but the opportunities for efficiencies—like predictive maintenance and improved analytics—are substantial. These advancements can lead to transformative innovations in drug development, personalized medicine, and clinical trials through the data-analyzing capabilities of GEN AI.

Furthermore, organizations must proactively evaluate their systems, develop, or acquire the necessary expertise, and engage with regulatory bodies for compliant integration of GEN AI technologies. However, with 80% of professionals indicating that regulatory frameworks do not support GEN AI adoption, and 70% lacking organizational policies or procedures for its use, there's a clear need for regulatory evolution and strategic policy development.

Additionally, key performance indicators (KPIs) for measuring the success and ROI of GEN AI implementations are not well-defined in most organizations. 44% of research participants indicated they do not have specific KPIs for GEN AI. For those that do, increased efficiency in processes is the primary metric, followed by enhanced customer experience and quality improvements in products or services. These insights underscore the nascent stage of GEN AI's

integration into the life sciences, but also its potential to mature rapidly as knowledge, regulatory support, and strategic implementation practices evolve.

It is evident and clear – life science organizations are grappling with varying levels of preparedness when it comes to data management, privacy, security, and regulatory concerns associated with the implementation of GEN AI. While there is a general trend of a high degree of familiarity with the concept of GEN AI, there is only moderate preparedness across different roles within organizations and varying revenue scales. There is also a consistent acknowledgment of room for improvement to overcome the barriers and challenges that business segments must first overcome.

Ensuring a comprehensive grasp of GEN AI's implications throughout an organization's functional roles necessitates the establishment of cross-functional training and knowledge sharing programs. Initiatives such as workshops covering the applications and implications of GEN AI in understandable terms, are both beneficial and necessary. Moreover, fostering collaborative efforts on projects that incorporate GEN AI, enriches the collective understanding, and promotes a consistent level of familiarity across disparate departments.

Understanding GEN AI encompasses acknowledging its significant influence throughout the industry and the entire product lifecycle, as well as the complex details of its operational frameworks. There is a distinction between appreciating the advantages and strategic value of GEN AI and mastering the specifics related to data prerequisites, model training, and assurance processes and procedures essential for its deployment in GxP regulated environments.
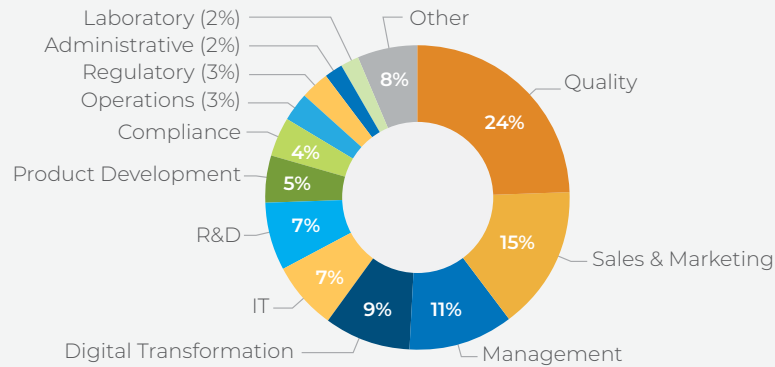
As FDA Commissioner, Dr. Robert Califf stated, **"Eventually our reviewers, compliance assessors and inspectorate, and the industries they regulate, will use AI in everything from data collection to regulatory assessments, coding, and post market surveillance. For us to be most effective and do our jobs as protectors of public health, it is essential that we embrace these groundbreaking technologies, not only to keep pace with the industries we regulate, but also to use regulatory oversight to improve the chance that they will be applied effectively, consistently, and fairly.[1]"**

[1] https://www.fda.gov/news-events/speeches-fda-officials/remarks-fda-commissioner-robert-m-califf-coalition-health-ai-chai-03052024
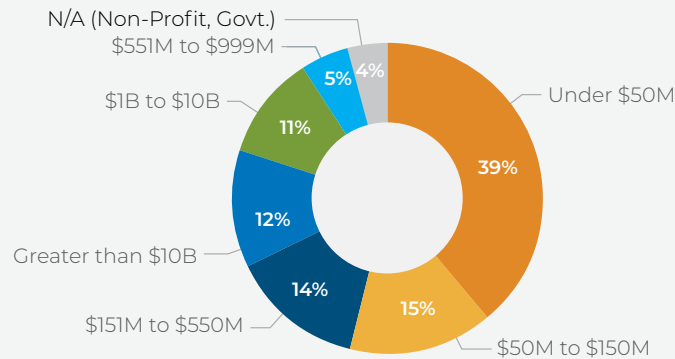
AXENDIA

Demographics

Axendia conducted a market research study and surveyed over 200 life science industry professionals and technology/software providers. This study explores the current landscape, opportunities, challenges, and use cases for GEN AI applications in life sciences.
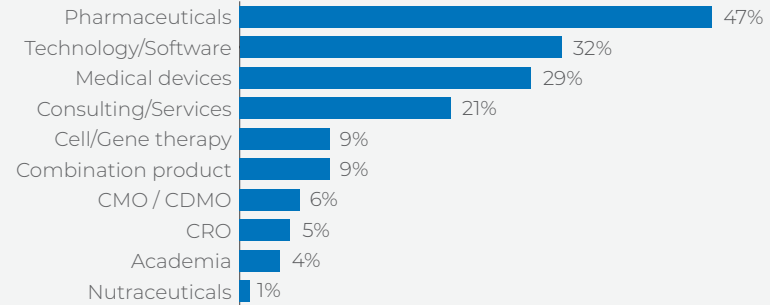
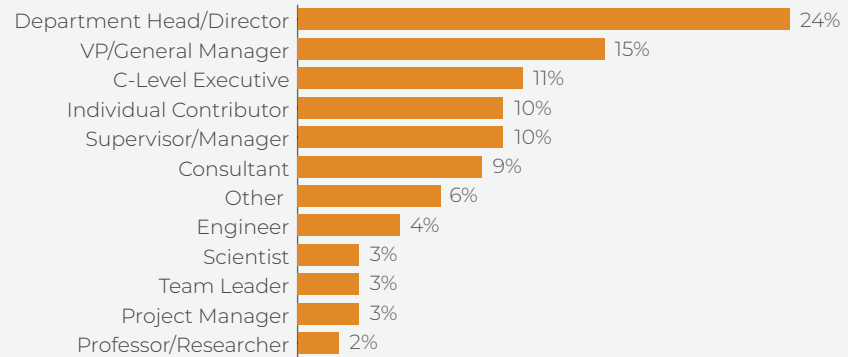## By company's products and services* (respondents selected all that apply)

Pharmaceuticals	47%
Technology/Software	32%
Medical devices	29%
Consulting/Services	21%
Cell/Gene therapy	9%
Combination product	9%
CMO / CDMO	6%
CRO	5%
Academia	4%
Nutraceuticals	1%

By current functional role*

- Laboratory (2%)
- Administrative (2%)
- Regulatory (3%)
- Operations (3%)
- Compliance 4%
- Product Development 5%
- R&D 7%
- IT 7%
- Digital Transformation 9%
- Management 11%
- Sales & Marketing 15%
- Quality 24%
- Other 8%

By level of responsibility*

Department Head/Director	24%
VP/General Manager	15%
C-Level Executive	11%
Individual Contributor	10%
Supervisor/Manager	10%
Consultant	9%
Other	6%
Engineer	4%
Scientist	3%
Team Leader	3%
Project Manager	3%
Professor/Researcher	2%

By company annual revenue* (USD)

- N/A (Non-Profit, Govt.) 4%
- $551M to $999M 5%
- $1B to $10B 11%
- Greater than $10B 12%
- $151M to $550M 14%
- $50M to $150M 15%
- Under $50M 39%

By company headquarters location*

- North America 61%
- Europe 24%
- Asia 9%
- South America 2%
- Africa 2%
- Australia 2%
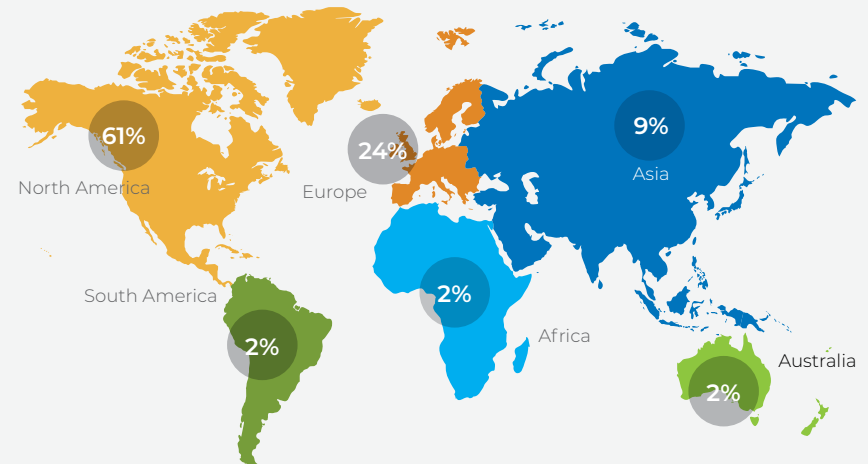
*Rounded to the nearest whole number.

Acknowledgments

An Axendia Market Research Report

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TetraScience is the Scientific Data and AI Cloud company with a mission to radically improve and extend human life. TetraScience combines the world's only open, purpose-built, and collaborative scientific data and AI cloud with deep scientific expertise across the value chain to accelerate and improve scientific outcomes. TetraScience is catalyzing the Scientific AI revolution by designing and industrializing AI-native scientific data sets, which it brings to life in a growing suite of next generation lab data management products, scientific use cases, and AI-based outcomes.

For more information, visit tetrascience.com

About Axendia

Axendia is a leading analyst and strategic advisory firm that focuses exclusively on the Life Sciences markets. We provide strategic advice that enables our clients to prepare for, adapt to, and overcome disruption. To this end, we conduct primary quantitative and qualitative research that our clients leverage to support their strategies and enables them to make informed decisions based on their unique needs. Industry stakeholders and regulators have relied on Axendia for trusted advice on Business, Regulatory and Technology issues and trends based on trusted sources. Axendia serves the entire Life Science ecosystem ranging from start-ups to Fortune 100 companies including: Life Science Organizations, Technology & Service Providers, and Regulatory Agencies.

Axendia professionals offer a unique combination of deep hands-on industry experience coupled with forward thinking insights. We contribute to our client's success by providing long-range visibility and helping them navigate the increasingly complex landscape. Axendia is recognized as a Top 10 Analytics consulting company by Pharma Tech Outlook and as a one of the 20 Most Promising Life Sciences Technology and Services providers by CIOReview. Axendia is recognized as a Top 10 Analytics Consulting company by Pharma Tech Outlook and as a one of the 20 Most Promising Life Sciences Technology and Services providers by CIOReview.

To discuss how this research impacts your organization, schedule an Analyst Inquiry on this topic.
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