

AI and Generative AI

A validation point of view



and Generative AI (GenAI) are revolutionizing the business landscape. AI analyzes historical data to forecast outcomes, while GenAI utilizes advanced deep-learning models to create novel content from the data and prompts it's trained with. The evolution of computer science enhances our capability to interpret data and make informed decisions, especially as computer integration deepens and data pools expand. This emphasizes the importance of thoughtfully incorporating GenAI solutions into life sciences businesses, underlining the crucial need for a validation-centric approach for this industry.

When considering the integration of any use case into a business process, three critical elements must be weighed: volume, cost of implementation and validation efforts. Achieving a harmonious balance among these factors is essential for realizing tangible value.

Industry benefits from leveraging GenAI

Harnessing the full potential of GenAI across the life sciences spectrum, from R&D and supply chain to validation, compliance, regulatory processes and pharmacovigilance, is crucial for unlocking value.

- ➔ Leveraging GenAI promises significant cost savings
- ➔ The potential for productivity enhancements through GenAI
- ➔ GenAI holds immense promise in labor-intensive processes, particularly in discovering new drug compounds

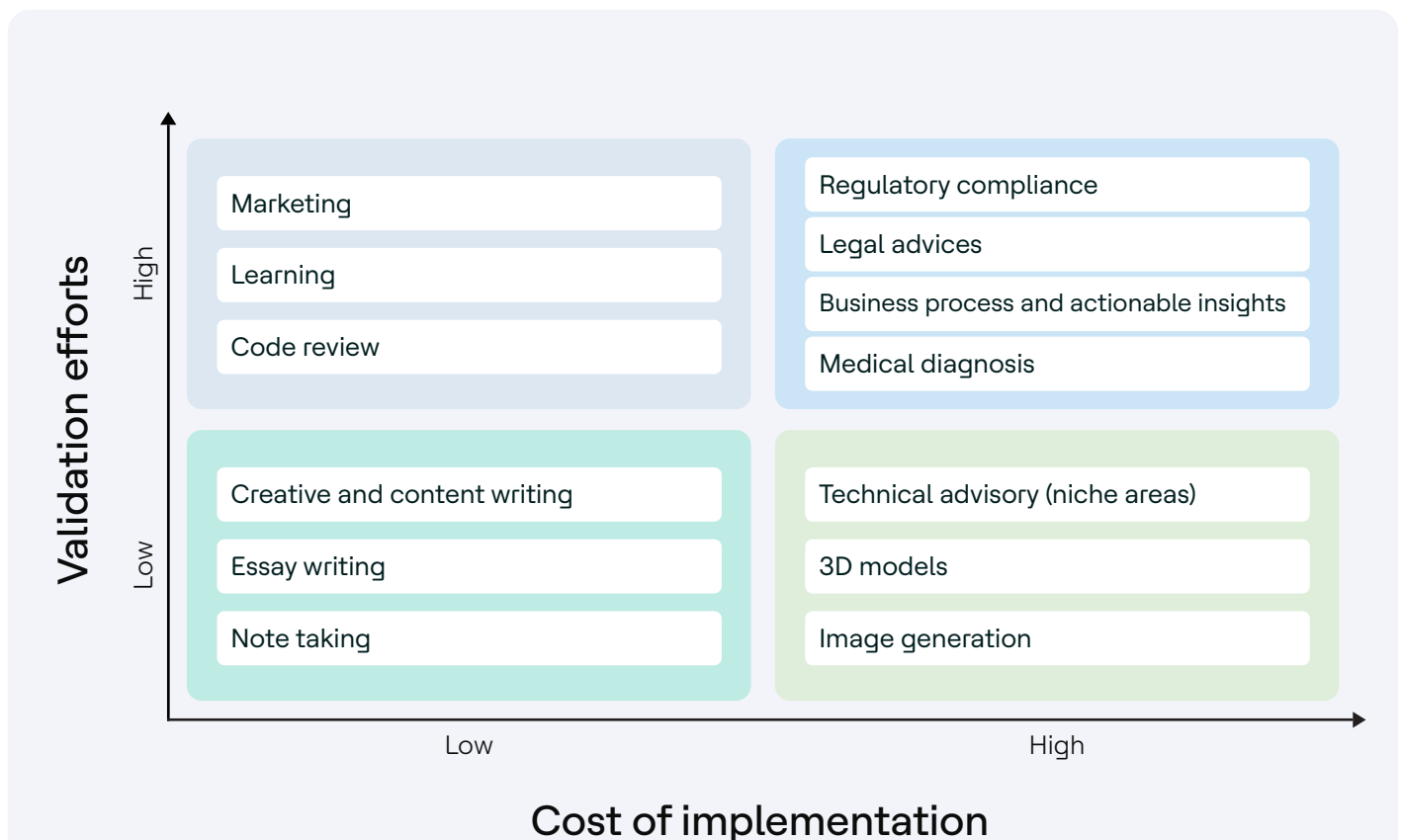


Fig 1: Cost of implementation versus validation efforts

Risks associated with AI/GenAI

The introduction of AI and GenAI presents the life sciences industry with significant challenges that need to be meticulously addressed to encourage broader adoption and propel these cutting-edge technologies forward.



Data bias

The risk of discrimination, unfairness, inaccuracies and bias, leading to data exploitation.



Copyright and ethics

There's a critical need to ensure that the content generated by AI and GenAI does not violate existing copyright or intellectual property rights.



Data privacy

The risks related to the usage of personal data, sensitive information disclosure, data privacy violations and the lack of data provenance.



Regulatory requirement

Organizations need to consider whether the use of AI/GenAI will fall under the scope of the upcoming new regulations such as the EU AI Act.



Ethical considerations

The distribution of harmful content and the lack of transparency with AI/GenAI outputs pose significant ethical concerns.



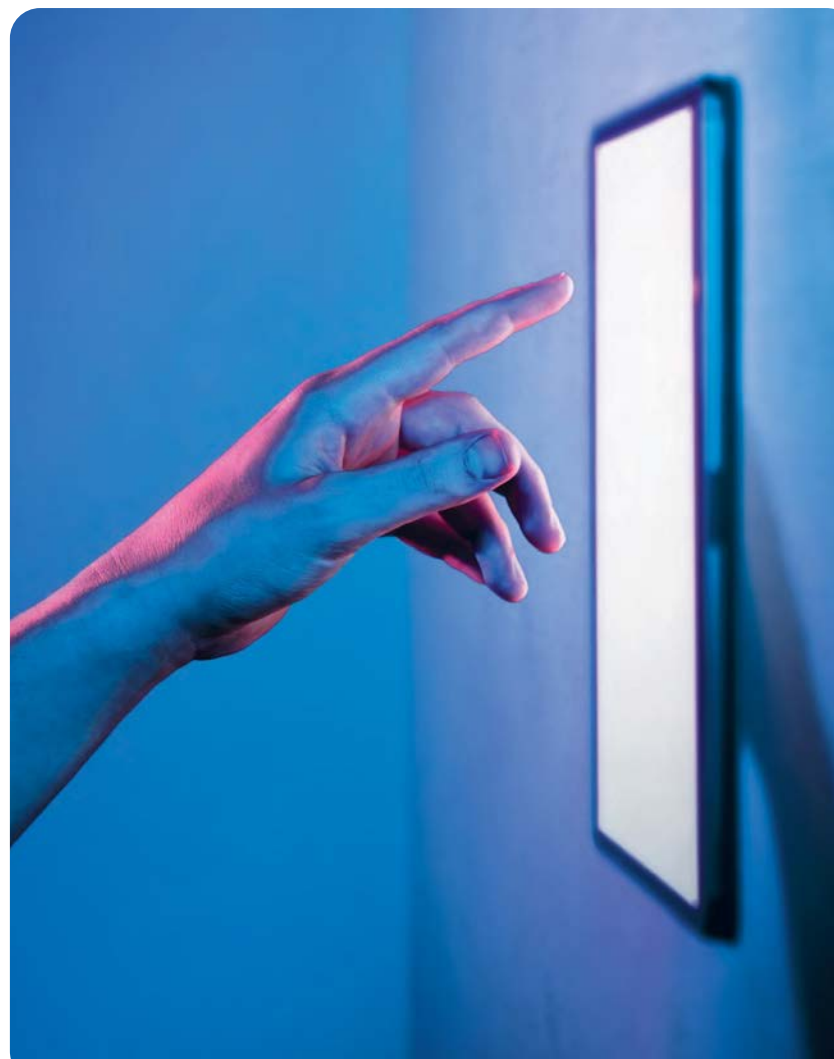
Compliance

Complying with privacy regulations, obtaining proper consent, legal considerations and licensed training data.

How can we validate GenAI solutions?

Some high-level approaches/considerations are:

- ➔ A good understanding of the business process and intended use of the AI model is critical for validation
- ➔ Most AI models are validated using the traditional validation approach, i.e., best practices in development or engineering and maintenance
- ➔ Data management is where it starts to diverge



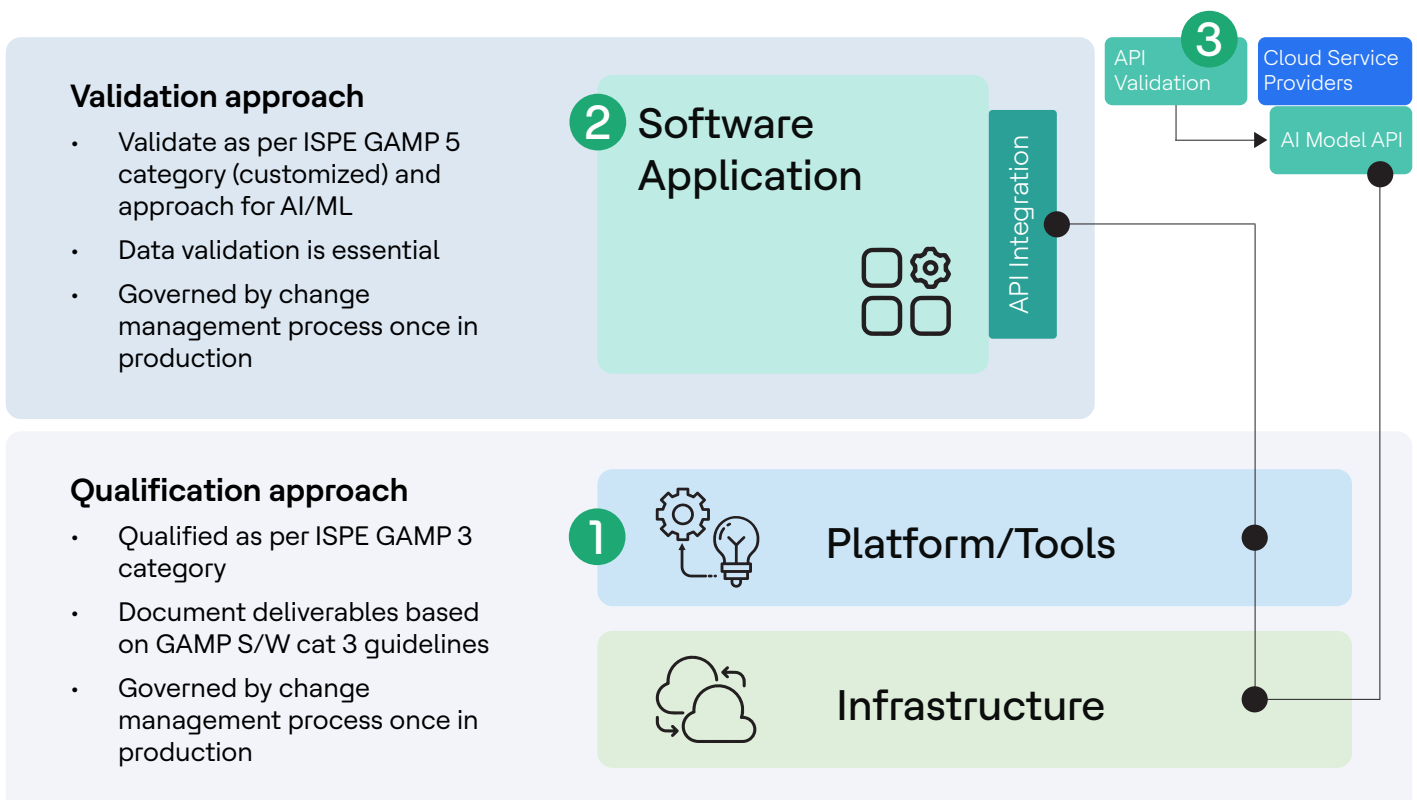
Key considerations for AI validation



➔ **1st layer - Infrastructure or platform**
- Qualified as per ISPE GAMP 3 category

➔ **2nd layer - Software application and AI model**
- Validated as per ISPE GAMP 5 category as these are customized solutions

➔ **3rd layer - API validation**
- API validation testing to be performed against the business objectives and expected outcomes



GxP (good practice) AI maturity

Validating GenAI or AI-based solutions is not a “one size fits all approach” and requires coordinating on a case-by-case basis. After the hype cycle, life sciences companies are rapidly exploring how to embrace this technology for GxP applications, leading to a critical need to have an AI maturity model for ‘GxP use case’ classification.

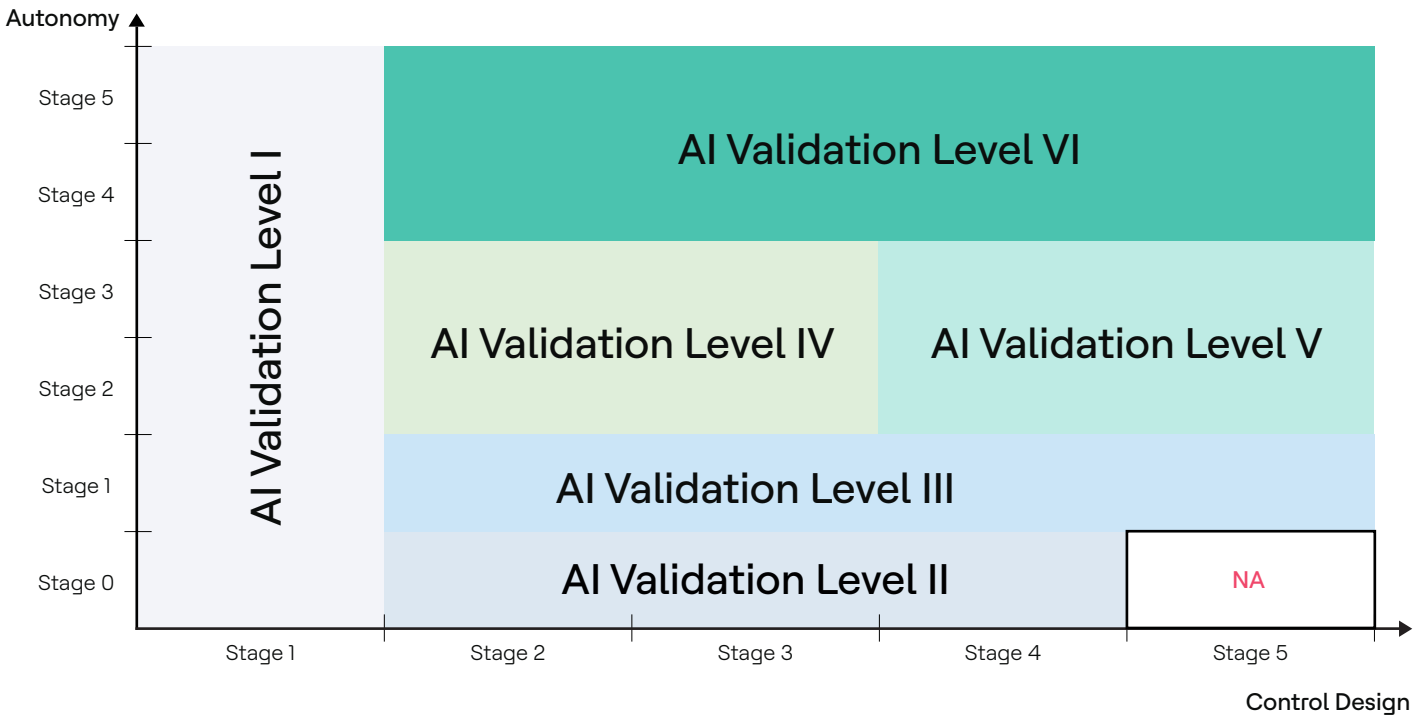


Fig 2: Based on the GxP use case classification, minimum validation activities and requirements are defined

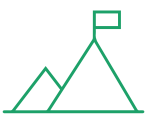
AI - Risk severity matrix

It is recommended that the risk management process is performed during the initial planning task by leveraging the AI maturity model, assessed against GxP hazards such as patient safety, product quality and data integrity.

		Risk Severity Matrix				
AI Maturity Level	Level VI	Autonomous Learning AI	High	Very High	Very High	Very High
	Level V	Self-triggered Learning AI - Without Human-in-Loop	Medium	High	High	High
	Level IV	Self-triggered Learning AI - Human-in-Loop	Low	Medium	High	High
	Level III	Piece-wise locked-state Learning AI	Low	Low	Medium	Medium
	Level II	Non-AI Applications	Low	Low	Low	Low
	Level I	Parallel AI	Low	Low	Low	Low
	Legend - Hazard Impact		Indirect impact to GxP process	Direct impact to GxP process with no direct impact to patient safety	Direct impact to patient safety with human in the loop	Direct and immediate impact to patient without human in the loop
		Low	Medium	High	Very High	
Process scenarios examples		Audit Management	Post-market Surveillance	1) Software in a medical device 2) Software as a medical device		

Fig 3: The risk and control frameworks are designed to help those tasked with the safe delivery of AI

Success story: Audit automation using GenAI for a leading life sciences client



Challenges

Audit management is a vital process for life sciences companies to ensure risks are regularly reviewed with a heightened sense of urgency around compliance to protect patient safety, product quality and data integrity. The audits are labor-intensive and require manual interventions. As part of the process, an auditor must verify documentation.



Objectives

The current approach for the client involved selective document analysis to identify potential gaps, followed by manual intervention for critical gap evaluation and resolution. The client is exploring the integration of GenAI to overcome limitations and enhance efficiency. This transition aims to proactively identify gaps, propose mitigation strategies and eventually enhance content with higher accuracy in a phased approach.



Solution

A GenAI-driven document auditing system was developed, which identifies gaps with enhanced accuracy and quality of output, like summarization, compared to the existing system.

This tool will help transition the current code-heavy business rule implementation to a GenAI-based model that facilitates easy integration and adaptation of new business rules, enhancing delivery speed.

It will create a more streamlined and efficient process using GenAI for applying and modifying rules and onboarding new documents from a scalability perspective, thereby lowering the cost of ownership.



Benefits

- 1 Enhanced productivity**
20% to 40% increase in productivity, minimizing non-value-added activities
- 2 Improved compliance**
Ensures audit readiness of systems and adherence to the current regulatory requirements
- 3 Reduces the processing time**
Auto-classification of the severity of finding and deploying a proactive approach by automating good documentation assistance per document type reduces the processing time by up to 30%



Conclusion

AI/GenAI has multiple use cases in compliance, quality and validation. Life sciences organizations can bolster their growth and productivity by incorporating AI/GenAI solutions into enterprise applications.

The promise of these solutions is immense, however critical thinking and thoughtful consideration of the key risk aspects that exist today are needed to fully realize its potential, avoid pitfalls and unlock true value tomorrow.

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