An Introduction to the transformative power of AI in shaping the pharmaceutical industry

A ProductLife Group report

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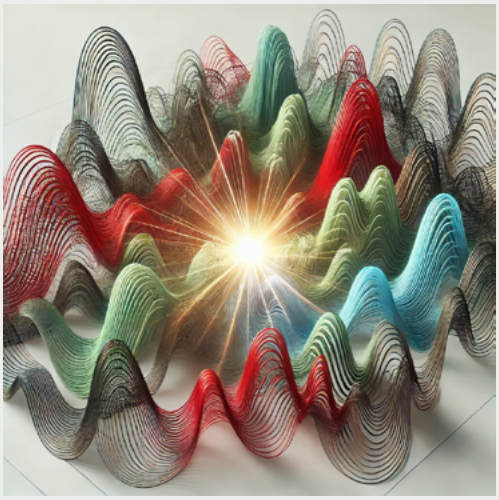
About this paper



An introduction to the transformative power of AI in shaping the pharmaceutical industry is a ProductLife Group (PLG) report which discusses the current acceleration in technology development applied to AI in the life sciences and how it is reflected in industry and scientific literature.

Dr. Momini Vaditya, MD, was the researcher for literature analysis. Jean-Luc Taborin, Head of Strategy and Digital Consulting served as advisor. Dr. Annie Jullien Pannelay, PharmD, MBA, Partner in the Consulting practice was the lead author for this paper, which includes the views from ProductLife experts namely:

- **Dr. Prashant Belathur, MD, Head of Safety and Vigilance at ProductLife Group**
- **Dr. Gabriele Breda, PhD, Research and Innovation Director**
- **Barbara Lassoff, Head of Delivery Services, DS Inpharmatics, a PLG Company**
- **Teresa Minero, Head of PLG Digital; Part of the ISPE EMEA Regulatory and Quality Harmonisation Steering Committee, Part of ISPE Pharma 4.0™ Steering Committee, Director at ISPE IBOD (International Board of Directors)**
- **Dr. Florian Pereme, PhD, Digital Innovation Lead at PLG**
- **Mariangela Prada, Head of PLG Market Access**
- **Wenna Zhang, Head of Medical Information, Commercial Eyes, a PLG Company**

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Executive summary

Rapid advancements in artificial intelligence (AI) are driven by a synchronisation in maturity of hardware, modeling capability and data availability. This is particularly evident in the Life Sciences and pharmaceutical industries, where there has been a surge in both industry literature and scientific publications on AI. It's important to recognise that AI is an umbrella term, encompassing a variety of technologies such as machine learning, deep learning, and generative AI.

When examining the publications related to AI in the life sciences, a clear trend emerges: a large focus on research and development (R&D). This is understandable, as R&D faces some of the greatest challenges that AI can help solve, particularly in dealing with large, heterogeneous datasets coupled with the ongoing struggle to understand complex diseases. In this space, AI has already demonstrated its value. Studies have shown that AI can shorten the drug discovery and development process. This progress is helping to address the industry's growing need for more efficient and effective research.

This heavy emphasis on R&D should be balanced with recognition of AI's growing influence in other critical areas of the pharmaceutical industry. One such area is regulatory affairs, where AI technologies like document intelligence and generative AI are helping specialised teams save time in the preparation of regulatory documents. Although human validation remains essential, AI is expected to continue delivering productivity gains in this domain.

In pharmacovigilance, AI is already making a massive impact. Validated tools are already used in routine practice, demonstrating the transformative potential of AI in tracking and managing drug safety data. The next frontier in pharmacovigilance lies in developing context-specific technologies, which could bring even greater benefits to this critical function.

Additionally, AI is finding its place in quality control, manufacturing, and engineering within pharma. Here, it is used to detect data integrity issues, predict production outcomes, and improve overall yields.

Despite these advances, several challenges remain, including difficulties in managing data, ensuring workforce adoption, and developing economic models that justify AI investments. Addressing these issues will be key to unlocking the full potential of AI in the pharmaceutical industry.

AI in the life sciences: A flurry of research

Artificial Intelligence (AI) is revolutionising the life sciences, as evidenced by the surge of publications in PubMed, a database of biomdical literature. In 2023, PubMed recorded 38,430 AI-related publications, a sharp increase from 6,811 in 2013. This growth, particularly over the past five years, highlights AI's growing impact. "The growth of AI publications is related to the release of new technologies and models. People are eager to explore different application domains, and AI development relies on cross-cutting technologies," says Dr. Gabriele Breda, the Head or Research and Innovation at ProductLife Group. This paper delves into the burgeoning volume and emerging themes covered in these publications, aligning them with current the life sciences trends and highlighting AI's transformative potential across industry functions. Before looking at the growing body of evidence on AI it is important to note that AI is an umbrella term to talk about a set of enabling technologies (See box 3). The AI language has been used for decades, yet in recent years, both the language and its actual applications are becoming mainstream (see box1). In the meantime, within the regulated the life sciences sector, different agencies have proposed different possible definitions (see box 2).

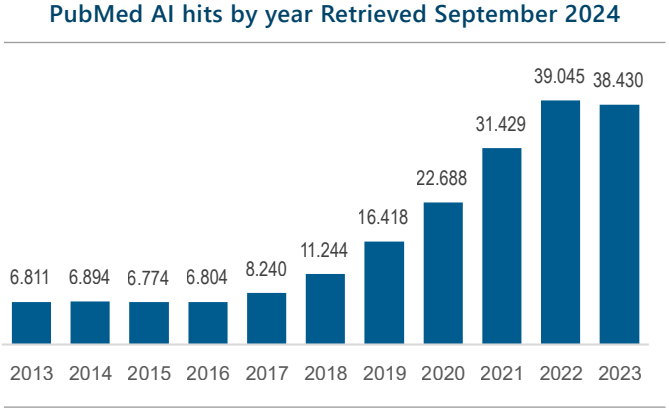

Figure 1

Objectives and methods

As a leading provider of consulting and outsourcing services for the Life Sciences industry, ProductLife Group's mission is to support innovation and enhance the efficiency of pharmaceutical, biotechnology, and healthcare organisations globally. By automating and streamlining operations through AI, we accelerate operational delivery and enhance quality, scope and robustness, directly benefiting our clients. This efficiency gain enables the life sciences companies to redirect resources towards developing innovative products, thereby improving patient outcomes and ensuring timely, cost-effective market entry.

Our commitment to leveraging AI aligns with our strategic goals of continuous innovation and efficiency. Monitoring AI trends and integrating these technologies into our operations is crucial for maintaining our competitive edge and delivering enhanced value to our clients. In an industry where regulatory compliance and speed to market are paramount, AI promises significant advantages, ensuring that all medicines, but especially life-saving products, reach patients faster, offer enhanced efficacy, higher compliance and ultimately improve patients outcomes. This focus underscores why keeping abreast of AI developments is not just an academic exercise but a pivotal component of our operational and strategic framework.

In this paper, we reviewed recent AI literature to identify trends and benchmark these insights against our internal activities. This comparative analysis informs future research and publications that ProductLife Group plans to conduct to remain at the forefront of AI innovation applied to the life science industry.

We conducted a review of AI-centric publications in the life sciences and pharmaceuticals, proceeding in iterative stages, focusing on industry literature. Our initial search targeted publications from consulting and pharma services companies, yielding 30 results. An internal panel scrutinized these documents, identifying sub-themes such as AI in regulatory affairs, medicines discovery, clinical trials, ethical considerations, supply chain and manufacturing, quality assurance, market access, strategy, and AI trends. We expanded our scope to include academic institutions and used techniques, such as reference harvesting (gathering references from key documents) and pearl growing (iteratively building searches), to collect 83 documents. These were categorised by their primary topics, forming the foundation of our analysis and interpretation by our internal experts, namely Dr. Prashanth Belathur, Dr. Gabriele Breda, Barbara Lassoff, Teresa Minero and Dr. Florian Pereme.

Representation of different functions in AI publications relevant to the life sciences

The findings revealed a pronounced emphasis on drug discovery and development, encompassing 39 papers, with 12 specifically addressing clinical trials. Additionally, 13 papers focused on global market trends and analysis. Ethical considerations and regulatory compliance were combined into a category comprising 9 papers. The areas of supply chain management and manufacturing quality assurance and control were each represented by 6 and 5 papers, respectively, while patient care and safety also accounted for 5 papers. A smaller set of 4 papers pertained to market access and strategy..

One paper we examined[1] relates an analysis conducted in detail across publications on AI and the life sciences.

This research confirms the focus of publications observed in our analysis with an academic perspective, since scientific databases were the primary focus in the Han paper: R&D publications represented over 60% of all the publications included in the Han paper, with regulatory affairs, clinical end and manufacturing representing respectively 11%, 9% and 5% of all papers included in the study, with 2% focused on quality control. It is important to note that even though authors labelled this category "Quality Control," the scope actually includes quality assurance in the broader sense, including for example traceability and equipment predictive maintenance analysis.

Figure 2

Category	# Publications	% Total analyzed
Research and Development	4600	62%
Regulatory Affairs	800	11%
Clinical End	650	9%
Manufacturing	350	5%
Quality Control	150	2%
Other Supporting Areas	900	12%
Total	7450	100%

Source: Han 2023- Han Yu, Revolutionizing Pharma: Unveiling the AI and LLM trends in the pharmaceutical industry[2]

Box 1: Why is AI Booming in 2024?

Dr. Florian Pereme

"We are living a harmonic synchronization where hardware capabilities meet the massive availability and distribution of AI models from foundation models to specific fine-tuned ones. The synchronization of those two elements matches the tail end of the '4th "communication" industrial revolution of data collection and structuration. This triple harmonic synchronization has led us to a specific junction happening right now: This new era of industrial revolution should align the human intelligence with the silicon intelligence," Says Dr. Florian Pereme, Digital Innovation Lead at PLG.

Harmonic curves describe systems that repeat periodically, and in this case, there is synchronized progress in three domains enabling the boom of artificial intelligence:

- **Hardware** – Technology enabling thinner silicon engraving means an increase in computing power in recent years, which is a major trigger for AI development
- **AI models chaining** – Refining existing models and building from the existing, combined with open-access libraries. This creates a self-improving process which results in more powerful models being developed in a shorter time
- **Industrial revolution 5.0** – Building on the legacy of industry 4.0, which has achieved massive data collection through IoT and sensors in manufacturing plants for example

Our take on research publications, industry demand and technology adoption

"AI use is relevant when data is heterogenous, which is the case in life sciences. For some years in life sciences we have generated large datasets, including in multi-omics, patient outcomes, and expanded the ways data is collected for example with a broader use of smart phone and wearables data collection options"

Gabriele Breda

Research and development

As per the European Federation of Pharmaceutical Industries and Associations (EFPIA), the health industries have the highest ratio of R&D investment to net sales. Research and development (R&D) represents around 15% of pharmaceutical revenues, depending on the source. Even though this contribution is important, it is far behind the 62% of papers focused on research and development within AI publications pertaining to the pharma industry. Firstly, this is expected because academic databases typically focus more on research. Secondly, the benefits of AI are more pronounced in the area of Research and Development. "AI use is relevant when data is heterogenous, which is the case in the life sciences. For some years we have generated large datasets, including in multi-omics, patient outcomes, and expanded the ways data is collected for example with a broader use of smart phone and wearables data collection options" says Gabriele Breda. In parallel, Gabriele observes the match with a general industry challenge: "We struggle to understand some diseases, such as auto-immune diseases and neuro-degenerative conditions", she says. As science still explores the full causes of many diseases and has identified multiple factors, AI can bring the data together and build a systemic approach, well suited to cracking those complex diseases. Even if still mainly exploratory, the use of AI in R&D has already delivered: multiple AI enabled programs completed the entire discovery and preclinical journey in less than four years, compared to the five to six years historical industry timelines[4].

Box 2: Different definitions of AI according to the regulatory authorities for medicines

FDA (Food and Drug Administration):

Artificial Intelligence (AI) and Machine Learning (ML) can be described as ***a branch of computer science, statistics, and engineering*** *that uses algorithms or models to* ***perform tasks*** *and* ***exhibit behaviors*** *such as* ***learning, making decisions, and making predictions.*** *ML is considered a subset of AI that allows models to be developed by training algorithms through analysis of data, without models being explicitly programmed.*

(Artificial Intelligence and Machine Learning (AI/ML) for Drug Development, 03/18/2024)

EMA (European Medicines Agency):

Artificial intelligence, refers to systems that display ***intelligent behaviour*** *by analysing their environment and taking actions – with some* ***degree of autonomy*** *– to achieve* ***specific goals.***

(Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle)

Regulatory affairs

"AI has significant potential in the area of regulatory intelligence," says regulatory operations expert Barbara Lassoff. "Through the use of LLMs* and generative AI, we will finally have the tools to go out and search prior research and regulatory guidance to get the information regulatory affairs professionals need to make decisions faster", she says. Indeed, in our industry literature sample, regulatory affairs were discussed in 9 papers mostly from the angle of regulatory compliance combined with legal and ethical aspects of AI use – that is about 10% of our industry literature sample, compared to an estimate of under 6-8% of regulatory affairs spending in the industry**: Regulatory topics are over-represented in the literature. This is driven notably by the multiple use for AI in regulatory affairs, many of them associated with mature technologies, such as Document Intelligence, which helps searching for documents, extracting data, and even compiling and mining regulatory intelligence. From a technical standpoint, Document Intelligence refers to the ability of machine learning clustering models, supported by text and keyword recognition through NLP***, to group similar documents. Beyond Document Intelligence, the most immediate area of application in regulatory affairs is in the automated generation of content to draft regulatory dossiers: Generative AI LLMs perform text and context recognition. "There is a strong trend of generative AI, on drafting those documents, taking into account templates, writing styles etc. with various applications all along the product life cycle documentation, from clinical to submission files and post-market surveillance," says Gabriele Breda. At ProductLife Group, we use the technology to speed up the writing process notably for CMC modules and MedTech technical documentation. Across uses, AI is an accelerator, and the expert human input is still at the center of the activity, to address the expertise and validation requirements needs for such functions[5]. In the future we expect AI will bring even more support to industry teams especially during critical times: "Regulatory Operations, always under pressure at the last step in the submission process, will benefit from the upstream improvements AI brings to regulatory affairs. AI will bring a streamlined submission preparation process to allow for the automation of repetitive tasks and enhanced compliance with global regulatory requirements," says Barbara Lassoff.

* LLM: Large Language Model

** We use medicines development documentation costs: Pharmaceutical companies are believed to incur about 25% of medicines development costs into the documentation. Using 15% of R&D costs, the share of documentation amounts to less than 4% of overall pharma investment. This cost associated with the product development needs to be topped up with the regulatory maintenance costs leading to our 6-8%

*** NLP: Natural Language processing

Box 3: Technologies underpinning AI at a glance

AI is a broad concept encompassing various digital technologies. It collects information, applies rules, and produces outcomes similar to human cognitive processes like thinking, learning, and decision-making. AI enhances problem-solving by automating complex tasks. Three examples of technologies belonging to the AI family include:

Machine Learning (ML):

ML is a branch of AI focused on using data and algorithms to mimic human learning, improving accuracy over time. It builds models that predict or make decisions based on data. ML models undergo either supervised learning (using input-output pairs), unsupervised learning (grouping data without guidance), or reinforcement learning (making decisions based on rewards from trial and error).

Deep Learning (DL):

DL, a subset of ML, uses neural networks for more flexible architectures. It automates feature extraction, allowing models to «learn how to learn» without extensive human input. DL is widely used in image processing, prediction, and recommendation systems. For example, a pharmaceutical company uses DL for automated line clearance, reducing human error and increasing efficiency.

Generative AI (GEN AI):

GEN AI focuses on creating original content, unlike ML and DL, which focus on analysis and predictions. GEN AI models, based on deep learning, require vast data and use transformers for processing multimodal data (text, images, sounds). LLMs (Large Language Models), a popular type, can perform various language tasks with minimal fine-tuning, making them versatile for problem-solving. In pharma, NLP-based Gen AI is used for report generation and quality management systems (NLP stands for Natural Language Processing, a field of artificial intelligence (AI) focused on the interaction between computers and human languages).

Pharmacovigilance

The role of AI in pharmacovigilance is growing, helping to analyse vast amounts of safety data and identify potential risks faster[6]. "Pharmacovigilance is a very fertile domain for AI, because there is a lot of data, and a need for analysis at regional and international level," says Gabriele Breda. She also points out that the current technology is mature for those activities, able to conduct descriptive analysis, understand and establish links across event families. "AI has most transformative potential in literature monitoring, case management and medical information," says Dr. Prashanth Belathur, the Head of Safety and Vigilance at ProductLife Group. Specifically in case management, major savings can be achieved: "AI tools can save up to 50% of the effort and time for each case at initial triage, data entry step, and some efforts in quality review and medical review workflow," says Prashanth. Case management database tools use machine learning and are able to learn progressively from their usage, ultimately proposing case classification and patient safety narratives using generative AI. "While manufacturers, regulatory authorities and service organizations such as ProductLife Group use existing validated tools in pharmacovigilance, the current activities consist in developing context-specific technologies by client," says Gabriele Breda. "This can materialize, for example, through development of specific classifiers not yet available on the market."

At PLG, the use of pilot proprietary tools is a reality [7]. "We have seen a significant reduction in time to generate localised standard responses from clinical papers and globally approved responses using a structured authoring tool." says Head of Medical Information, Wenna Zhang. "We have teams working alongside AI to undertake literature searches and write responses, and then test the accuracy of the AI generated response" she says. In time, medical information teams may shift from performing routine tasks to oversight of AI execution, freeing up time to focus on more complex activities. "We are confident that AI will support our human medical information teams, but it won't replace them completely", says Wenna, highlighting that adoption involves keeping a human in the loop, in line with the position of regulators[8].

Despite high maturity in pharmacovigilance, the research identified is included with other topics within both our industry literature sample and the academic analysis. Generally speaking, there is a split between academic publications looking at how new data sources, such as social media can support pharmacovigilance, whereas commercial AI enabled tools are discussed through case stories in industry events.

Box 4: Ensuring data reliability

Suggestions of practices to ensure data reliability:

1. **Data Quality Assurance:** Implement strong validation processes, handle missing or inconsistent data, and regularly clean datasets to ensure quality.
2. **Data Privacy and Security:** Comply with privacy regulations, secure data with encryption and access controls, and use anonymization to protect sensitive information.
3. **Diverse and Representative Datasets:** Ensure datasets reflect real-world diversity, regularly assess for biases, and address disparities.
4. **Continuous Monitoring:** Monitor AI model performance in real time, detect anomalies, and retrain as needed.
5. Version Control: Track dataset changes, maintain version control, and retrain models with relevant data.
6. Explainability and Interpretability: Use models that allow insight into decision-making processes and explain AI predictions.

Additional suggestions associated with learned behaviours:

1. **Transparent Models** Update: Retrain models ethically, avoiding reinforcement of biased behavior.
2. **Human Oversight:** Include human oversight to review AI outputs and intervene when necessary.
3. **Feedback Mechanisms:** Implement feedback loops to refine models based on user input.
4. **Ethical Guidelines and Governance:** Establish and regularly update ethical guidelines for AI governance.
5. **Transparency:** Communicate openly about AI capabilities and limitations to build trust.

Quality, manufacturing and engineering

While academic publications focused on manufacturing represented 5% of the Han paper sample, our analysis of the industry literature offers a stronger representation – supply chain management and manufacturing & quality together represented 13% of the papers retrieved. AI-driven automation in manufacturing is optimising production processes, improving quality assurance and control[9]. In those areas, the trend is materialising, underpinned by industry 4.0 (and now also 5.0) e.g., the use of advanced digital technologies and automation.

This allows for automated production lines that can run with less human intervention, real time monitoring and control, leading to more consistent product quality and predictive maintenance of equipment, reducing downtime and improving operational efficiency. "The applications of AI in quality assurance are very broad and diverse," says Gabriele Breda, pointing to the improvement of production models. Indeed, there is a very large array of use cases in this area[10], including, for example, the use of machine learning and trending to detect data integrity issues, or a Predictive Production Yield, AI based case study. Those are only two examples included in a rich collection of case studies Teresa Minero collected for ISPE in the "Pharma 4.0 Baseline Guide": "As you can see, the journey of truly adopting AI in Pharma and specifically in "Quality& Manufacturing & Engineering," considering the ISPE sample (400 respondents in the ISPE network around the globe) is still at the beginning, the game is open, with a lot of running evaluation and pilots, and way fewer AI applications adopted in large scale or even in small scale," she says.

"The applications of AI in Quality Assurance are very broad and diverse"

Gabriele Breda

Market access, market insights

Recent literature[11] has concluded that AI is still underutilized in pricing and market access in pharma. However, the growing amount and complexity of data on medicines prices, health economic metrics, etc. means AI has potential to support the collection, the review of the data submitted for reimbursement purposes and the price negotiations. "In the foreseeable future, AI can really have a big impact on market access" says Mariangela Prada, Head of PLG Market Access. At this stage, despite this huge potential for AI to streamline reimbursement processes and enable sharp HEOR* data analytics, the systems without human supervision are at risk of producing biased outcomes. This is why deep expertise is still required in this area, and in particular a profound knowledge of the different healthcare markets and of the reimbursement regulations and guidelines, combined with timely adoption of AI-driven models.

The application of AI in this area can also support in predicting and anticipating the evolving health models/ market, in the context of innovative approaches to support the products' therapeutic value.

"AI can support the optimization of clinical trial design and the approval processes, reduce time to access and standardize regulatory processes in different countries and regions, predict the market trends, supporting the whole patient access process. At PLG we work to combine our human expertise with AI and technology to sustain innovative approaches aimed at optimizing patients' ability to benefit from new products," says Mariangela Prada. In the area of market insights and product strategy, the use of big data is already leveraged by PLG teams to support successful product launches through a granular understanding of both clinicians' and patients' needs.

* HEOR: Health Economics and Outcomes Research

"In the foreseeable future, AI can really have a big impact on market access"

Mariangela Prada

Looking Ahead: Challenges and Opportunities in AI Adoption

As AI continues to advance in the pharmaceutical industry, significant opportunities and challenges lie ahead. Three key areas need to be further explored to maximise the value of AI for the life sciences: navigating the data challenges, ensuring workflow and people training for integration, and working out the gains underpinning the economic model justifying AI investments.

Data is the first "asset" of AI and also its first challenges. In Pharma 4.0, the industry focused on "data integrity" through ALCOA+ principles*. While this ensures data remains secure and unaltered, in the context of AI, we need to go further by also focusing on data reliability, ensuring data is intact, complete and accurate, adequately representing the activities or facts it relates to (see box 4[12]). This need for reliability and trust is connected with the data protection concept. With the growing volume of biopharma data, threat intelligence will remain crucial and may be supported by AI-based approaches to augment cybersecurity experts' efforts. One critical challenge is the need for clear validation and accuracy of AI-driven systems. During an interaction with pharma leaders, at DIA in 2024[13], a poll amongst 62 industry leaders identified computer system validation and accuracy questions as the top challenges to the adoption of AI for pharma.

In addition to data and validation, important operational and human challenges need attention. At people level, the adoption of AI means closing the skills gap to bring in the advanced expertise needed to implement AI. Extensive training or recruitment of specialised talent are both are costly and resource intensive. At process level, embedding AI into existing workflows requires more than just technology adoption because AI tools must seamlessly fit into current workflows. This item came first on the latest ISPE survey[14], which highlighted that managing the cultural and procedural changes necessary for effective adoption demands change management efforts to ensure AI enhances, rather than disrupts, operations.

Since developing, validating and deploying AI systems require significant financial and human resources, a structured assessment of the gains from AI adoption is necessary to understand where AI delivers proven, impactful results. This demand for an economic model that justifies AI is partially met by some estimates notably in R&D timeline reductions[6]. It is important for the industry to make an effort to measure the impact of AI, the savings generated, and possibly to share those learnings for later adopters to learn from the vanguards.

The way forward: Adopt or Adapt?

As the pharmaceutical industry embraces AI-driven transformation, companies face a pivotal decision: Should they adopt AI into their existing systems for immediate gains, or adapt their entire approach to secure long-term, strategic advantages? Adoption can streamline processes and boost efficiency in the short term, integrating advanced tools into current workflows.

On the other hand, adaptation requires a deeper transformation – overhauling systems, retraining teams, and building an agile infrastructure capable of evolving alongside AI advancements. The real question is: will companies focus on the quick wins today, or reimagine their future to stay competitive in a rapidly changing landscape?

* ALCOA+: Ensuring data is Attributable, Legible, Contemporaneous, Original, Accurate, the "+" includes the additional principles: Complete, Consistent, Enduring, and Available

Declaration of generative AI and AI assisted technologies in the writing process

During the preparation of this work, the author(s) used Open AI ChatGPT4 for words/ sentences polishing. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

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About ProductLife Group

ProductLife Group's mission is to support patient access to safe and effective healthcare solutions by delivering worldwide consulting and outsourcing services throughout the entire product life.

Combining local expertise with a global reach spanning more than 150 countries, PLG is the Life Sciences Industries reference strategic partner for the development, market introduction, and life cycle management of product portfolios and related business and digital transformation.

With a goal of continuously improving the value delivered to teams and clients, PLG is committed to long-term partnership, innovation, flexibility, and cost efficiency.

An Introduction to the transformative power of AI in shaping the pharmaceutical industry

The body of evidence associated with AI in the life sciences has surged over the past five years, signaling that while change is underway, significant transformative potential remains. To realise this potential, the industry must tackle key challenges and make informed decisions in functions encompassing regulatory affairs, manufacturing, vigilances, patient access and market insights and of course, research and development.

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