ARTIFICIAL INTELLIGENCE IN PHARMA

Empowering Industrial Pharmacists for the Digital Era

Executive Summary

Artificial Intelligence (AI) is rapidly becoming an essential driver for innovation and efficiency within the pharmaceutical industry. Its applications span a wide range of activities, including process automation, clinical research optimization, predictive maintenance, regulatory intelligence, and quality control enhancement. AI tools offer the possibility to manage complex datasets, detect patterns, forecast risks, and accelerate decision-making processes, supporting the industry's ongoing evolution toward more digitalized and data-driven operations.

Despite the significant opportunities, the adoption of AI technologies brings with it important challenges. Data security, model validation, regulatory uncertainty, ethical governance, and workforce adaptation are key issues that must be proactively addressed to ensure safe and responsible AI integration. Current regulatory initiatives, such as the EU AI Act and new EMA and FDA guidance, are beginning to shape the framework within which AI can be adopted in a compliant manner.

In this context, industrial pharmacists are uniquely positioned to ensure the effective and ethical deployment of AI solutions. Their scientific expertise, combined with a deep understanding of regulatory requirements and quality systems, enables them to critically assess AI models, oversee validation activities, and contribute to risk management strategies. Industrial pharmacists also serve as key interpreters of AI-driven insights, ensuring that outputs are aligned with product quality, patient safety, and compliance imperatives.

As companies move towards AI-enhanced operations, industrial pharmacists will be vital in ensuring that innovation does not compromise regulatory rigor or ethical standards. Their active involvement will be a critical factor in translating technological advances into tangible improvements in pharmaceutical quality, efficiency, and patient outcomes.

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Introduction

Artificial Intelligence (AI) is reshaping industries by enabling new efficiencies, advancing research capabilities, and transforming professional roles. In the (bio-)pharmaceutical industry, AI has emerged as a powerful tool, not only impacting research and development (R&D), clinical trials, regulatory compliance, supply chain management, and patient-centered care.

AI is transforming industrial pharmacists' roles, enabling advanced data analysis, accelerating drug development, personalizing patient care, enhancing production processes and streamlining workflows.

This whitepaper created by the European Industrial Pharmacists Group (EIPG) in collaboration with the International Society for Pharmaceutical Engineering (ISPE) explores AI's practical applications within the pharmaceutical industry, its impact on the industrial pharmacist's role, and the challenges which come with its integration.

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Glossary

Term	Definition
AI	Artificial Intelligence
ALTAI	Assessment List for Trustworthy Artificial Intelligence
API	Active Pharmaceutical Ingredient
AR	Augmented Reality
CAPA	Corrective Action & Preventive Action
CDRH	Center for Devices and Radiological Health
CMO	Contract Manufacturing Organization
CNN	Convolutional Neural Network
CQAs	Critical Quality Attributes
CPPs	Critical Process Parameters
DI	Data Integrity
DL	Deep Learning
EIPG	European Industrial Pharmacists Group
EMA	European Medicines Agency
ERP	Enterprise Resource Planning
EU	European Union
FDA	Food and Drug Administration
FDP	Federated Data Platform
GAN	Generative Adversarial Network
GAMP5	Good Automated Manufacturing Practice version 5
GENAI	Generative AI
GDPR	General Data Protection Regulation
GMLP	Good Machine Learning Practice
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agencies
HTA	Health Technology Assessment
ISPE	International Society for Pharmaceutical Engineering
LLM	Large Language Models
LSTM	Long Short-Term Memory Network
MES	Manufacturing Execution System
ML	Machine Learning
NHS	National Health Service
NN	Neural Network
NLP	Natural Language Processing
OOS	Out-Of-Specifications
OOT	Out-Of-Trend
OCR	Optical Character Recognition
PAT	Process Analytical Technologies
PQR	Product Quality Review
QA	Quality Assurance
QC	Quality Control
QRM	Quality Risk Management
R&D	Research and Development
RCI	Root Cause Investigation
RNN	Recurrent Neural Network
SQL	Structured Query Language
SVM	Support Vector Machines
VAEs	Variational Autoencoders

3. Overview of Artificial Intelligence in the pharmaceutical industry

3.1 Artificial Intelligence definitions

Artificial Intelligence is emerging as a powerful ally in addressing modern challenges in clinical development, drug discovery and production, quality control, and regulatory compliance . It can enable the automation and optimization of processes and workflows that traditionally require high levels of human involvement.

Some definitions of AI from Pharmaceutical regulators:

> *FDA: "Artificial Intelligence is a branch of computer science, statistics, and engineering that uses algorithms or models that exhibits behaviors such as learning, making decisions and making predictions"*
>
> *EMA: "Artificial Intelligence refers to systems that display intelligent behavior by analyzing their environment and taking action - with some degree of autonomy – to achieve specific goals".*

Quality, safety, and efficacy of drugs are paramount in the pharmaceutical industry. It is important to highlight that AI is not about replacing humans but rather augmenting their capabilities, enabling them to manage complexity with greater transparency and precision and to make more informed decisions. For instance, AI algorithms are increasingly used in clinical trials to predict patient responses, significantly improving patient selection accuracy and reducing trial duration.

3.2 AI technology adoption: Pharmaceutical needs & concerns

3.2.1 Industrial Pharmacists need AI

The pharmaceutical industry is one of the most regulated fields, in which there is constant change. Guidelines, frameworks, regulations, requirements are continuously evolving, and reference documents are continuously published worldwide.

The aim of pharmaceutical companies is to stay tuned on regulations, to respect them while optimizing processes along the entire supply chain, ensuring product quality and safety. To achieve the goal, companies first need digitalization, use innovative technologies and systems to switch from a paper-based document-centric approach to digital and automatic data-driven approach. Digitalization, raising efficiency targets and increasing compliance requirements are the fundamental pillars for adoption of AI within the pharmaceutical industry.

3.2.2 Concerns about AI

Despite the promising results that AI can give, the pharmaceutical sector is still often resistant to its adoption due to the following facts:

* The digitalization, foundation of AI requires massive and expensive changes in integration with existing systems and processes, in operations, functions, and departments, as well as a shift in the organization's culture.
* Cybersecurity and data privacy are very strict in pharmaceutical fields and required to safeguard patient data. Regulations such as the GDPR are valid for digital systems in general but are even more difficult to implement in the new evolving AI applications. They remain from major concerns related to AI.
* All digital systems which might affect pharmaceutical products need thorough Computer Systems Validation, according to GAMP5. The respective AI models would need to undergo validation too, although the current GAMP5 framework is not yet suited for AI, however a new draft has been published by ISPE. There is a lack of regulatory guidance for AI Models aspects not covered by existing computer system validation in this heavily regulated environment with low tolerance for risk/uncertainties.
* Need for an ongoing education to become/remain proficient and updated in these evolving tools. This includes training in interpreting AI-generated insights, understanding algorithm limitations, and navigating ethical, social and regulatory considerations. This means also creating new roles and demands for skilled personnel.
* AI systems can perpetuate biases present in their training data, which could lead to inequitable healthcare outcomes. Industrial pharmacists must advocate for transparency in AI models and actively review the outputs for potential biases, especially in patient care decisions. The AI models should be trustworthy: reliable, easily interpretable, transparent (against hallucinations, overfitting, biases etc.), and trained through quality and representative learning processes.
* Over-reliance on AI may erode the industrial pharmacists' clinical judgment. Industrial pharmacists must balance AI insights with their expertise to ensure high-quality patient – and product care, especially in cases that require nuanced, human-centered decision-making.

3.3 New AI Guidelines - State of the art

Several institutions have published some first assessments, papers and guideline proposals regarding the implications of AI on the pharmaceutical industry since the early 2020's. We will list the major publications here.

* In July 2020, the High-Level Expert Group on Artificial Intelligence (AI HLEG) presented their Assessment List for Trustworthy Artificial Intelligence (ALTAI), a tool with basic ethical principles to support AI developers and deployers in developing Trustworthy AI.
* Between 2021 and 2023 the FDA and its medical device division (CDRH) have published one discussion paper on AI/ML in drug manufacturing and a guide called "Good Machine Learning Practice for Medical Device Development" (GMLP) with some use cases, but they are waiting for the agency to develop a more concrete guidance, for which there is the need for stakeholder's feedback.
* A Limited industry guidance has been proposed and outlined in the ISPE GAMP 5, second edition, was published in July 2022 (Appendix D11).

* In Europe, only recently (2024), a regulatory document has been released by European Committee with the aim to regulate as much as possible AI in its applications: the EU AI ACT.
* EMA published, in September 2024, the final version of the "Reflection paper", that provides considerations on the use of AI/ML in the lifecycle of medicinal products, including medicinal products development, authorization, and post-authorization. The final version has been presented at the workshop 'HMA-EMA multi-stakeholder workshop on Artificial Intelligence – enabling safe and responsible use of AI' (November 2024). In this occasion also the multi-annual AI workplan has been discussed.
* FDA has just released (January 2025) two draft guidance that collect respectively AI recommendations to support decision making for Drug and Biological products for Industries and other Interested parties [9] and recommendations to support lifecycle management and marketing for AI-enabled device Software functions for industry and FDA staff [10].
  In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

4. Preparing for AI integration

4.1 Integration of AI solutions in company processes

When AI needs to be integrated into company processes, some basic principles should be followed. Our advice is to create a solid QRM framework: performance requirements of AI will vary greatly depending on patient proximity, from upstream process control (generally lower risk) to downstream QA decision-making (higher risk). Subsequently solid data governance program should be developed to at least understand biases in the data sets to be used for any future decision-making.

The suggestion is to use as much as possible informal qualitative tools (e.g., data and process mapping) to clearly explain the intended performance of the model during regulatory inspection and to implement a good AI standard prior to initiating development activities so that any knowledge about the model can be referenced within the risk management program alongside Quality oversight.

Process automation requires a shift toward in-line or on-line process analytic technologies (PAT) that enable continuous measurements of critical parameters and critical quality attributes (CQAs).

4.2 Interdisciplinary Teams

One of the most important needs for AI integration is the availability of Interdisciplinary teams, made up of skilled personnel. Various professionals need to contribute to the AI models' development processes. They must work together to create and validate the solution according to quality and regulatory standards.

* Project Manager: for overseeing the entire development process and organizing task, set priorities and ensure deadlines are met.
* IT Teams: for cybersecurity and collaboration with expert engineers.

* Data Scientists and data engineers: for extracting insights and knowledge from data through their expertise in AI (development, training, test of ML and DL models) as well as in data collection, processing (cleaning, statistical analysis etc.) and visualization.
* Domain and subject matter experts (e.g. industrial pharmacists): for providing critical insights and context on meaning of data, realizing the link between results and the specific problem the AI models aim to solve.
* Quality assurance team (often led by an industrial pharmacist): for testing and validation, ensuring that AI model performs as expected and it aligns with quality and regulatory standards.

5. Benefits of implementing Artificial Intelligence

5.1 AI from Research to Distribution

Driving innovation and efficiency, AI gives companies a competitive advantage in end-to-end manufacturing, regulatory affairs, market access activities and financial performance.

The adoption of AI in the pharmaceutical sector is transforming production processes and opening new opportunities to improve operational efficiency and ensure medication safety. Especially AI applications in Quality Assurance (QA) and Quality Control (QC) are gaining increasing attention.

The use of advanced technologies such as machine learning algorithms, computer vision, and predictive models is changing how we monitor the quality of pharmaceutical products - from research to distribution.

It can help in managing and reducing the costs, catching early production deviations and then providing smaller impact on product wastage or rework activities (reducing also workload on operators). Moreover, optimizing the employees' time allows them to focus on more strategic and science-focused activities and therefore improve overall job satisfaction, engagement and productivity (and then again cost drop).

5.1.1 AI for Pharmaceutical Quality Operations

The pharmaceutical industry increasingly needs intelligent solutions, especially to enhance quality operations. AI can support this in several keyways:

1. Streamlining regulations and documentation:

AI can offer actionable insights on how a company's products and procedures align with global and local regulatory standards. It also helps automate documentation tasks, such as translating, drafting, or updating change control documents, making compliance more efficient.

2. Accelerating problem detection and resolution:

Through real-time monitoring and automation of routine tasks, AI enables quicker identification of issues and proactive corrective actions. For example, it can optimize CAPA processes by analyzing previous cases and suggesting preventive measures. It can also automate data monitoring to identify Critical

Quality Attributes (CQAs) and Critical Process Parameters (CPPs), enhancing process control and reducing variability and costs.

3. Enhancing data analytics and decision-making:

AI tools can analyze historical data to uncover patterns, assess risks, and support more informed decisions. This empowers quality teams to understand root causes and improve operational performance through data-driven strategies. This also leads to important input for industrial pharmacists working in pharmacovigilance, AI can ease analyzing patient and product data to identify potential risks or adverse events.

Some further examples of applications where AI can greatly enhance QA/QC processes:

* Automated Inspection: Detecting defects in packaging and labeling using computer vision.
* Data Analysis: Analyzing batch records and lab results for anomalies.
* Predictive Maintenance: Identifying equipment failures before they occur.
* Process Optimization: Enhancing manufacturing processes through real-time monitoring.
* Document Management: Automating compliance checks and record-keeping.
* Root Cause Analysis: Identifying possible reasons for deviations faster.
* Supply Chain Monitoring: Tracking raw material quality and detecting inconsistencies.
* Risk Assessment: Predicting potential quality issues based on historical data.

Adopting AI by industrial pharmacists working in pharmaceutical QA/QC processes can greatly enhance efficiency, reduce operational risks, and ultimately improve quality and patient safety.

6. Future Outlook

Approximately 50% of global healthcare companies plan to implement AI strategies by 2025 [30].

United Kingdom has just invested 330M $ to create a Federated Data Platform (FDP) to collect all the data produced by the NHS, the British healthcare system, and to use them for multiple purposes and use cases where AI is the leading actor.

Some pilot studies have just successfully implemented with AI within the healthcare sector:

* Optimization of the waiting lists: algorithms to reduce time, to optimize access to health care structures and operating rooms and available resources.
* Assistances coordination (integration hospital – territory): sharing info between equipes to allow primary treatments to patients.
* Vaccinations: algorithms to schedule and monitor the vaccination campaigns.
* Population health management: planning of the services aimed at satisfying the population's needs (e.g. predictive algorithms to understand the health trend and anticipate needs allocating resources correctly).
* Supply: analyses of historical data to supply devices and drugs

More directly related to the pharmaceutical industry, key applications of AI could be:

* Enhanced Quality Control and Assurance: AI systems, particularly machine learning and computer vision, improve quality assurance by detecting defects and inconsistencies in production lines.
    - Real-Time Defect Detection: Computer vision systems can identify defects in tablets, capsules, and packaging with high accuracy. AI-powered tools can be used to monitor quality at the microscopic level.
    - Predictive Maintenance: AI models analyze equipment performance and predict potential failures, allowing maintenance to be scheduled proactively. This reduces unplanned downtime and keeps production lines running smoothly.
* Process Optimization and Yield Improvement: AI-driven predictive analytics can optimize production processes by analyzing variables like temperature, pressure, and mixing times.
    - Optimizing Chemical Reactions: AI can determine optimal reaction conditions, enhancing yield and quality. For example, companies using AI in active pharmaceutical ingredient (API) synthesis achieve greater consistency as AI detects real-time deviations.
    - Continuous Manufacturing: AI monitors and controls each step of production in continuous manufacturing, enabling consistent output, reduced errors, and minimal waste.
* Supply Chain and Inventory Management in Production: AI streamlines inventory control and anticipates supply needs, ensuring an uninterrupted supply of raw materials essential for production.
    - Demand Forecasting and Inventory Optimization: Machine learning models predict future material needs by analyzing demand data and patterns, allowing for effective stock management.
    - Automated Ordering and Supplier Management: AI tools automate procurement, identify optimal suppliers, and ensure stock levels remain adequate, mitigating supply chain risks.
* Ensuring Regulatory Compliance: AI assists with compliance by automating documentation, tracking conditions, and ensuring adherence to GMP standards.
    - Automated Documentation and Traceability: AI-powered systems record each production step, tracking batches, raw material usage, and quality checks, simplifying the documentation process.
    - Digital Twins for Simulation and Testing: Digital twins are virtual replicas used for testing and simulating production scenarios, allowing pharmacists to refine processes and ensure readiness before making physical adjustments.
* Personalized Medicine: By integrating genetic and environmental data, AI enables individualized treatment approaches. Industrial pharmacists can leverage AI to predict which drug formulations and dosages will be most effective for specific patient profiles, optimizing therapeutic outcomes and reducing side effects.
* Pharmacovigilance: AI models can automatically analyze adverse event reports and electronic health records. It then identifies potential safety signals earlier by detecting patterns and

anomalies in large datasets. For industrial pharmacists, this tool could streamline the signal triage process, prioritize high-risk cases, and support faster, more accurate safety assessments, enhancing drug safety monitoring and regulatory compliance.

* Market access: AI tools like natural language processing (NLP) and machine learning can be used to analyze real-time health policy updates, pricing databases, HTA (Health Technology Assessment) reports, and competitor product launches across global markets. It provides industrial pharmacists with actionable insights into pricing strategies, reimbursement pathways, and value dossier development. By forecasting payer acceptance and identifying regional access barriers, the tool supports evidence-based decisions to accelerate and optimize market entry.

6.1 The future role of the industrial pharmacist

The role of industrial pharmacists in the pharmaceutical industry is expected to evolve alongside AI, with new opportunities emerging across various domains:

* Expanded Interdisciplinary Collaboration: AI-facilitated insights are increasingly relevant to multiple healthcare roles. Industrial pharmacists will work closely with bioinformaticians, data scientists, and regulatory experts to ensure holistic approaches to drug development, patient safety, and compliance. Industrial pharmacists can lead these interdisciplinary collaboration groups effectively, due to their vast knowledge of the product and patient requirements, avoiding non-compliance due to AI implementation.
* Evolution into Data Interpretation Specialists: As AI automates repetitive tasks, industrial pharmacists are likely to become specialists in data interpretation and consultants for AI-driven decisions. This evolving role requires pharmacists to guide the ethical use of AI in healthcare and verify its alignment with patient care standards.
* Precision in Drug Formulation: With AI advancements, industrial pharmacists can anticipate innovations in formulation and dosing, such as AI-customized compounds based on patient-specific genetic data, offering unprecedented accuracy in treatment options.
* Proactive Patient Care Through Predictive Analytics: AI's predictive capabilities will enable industrial pharmacists to play proactive roles in preventive medicine, particularly in chronic disease management. Predictive analytics will allow for early intervention strategies, resulting in improved patient outcomes.

7. Overview of Artificial Intelligence Technology

7.1 Artificial Intelligence Models

Artificial Intelligence enables machines to learn and perform tasks (imitating) that normally require human intelligence.

Artificial Intelligence systems can be hierarchically classified as follows:

* Machine Learning (ML): subset of AI achieved to discover patterns in data to make predictions or decisions on their own.
* Deep Learning (DL): subclass of machine learning algorithms that usually involve Neural Networks (structures with many layers that imitate human brain).
* Generative AI (GEN AI): models that use deep Neural Networks to generate new and realistic content based on existing models or datasets that closely resemble the original data

These models are revolutionizing drug development, improving clinical decision-making, and accelerating the discovery of new treatments.

7.1.1 Machine Learning

Machine Learning is a subset of AI where systems learn from data to make predictions or decisions without being explicitly programmed. It involves algorithms that recognize patterns and make data-driven predictions or decisions.

Common ML Models used in Pharmaceutical Industry:

* Decision Trees: Such as Random Forest, a powerful ensemble learning algorithm used for classification and regression tasks. It is widely used for analyzing patient data, predicting clinical outcomes, and identifying biomarkers.
* Support Vector Machines (SVM): Used both for classification and regression tasks, such as distinguishing between active and inactive drug compounds or predicting adverse drug reactions.
* Bayesian Models: Probabilistic graphical models focus on probabilistic reasoning and statistical inference. They can model drug interactions, patient's outcome and disease progression.

Applications: Predicting clinical outcomes, identifying biomarkers, and classifying molecules as active or inactive.

7.1.2 Deep Learning

Deep Learning is a subset of Machine Learning that uses neural networks with many layers (deep networks) to learn from large amounts of data, especially unstructured data like images, text, or sequences.

Common DL Models used in Pharmaceutical Industry:

* Convolutional Neural Networks (CNNs): Used primarily for image-based tasks, such as analyzing medical images (e.g., MRI scans, histopathology images) and identifying anomalies in biological images. ResNet is one of the most popular CNN in pharmaceutical applications due to its ability to train very deep neural networks by using skip or residual connections.
* Recurrent Neural Networks (RNNs): These models are used for time-series analysis or sequential data, such as analyzing gene sequences or predicting patient outcomes over time. LSTM (Long Short-Term Memory) network is the most used RNN in pharmaceutical industry due to its ability to handle sequential data with long-term dependencies, making it well-suited for drug response and interaction prediction and genomic analysis.

Applications: Drug discovery, medical image analysis, predicting patient responses, genetic sequence analysis, optimize production

7.1.3 Generative AI

Generative AI focuses on creating new, realistic data that mimics real-world data, such as generating text, images, or even molecules. It is particularly useful in drug discovery and molecule design.

Common GEN AI Models used in Pharmaceutical Industry:

* Generative Adversarial Networks (GANs): Consist of two neural networks (a generator and a discriminator) that work together to generate a content. The most common used are the CGANs (Conditional Generative GANs), that allow them to generate drug-like molecules with specific properties such as bioactivity, solubility or toxicity profiles, or MolGAN, that uses a combination of GANs and reinforcement Learning to generate molecular graphs that exhibit desirable chemical and pharmacological properties.
* Variational Autoencoders (VAEs): These models are used for generating new molecules by learning a compact representation of molecular structures and enabling the generation of novel compounds with specific biological activity. The most common is ChemVAE, which is specifically designed for generating novel molecules with drug-like properties.

Applications: Molecule generation, drug optimization, and simulating interactions between drugs and biological targets.

7.1.3.1 Natural Language Processing

Natural Language Processing (NLP) Models are a special category of GEN AI Models, especially they belong to the Transformer Model group. They used both to process/understand and generate natural language, which is crucial for analyzing large volumes of scientific texts, medical records, and research papers.

Common NLP Models used in Pharmaceutical Industry:

* BERT - Bidirectional Encoder Representations from Transformers (Google): A pre-trained transformer model that is effective at understanding the context of words in a sentence. In the pharmaceutical industry, it is used to extract information from research papers, clinical trial reports, and medical records.
* GPT - Generative Pre-trained Transformer: A model like ChatGPT (Open AI) that is fine-tuned for generating human-like text. It can be used for summarizing scientific articles, answering queries about drugs or treatments, and even generating new hypotheses based on existing research data.

Applications: Extracting insights from scientific literature, analyzing clinical trial results, and processing electronic health records.

7.1.4 Traditional AI vs Generative AI

Generative AI is a new form of AI and can be viewed as something revolutionary with respect to Traditional AI.

Firstly because, while 'Traditional AI' makes predictions or classifications based on labelled data or predefined rules, GEN AI can generate new data resembling data learned (e.g. producing output texts similar in style to the texts used for training).

Secondly because, in recent years, Generative tools implemented are being spread and sold all around the world due to their potentiality and the tangibility of their outputs. Indeed, final users (even without technical background) can now use these models as virtual assistants, interacting with them to achieve new original content, find quick responses to specific questions or help streamlining time-consuming common activities (text summarization etc.).

In addition to the benefits listed in paragraph 6, additional advantages associated with the use of AI in general (including traditional AI and GEN AI) are listed below. The ones specifically born with Generative Models are selectively indicated by bracket description.

* Improving accuracy and precision of analyses, reducing risk of human error.
* Enhancing decision-making capabilities.
* Providing insights, helping to make better decisions.
* Providing automatic recommendations (GEN AI benefit).
* Creating realistic data based on existing models (GEN AI benefit).
* Increasing efficiency and productivity.
* Catalyzing creativity (GEN AI benefit).

7.1.5 Artificial Intelligence Tools in Pharma

Common tools in pharmaceutical industry used to analyze data and build predictive models that identify complex patterns in clinical, genomic, laboratory, and manufacturing data or simply use foundation models:

* TensorFlow (Google): An open-source framework widely used for building deep learning models in the pharmaceutical industry, such as for analyzing medical images, predicting treatment responses, or optimizing production.
* PyTorch (Facebook): Another popular open-source framework for building AI models in complex settings like drug discovery and personalized treatments.
* AutoML (Google): A system to automate the creation and optimization of machine learning models, helping to accelerate drug discovery and improve research efficiency.
* IBM Watson for Drug Discovery: Uses machine learning and natural language processing to analyze scientific literature, clinical data, and other sources, helping to discover new drugs and biomarkers.
* DeepChem: An open-source library based on deep learning for chemical and pharmacological analysis. It's used to build predictive models of drug-protein interactions, bioactivity, and toxicity.
* Schrödinger (Maestro): A platform that uses AI to simulate molecular behavior and predict the efficacy of new molecules.
* OpenEye: Software for molecular design and chemical simulations that uses AI algorithms to optimize the search for new drugs.

- Zebra Medical Vision: Uses AI to analyze medical images and detect diseases at an early stage, supporting diagnosis and treatment.
- Copilot (Microsoft 365): AI-powered tool that helps with a wide range of tasks. It uses a combination of foundation models, allowing to match the specific needs of each feature – e.g., speed, compliance – to the right model. It has different functions:
    - Microsoft 365 apps: Apps like Word, Excel, PowerPoint, Outlook, Teams, and Loop work with Copilot to support users' work helping users, for example, to create, understand, and edit documents.
    - Microsoft 365 Copilot Chat: users can draft content, review them, and get answers to questions using open-ended prompts. This information is securely grounded in work data.
    - Microsoft Graph: it includes information on users, their activities, and the organization data they can access. The Microsoft Graph API brings a personalized context into the prompt, like information from a user's emails, chats, documents, and meetings

  Microsoft 365 Copilot enhances search relevance and accuracy by using advanced lexical and semantic understanding, resulting in more contextually precise information retrieval. Copilot preserves security, compliance, and privacy, ensuring organizational boundaries are respected while offering seamless user experience.

7.2 Artificial Models needs

Artificial Intelligence Models need to be trustworthy and reliable. To ensure that, at least 3 keys factors should be taken into account if AI-driven solutions are adopted:

- Training with large, high quality and relevant data sets.
- For learning purposes, the process of providing data to AI systems must be accurate and representative (data must represent both process successes and failures).
- Human-in-the-loop: To ensure the highest quality of training data the human must be active during the training and validation phase and must be able to interpret the information generated by AI.

Humans, and not machines, are ultimately responsible for assuring that high-quality drugs are available to patients.

7.3 Validation Strategy and Execution

7.3.1 AI Challenges for Model validation

Some of the challenges for AI use highlighted in [9]:

- Bias could be introduced in the process and carry doubt on the reliability of AI-driven results.
- The complexity of the methodology of development requires transparency.
- Interpretability, explainability and quantification of models' outputs may be difficult due to uncertainty of the accuracy of the models.

* Potential for the model's performance to change over time or across deployment environments when new data inputs are introduced and these inputs differ from the data on which the model was trained (i.e., data drift) requiring life cycle maintenance of these models

As just seen in 3.2.2 paragraph, one of the main concerns about the adoption of AI Tools relies on the difficulty to achieve trustworthy models.

To understand when the models stand for trustworthy and compliant with project execution, assuring at the same time the highest data security in compliance with GxP regulations, it is important to prior described the difference between qualification and validation highlighted in [26]: "Qualification provides the scientific evidence that the model functions appropriately within the Good Machine Learning Practice framework, while validation demonstrates that risks arising from the use of the model in a GXP environment are controlled according to its "intended performance".

In this sense the AI Models used should be verifiable during the validation phase to be reliable, easily interpretable, transparent (against hallucinations, overfitting, biases etc.), and trained through quality and representative learning processes. Data used to develop and train AI models should be relevant and representative (e.g., including key and sufficient data of the target patient population or the manufacturing process) and reliable (i.e., accurate, complete, and traceable).

The same authors provide another key concept on the matter:

> *"Demonstrating either of these requirements during regulatory inspection is tricky for AI/ML and likely must rely heavily on risk management. The burden will be on the company to demonstrate how the use of the model within the validated process does not add unnecessary risk to patient safety. Considering this burden, a black-box defense will likely not be tolerated, as it does not mitigate the potential for risks such as biases in model performance".*

The EMA Reflection Paper [7] highlights on purpose:

> *"To build trust in the effectiveness, reliability, and fairness of AI/ML tools, a human-centric approach should guide all development and deployment of AI and ML. This requires not only that active measures are taken during data collection and modelling but also that both user and patient reported outcome and experience measures are included in the evaluation of AI/ML tools when they interface with an individual user or patient".*

Note that the direct consequence of that is the need of an ongoing education of all parts involved in the process, from the development to the final user, on the evolving AI tools (this was another of the major concerns about adoption of AI solutions cited in 3.2.2 paragraph).

7.3.2 Suggestions to Overcome AI Challenges

To address the challenges of creating trustworthy models (and data), companies need to implement robust validation strategies at every stage of AI lifecycle – from data collection and training to model deployment.

7.3.2.1 Data and Models principles

Following the Assessment List for trustworthy AI [8], that aims to help with AI systems that are being developed, deployed, procured or used, the AI systems should adhere to some basic ethical principles for Trustworthy Artificial Intelligence (AI):

* Human Oversight: Human should be always at the center of the activity when dealing with AI systems in terms of outputs control and, when needed, intervention. Continuous monitoring to detect anomalies or deviations from expected behavior is a key factor in this context. A solution in these cases could be a re-training of the model.
* Technical Robustness and Safety: implement strong validation processes that use a preventative approach to risks, ensure models are based on reliable and quality data and that models are compliant with specific security standards (encryption, access control etc.).
* Privacy and Data Governance: ensure the data anonymization and respect for person's mental and physical integrity. Be aware if AI system follows GDPR measures about protection of sensitive information.
* Transparency: this concept includes important features that AI systems should always get. Among them, the traceability (a detailed and easily trackable documentation about all the changed made – e.g. version control, data input modifications etc.), explainability (ability to explain technical steps and rationales about decision or predictions made) and open communication about limitations of the system.
* Diversity, Non-discrimination and Fairness: promote inclusion and diversity to avoid both biases in models and discrimination against people in the use of the system.
* Societal and Environmental Well-being: carefully evaluate the effect of technology both on social and physical environment maintaining people well-being and ecological responsibility.
* Accountability: ensuring responsibility for development, deployment and/or use of AI systems through auditability and risk management.

7.3.2.2 Training the Workforce

For successful AI implementation, the workforce must be trained not only in how to use AI tools but also in how to interpret, validate, and trust these models.

Training Strategies for AI Workforce:

* Technical Training: Providing foundational knowledge in machine learning algorithms, data preprocessing, model validation techniques, and understanding the mathematical principles behind AI. This training ensures that people can develop, maintain, and improve AI models effectively.

* Ethics and Responsible AI: Equipping teams with knowledge about AI ethics, fairness, and bias mitigation is crucial. Training should emphasize the importance of ensuring that AI models are fair, transparent, and accountable, particularly in regulated fields like Healthcare and Pharma.
* Cross-disciplinary Collaboration (cross-industry): Encouraging collaboration between domain experts (e.g., medical professionals in healthcare AI projects) and AI specialists spreading innovation, leading to improved QA processes and outcomes and finally ensuring that models are developed with domain-specific knowledge in mind, increasing their relevance, trustworthiness, and interpretability.
* Continuous Learning: AI and machine learning evolve rapidly, so creating a culture of continuous learning is vital. This can include workshops, seminars, or online courses to keep the workforce updated on the latest developments in AI technology and validation techniques.

8. Conclusion

The integration of Artificial Intelligence (AI) into the pharmaceutical sector is reshaping traditional paradigms across the research, development, manufacturing, quality assurance, regulatory, pharmacovigilance, and patient care domains. AI technologies, spanning from machine learning to deep learning and generative AI, have demonstrated the potential to enhance operational efficiency, improve quality standards, accelerate regulatory processes, and ultimately, contribute to better patient safety and health outcomes.

Nevertheless, the adoption of AI also presents significant challenges, including the need for reliable data governance, data integrity, cybersecurity, ethical safeguards, continuous model validation, and alignment with evolving regulatory frameworks such as the EU AI Act, the EMA Reflection Paper, and FDA guidance documents. Addressing these challenges requires not only technological adaptation but also the strengthening of a human-centered approach to AI governance.

Within this evolving landscape, the industrial pharmacist plays a central and strategic role. Pharmacists are entrusted with ensuring that AI models are implemented in a way that maintains scientific robustness, regulatory compliance, transparency, and patient safety. Their expertise enables them to bridge the gap between technology and pharmaceutical practice, contributing to AI model validation, risk management, bias detection, and ethical oversight.

Moreover, industrial pharmacists are called to lead interdisciplinary collaborations, interpret AI-generated insights, and guide innovation with a focus on patient-centric outcomes. Their proactive engagement in the development, monitoring, and continuous improvement of AI applications will be fundamental to building trust in AI systems and safeguarding pharmaceutical standards.

In conclusion, AI represents a transformative opportunity for the pharmaceutical industry. Its successful integration will largely depend on the commitment and leadership of industrial pharmacists, who, through their competencies and ethical responsibility, will drive the evolution towards a more digital, efficient, and patient centric future.

9. References

Regulatory Authorities

1. Regulatory Science to 2025 - Strategic reflection (EMA, 2020) www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf
2. ISPE GAMP 5 second edition (2022) https://ispe.org/sites/default/files/publications/guidance-documents/2022-TOC/ISPE-GAMP5-Ed2_TOC.pdf
3. EU AI ACT (2024): https://artificialintelligenceact.eu/
4. GMLP guide from FDA (2021): www.fda.gov/media/153486/download
5. Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments. Federal Register. Published March 1, 2023. Accessed July 10, 2023. https://www.federalregister.gov/documents/2023/03/01/2023-04206/discussion-paper-artificial-intelligence-in-drug-manufacturing-notice-request-for-information-and
6. HMA-EMA multi-stakeholder workshop on Artificial Intelligence – enabling safe and responsible use of AI (November 2024) – Multiannual AI workplan 2023-2028 https://www.ema.europa.eu/en/documents/work-programme/multi-annual-artificial-intelligence-workplan-2023-2028-hma-ema-joint-big-data-steering-group_en.pdf
7. Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle (EMA) https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf
8. Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self-assessment https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment
9. Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products - Draft Guidance for Industry and Other Interested Parties https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological
10. Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations - Draft Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing

Artificial Intelligence Publications

11. Neural-network applications for analysis of adverse drug reactions https://pubmed.ncbi.nlm.nih.gov/8220635/
12. J. L. Painter et al., "Enhancing Drug Safety Documentation Search Capabilities with Large Language Models: A User-Centric Approach," 2023 International Conference on

Computational Science and Computational Intelligence (CSCI), Las Vegas, NV, USA, 2023, pp. 49-56, doi: 10.1109/CSCI62032.2023.00015. https://ieeexplore.ieee.org/document/10590353

13. Dong, Guojun et al. “Optimizing Signal Management in a Vaccine Adverse Event Reporting System: A Proof-of-Concept with COVID-19 Vaccines Using Signs, Symptoms, and Natural Language Processing.” Drug Safety 47 (2023): 173 - 182. https://www.semanticscholar.org/paper/Optimizing-Signal-Management-in-a-Vaccine-Adverse-A-Dong-Bate/6a8a6cb33404907abcce31e9b5ce7e9ff19e284c
14. Bridging the Gap in Drug Safety Data Analysis: Large Language Models for SQL Query Generation https://arxiv.org/abs/2406.10690v2
15. Assessing GPT-4 for cell type annotation in single-cell RNA-seq analysis https://www.nature.com/articles/s41592-024-02235-4
16. Evaluating eligibility criteria of oncology trials using real-world data and AI https://www.nature.com/articles/s41586-021-03430-5
17. Use of machine learning in prediction of granule particle size distribution and tablet tensile strength in commercial pharmaceutical manufacturing https://www.sciencedirect.com/science/article/abs/pii/S0378517321009522
18. genAI in medical affairs: use cases https://medicalaffairs.org/gen-ai-use-cases
19. Artificial Intelligence in Drug Manufacturing https://www.fda.gov/media/165743/download
20. https://www.scilife.io/blog/ai-pharma-innovation-challenges
21. https://www.xenonstack.com/blog/generative-ai-in-pharmaceutical
22. AI’s influence on pharma quality. How intelligence-driven solutions can refine pharma’s quality operations (13th December 2023) https://www.pharmamanufacturing.com/quality-risk/article/33016327/ais-influence-on-pharma-quality?o_eid=9392C4952823E0T&oly_enc_id=9392C4952823E0T&rdx.ident[pull]=omeda|9392C4952823E0T&utm_campaign=CPS240214008&utm_medium=email&utm_source=PHAR+Daily+Dose
23. Automation Downstream Controls Quality (Susan Haigney, August 21st, 2024) https://www.biopharminternational.com/view/automation-downstream-controls-quality
24. Breaking down pharma compliance barriers (March 7, 2024) https://www.pharmamanufacturing.com/compliance/article/33038217/breaking-down-pharma-compliance-barriers
25. Preparing A Framework for Artificial Intelligence and Machine Learning Validation: A 3-Step Approach (July 20th, 2023) https://www.pharmaceuticalonline.com/doc/preparing-a-framework-for-artificial-intelligence-and-machine-learning-validation-a-step-approach-0001
26. Revitalizing Quality Management Processes through Digitalization (December 2, 2023) https://www.pharmtech.com/view/revitalizing-quality-management-processes-through-digitalization

27. Automated bioprocessing – 7 advantages of automation (April 2023) https://www.susupport.com/knowledge/single-use-technology/automated-bioprocessing-advantages-automation
28. Mirasol, F. Evaluating the Use of Continuous Chromatography. BioPharm International 2024, 37 (6) 21- 22 https://www.biopharminternational.com/view/evaluating-the-use-of-continuous-chromatography
29. Markarian, J. Streamlining Downstream Processes. BioPharm International 36 (8) 2023 19-21 https://www.biopharminternational.com/view/streamlining-downstream-processes
30. Fisher, A. The Future is the Present: Artificial Intelligence in Pharmaceutical Manufacturing. Pharmaceutical Technology 2023 47 https://www.pharmtech.com/view/the-future-is-the-present-artificial-intelligence-in-pharmaceutical-manufacturing

From EIPG

31. Pharmacist 5.0 – Evolving with Artificial Intelligence drivers in the Biopharma industry (David O' Grady, EIPG Webinar - November 2024)

Others

32. Webinar "AI nell'health care: Aspetti normativi e buone pratiche" (December 2024)

Appendix: Use Cases & Fields of Application

Pharmaceutical sector can benefit of Artificial Intelligence within Pre-clinical and R&D, Clinical, Regulatory, Manufacturing (Development, Maintenance, Production, Quality Assurance, Quality Control, Logistic and Supply chain) and Pharmacovigilance fields. Between them, of more interest from pharmacists' point of view seems to be Clinical, Regulatory, Manufacturing applications. For each one of them, a list of use cases will be detailed in the next paragraphs.

Note: The reported use cases have been retrieved both from a subset of cases in Pharma 4.0 baseline guide, other ISPE pharma publications and experiences of team EIPG-ISPE. In particular, from Pharma 4.0 guide, only the use cases that involve AI applications have been selected.

Clinical Use Cases

I. Streamline Eligibility in Clinical Trials

Overview:

* Company Type: Undefined
* Company name: Anonymous
* Focus Areas: Clinical
* AI Method: AI-Trial Pathfinder

Description:

A framework named Trial Pathfinder is developed to integrate cancer real-world data and systematically analyze the hazard ratio of the overall survival for cohorts that are defined by different eligibility criteria (patient characteristics, diagnoses, laboratory values, biomarkers, previous treatments), relaxing them.

This tool has demonstrated to allow more inclusive clinical trials substantially increasing patients enrolled (53% more people can potentially benefit treatments), while achieving a lower hazard ratio of the overall survival (decrease of 0.13 with respect to the original trial criteria).

Benefits:

* Efficiency increase: Streamlined candidate selection.
* Quality increase: Track of real-time data, design of adaptive and more inclusive trial protocols by relaxing eligibility criteria

Regulatory Use Cases

II. Regulatory Intelligence Assistant

Overview:

- Company Type: Agrochemical
- Company name: Anonymous
- Focus Areas: Regulatory
- AI Method: NLP

Description:

A Regulatory intelligence tracking system is created to monitor changes in guidelines and regulations avoiding manual processes through:

- An NLP model, used to develop a workflow for semi-automate information acquisition and summaries.
- A regulatory intelligence assistant, that provides user-friendly question-and-answer access to updated regulatory information, safety alerts and risk categorization for compounds of interest

Benefits:

- Time saving: Lower manual workloads in less time and with less errors.
- Compliance Increase: Ensured that compounds are always up to regulatory standards supporting regulatory compliance in an ever-changing landscape

III. Smart Regulatory Compliance Management

Overview:

- Company Type: Pharmaceutical
- Company name: Anonymous
- Focus Areas: Regulatory/Quality Assurance
- AI Method: NLP

Description:

An automatically updating data lake has been created to collect:

- External feeds: FDA warning letters, biological license application review reports, white papers and industry benchmark repositories.
- Internal feeds: deviations, corrective and preventative actions, risks and response to regulatory questions.

An NLP model is used to extract critical concepts, capture risk management information and optimize formulations, commercial supply and post-market regulatory compliance of products. User-friendly visualizations within the platform allow to navigate the information and recommendations to act upon.

Benefits:

- Time saving: Lower manual workloads in less time and with less errors.
- Quality Increase: Accurate identification of anomalies in compliance processes.
- Compliance Increase: Ensured adherence to GMP standards and regulations and reduced risk of failed inspections.

Manufacturing Use Cases

IV. Process development optimization with Digital Twin

Overview:

- Company Type: Small Pharmaceutical Company & Medium Solid CMO
- Company name: Anonymous
- Focus Areas: Manufacturing/Development
- AI Method: Digital twin with ML

Description:

A digital twin has been developed for a continuous direct compression line for solid drug product and process design. It embeds:

- Residence time distribution (RTD) models obtained from discrete element method (DEM) simulations.
- ML data-driven models obtained from process data in flowsheet.
- The MLs capture changes in mechanical properties of the material, as a function of process variables and material properties, then predicting critical process parameters, blender, and tablet press, and critical quality attributes - like tablet composition, embeds, and hardness.

The digital twin allows the study of the steady state operation in the design space, the impact of operating conditions, material and process parameters, and the dynamic response to disturbances.

This is used to de-risk and optimize drug product and process development while reducing the number of experiments.

Benefits:

- Quality Increase: Early project de-risking.
- Efficiency Increase: Reduction in the use of manufacturing equipment, rework and quality investigations.
- Productivity Increase: Optimization of process development guided by Digital Twin.
- Compliance Increase: Guidance in the response to new drug product market approval queries using flowsheet modelling.

V. AI-Assisted Predictive Calibration/maintenance of Cleanroom Monitoring Sensors

Overview:

- Company Type: Big/Global Pharmaceutical Company, Biotech
- Company name: Anonymous Pharma
- Focus Areas: Manufacturing/Maintenance
- AI Method: Neural Network

Description:

AI-assisted predictive calibration based on an IoT platform receives the respective sensor data of the cleanroom monitoring systems from a global data historian platform. The AI model (Neural Network), integrated within the platform, constantly analyzes the sensor behavior data (status/health), predicts sensor drifts and gross failures and triggers a notification to the ERP system in order to initiate a work order for re-calibration or replacement of the respective sensor. Augmented Reality (AR) supports pathfinding and maintenance operations.

Benefits:

- Time Saving: Only calibrate when needed. Changing the calibration strategy from Periodic Maintenance to Condition Based Maintenance and allow to recalibrate the instruments only when their performance has degraded.
- Cost Saving: Less resource needs due to minimized calibration-related effort.
- Efficiency Increase: AR-guided path finding to sensor location and calibration procedure.
- Productivity Increase: Less down time due to minimized calibration effort and less deviation management due to uncalibrated sensors.
- Compliance Increase: Minimizing number of uncalibrated sensors, less deviations.
- Confidence Increase: Add more confidence in the actual recorded parameter values by early failure prediction.

VI. Automated Line Clearance with Image Recognition/ML/AR

Overview:

- Company Type: Big/Global Pharmaceutical Company, Solid/Sterile
- Company name: Anonymous (among big five pharmaceutical companies in Switzerland)
- Focus Areas: Manufacturing/Quality Assurance/Production
- AI Method: ML

Description:

A GxP-compliant platform is implemented to streamline some line clearance processes. It includes different functions:

- Object detection of pre-defined items at defined key points (camera positions) through AI models trained and validated over data collected (around 50-100 pictures per object). The system has high tolerance due to different perspectives, changing light conditions and backgrounds, and moving machine parts.
- Operator double-checks based on images with marked objects to enable manual interventions by operators, if necessary.
- Report for line clearance and communication of results to MES (if available).

During execution of line clearance processes, the automated line clearance can be extended with AR to guide the operator to the right position of the room to perform manual checks.

Benefits:

- Time saving: Reduced time-consuming checks from operators.
- Quality increase: Improved quality in line clearance due to reduced human errors.
- Efficiency Increase: Faster line clearance through simultaneous checks of multiple positions, particularly in "difficult" and critical areas.
- Productivity Increase: Process optimization with a focus on rectifying deviations and faults.

VII. Manufacturing Deviations Analysis with NLP

Overview:

- Company Type: Big/Global Pharmaceutical Company, Life Science, Electronics
- Company name: Merck Group
- Focus Areas: Manufacturing/Quality Assurance
- AI Method: NLP

Description:

An NLP-based solution was designed, developed and trained to create a language model, represent text as semantic vectors, find semantic textual similarities and find clusters of similar/recurrent deviations.

The solution is also equipped with search engine, dashboarding, analytics and reporting tools that help quality management teams executing analyses, making tactical decisions and define efficient RCI and CAPAs, overcoming difficulties in finding pattern into the high-volume unstructured data available.

NLP algorithms were re-trained and re-deployed each quarter to ensure language diversity is efficiently covered.

Benefits:

- Time saving: Significant reduction in time and effort for manual reading and understanding deviations, RCIs, CAPAs.
- Productivity Increase: Machine-assisted decision support for tagging the deviations at early stages to trigger appropriate RCI.
- Transformational: New "digital" culture that allows collaboration and transparency into deviation management processes.

VIII. COINs, Complaints Intake Support Chat Bot

Overview:

- Company Type: Big/Global Pharmaceutical Company, Biopharmaceutical
- Company name: Anonymous
- Focus Areas: Manufacturing/Quality Assurance/Regulatory
- AI Method: NLP, ML, OCR

Description:

An AI chatbot solution, based on a cloud SaaS infrastructure, has been developed to help affiliates responsible for compliant intake simplifying, searching and highlighting information and keywords in documents, classifying complaints, translating text, optimizing research. In particular, it is equipped with:

- Optical Character Recognition (OCR) to convert images or PDFs into readable text.

- NLP to elicit keywords from each page of the document, cluster them as topic on pages and perform efficient search.
- ML model trained to support the question and response for small talk with users.

Higher user satisfaction is registered due to the simplified platform compared to standard document management system.

Benefits:

- Time saving: Half time needed for document review with improved accuracy.
- Productivity increase: Slicing down complex documents to only relevant information and keywords.
- Efficiency increase: Less manual work to retrieve information from SOP documents
- Transformation: Ease of scale (one central and reliable platform for all users) and new digital culture of the team.

IX. Using ML and Trending to Detect Data Integrity Issues

Overview:

- Company Type: Big/Global Pharmaceutical Company, Biopharmaceutical
- Company name: Anonymous
- Focus Areas: Manufacturing/Quality Assurance/Quality Control
- AI Method: ML

Description:

Machine Learning and trending analysis are used to sift through large volumes of data (Audit Trails on Lab Instruments) to detect potential data integrity issues during review.

Business rules have been set initially to search for known DI issues, then ML algorithms have been used to make deeper cluster analysis and outlier detection on documents to identify potential new business rules.

Benefits:

- Time Saving: Automated search means the reviewers no longer need to spend the time doing a manual search of the data to find the potential DI issues.
- Efficiency Increase: Reviewers will spend their time reviewing the impact of the issues found by the ML rather than manually finding the issues.
- Quality and Compliance Increase: ML analysis can detect new and potential issues. Additionally, with automation, the rate of data analysis could be increased to a point that would be efficient for a human to do it, such as testing monthly instead of yearly.
- Transformation: Transition from manual to fully digital search, leveraging the use of ML.

X. AI-driven Predictive Quality Control

Overview:

- Company Type: Small Pharmaceutical Company & Medium Solid CMO
- Company name: Anonymous
- Focus Areas: Manufacturing/Quality Control
- AI Method: ML

Description:

A pharmaceutical QC lab implemented an AI-powered predictive analytics system to monitor dissolution test results across multiple stability studies. The AI detected a slow decline in dissolution rates over six months, correlating it with variations in tablet compression force and aging effects.

By identifying the trend early, the lab took preventive measures to adjust manufacturing parameters before an OOS failure occurred during routine stability testing.

This AI-driven approach streamlined the PQR process, ensuring regulatory compliance and reducing deviations.

Benefits:

- Efficiency Increase: Trend analysis automation and manual data review reduction in PQR reporting.
- Compliance Increase: Improved CPV compliance ensuring continuous process verification with AI.
- Time saving: Reduced lab investigation with early detection and prevention of OOT/OOS.

XI. Inventory Optimization and Predictions

Overview:

- Company Type: Undefined
- Company name: Anonymous
- Focus Areas: Manufacturing/Logistic and Supply Chain
- AI Method: ML

Description:

Some market ERP use Machine Learning to analyze past sales, seasonal trends and patterns, and other factors to predict demand and future material needs, allowing effective stock management. These forecasts are used to maintain optimal stock levels, avoiding overstocking or stockouts and ensuring availability for patients.

Benefits:

* Efficiency increase: Streamlined inventory control, supply needs anticipation and adequate stock levels assurance.
* Productivity increase: Uninterrupted supply of raw materials for production.
* Quality increase: Improved planning of drug rotation, reduced risk of ineffective medications on the market, prediction of shelf life and efficacy of pharmaceutical products.