Navigating the Modern Challenges of Implementing and Validating Computerized Systems in Pharma 4.0

Mitja Cerovšek, Kristian Peklaj

Abstract:

The validation of computerized systems in the pharmaceutical industry is increasingly complex due to the rapid advancement of digital technologies. Ensuring compliance with Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and data integrity (DI) standards requires structured documentation and adherence to regulatory guidelines, such as GAMP 5. This study explores the leveraging method to optimize validation efforts, reduce redundant testing, and streamline compliance. It also examines the impact of modern technologies, including artificial intelligence (AI), machine learning (ML), blockchain, and cloud computing, on validation processes. The findings highlight both the challenges and opportunities these technologies present in enhancing efficiency, automation, and data security within Pharma 4.0. Ultimately, the research underscores the need for structured, traceable documentation and risk-based approaches to ensure regulatory compliance in an evolving digital landscape.

Keywords:
Computerized system validation, pharmaceutical industry, GAMP 5, data integrity, regulatory compliance, AI, machine learning, blockchain, cloud computing, Pharma 4.0.

1 Introduction

Computerised systems are considered complex equipment for a reason, as systems have become really powerful in recent years and offer endless possibilities for use, analysis, data collection, and reporting of results. These endless possibilities of use also mean endless possible errors to occur. Due to the difficulty and complexity of today's computerized systems, their validation is a tough challenge. This study explores whether the validation process for modern computerized systems in the pharmaceutical industry can be enhanced to ensure compliance with GMP, GLP and DI standards while addressing the challenges posed by modern technologies. The purpose of this research is to present the validation documentation required for establishing a new laboratory computerized system in accordance with the GAMP 5 guidelines. The research focuses on the leveraging method, which allows utilizing existing, verified data (e.g., supplier documentation, system specifications) to streamline the validation process, especially for components that have been previously qualified. The study emphasizes the importance of supplier assessment to ensure that the supplier meets the necessary requirements for DI and quality management. It also explores various documents necessary for validation, such as User Requirements Specifications (URS), risk assessments, system specifications, and Qualification Plan (QP). Additionally, the research highlights the significance of structured, traceable documentation, such as the Traceability Matrix (TM), to ensure proper alignment of requirements, specifications, and testing. We considered the potential impact of modern technologies, such as AI, on computerized system validation and regulatory compliance, ensuring alignment with evolving industry standards.

Dr. Mitja Cerovšek, univ. dipl. inž., Iskra PIO, d. o. o., Šentjernej, **Kristian Peklaj**, mag. inž., Novartis, d. o. o., Ljubljana

2 Theoretical foundations

The most important requirements that are mandated by the regulation and must be considered in every project involving the implementation of a new computerized system have been extracted.

Taking into account good practices from the GAMP 5 and ALCOA++ guidelines, possible simplifications and improvements of the validation process were presented to the reader. Due to the complexity of these systems, the leveraging method is applied, using the supplier's technical specifications and test documentation.

Industry 4.0, which enables real-time process monitoring, digital technologies such as ML and Process Analytical Technologies (PAT) is increasing systems complexity, thereby heightening the risks of ensuring proper data integrity. The GAMP 5 and ISA-95 guidelines mitigate the potential risks of modern technologies by standardizing data management [1].

The implementation of the computerized system must be carried out in accordance with the legislation and pharmacopoeias that must be followed in order to produce pharmaceutical products. Using the compilation method, the literature on the requirements of European legislation, the European and American Pharmacopoeia, and relevant guidelines was reviewed. From the obtained information, it was determined whether adherence to the guidelines meets the regulatory requirements. Directive 2004/10/EC ensures the harmonization of GLP regulations for non-clinical safety testing, emphasizing the need for validated computerized systems for data handling and system maintenance. EudraLex Volume 4, which includes GMP guidelines, outlines requirements for computerized systems, equipment, documentation, and qualification to maintain compliance [2]. The European Pharmacopoeia (Ph. Eur.) does not provide specific regulations on computerized systems or their validation but directs researchers to EDQM regulatory guidelines. These guidelines include the "Qualification of Equipment - Basic Document," which outlines requirements for testing and calibration laboratories, and details the validation process for computerized systems based on their complexity. Validation includes stages such as Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), with ongoing inspections, security measures, and user training, ensuring the systems meet requirements, are protected from risks, and maintain data integrity [3].

At the same time, innovative approaches in the guidelines were explored that could optimize the complex validation of computerized systems. To validate modern systems such as cloud computing, ML, AI, and blockchain, it is essential to thoroughly understand these technologies, their unique characteristics, and the regulatory challenges they present in the context of pharmaceutical compliance.

In conclusion, the study provides a comprehensive overview of the essential documentation and processes required for the successful validation of computerized systems in the pharmaceutical industry. It underscores the importance of structured documentation, clear communication between stakeholders, and adherence to regulatory guidelines to ensure the system's functionality, compliance, and DI.

3 Methods

We conducted an analysis of journals focusing on modern technologies, such as cloud computing, machine learning, artificial intelligence, blockchain, and their validation within the pharmaceutical industry. The objective was to identify and highlight potential challenges associated with the implementation and validation of computerized systems in this highly regulated sector. The review emphasized issues related to data integrity, regulatory compliance, and the dynamic nature of these technologies, which often require innovative validation approaches. By exposing these challenges, the analysis provides insights into the complexities of adopting advanced digital systems while ensuring they meet stringent industry standards and regulatory expectations.

This study highlight the validation documentation necessary for the establishment of a new computerized system in the pharmaceutical industry. Through an analysis of the GAMP 5 guidelines, the study identified the frequent use of the leveraging method, which allows the reuse of already verified information or systems to streamline the validation process. For instance, if an identical system, such as a balance, has already been qualified, the results from the previous system can be applied to the new installation, reducing the need for additional testing. In cases where the leveraging method is used, certain tests, like OQ, can be skipped, and only IQ and PQ tests may be performed. The study found the leveraging method particularly useful when relying on test documentation provided by system suppliers. By leveraging the manufacturer's test documentation, system specifications, and configuration specifications, the validation process is more efficient. However, all supplier qualification documentation must be pre-approved by the customer. One critical component of qualification documentation is the TM, which clearly links the URS to the test specifications. It is recommended that the TM is prepared by the author of the test documentation to ensure accuracy and clarity.

GAMP 5 outlines best practices for managing computerized systems through four key phases: concept, project, operation, and retirement. At implementation of a new computerised system we focus on first two phases. In the concept phase, companies evaluate automation opportunities and decide on system implementation strategy. The project

phase covers planning, defining technical specifications, configuring the system, and preparing test documentation, leading to validation and approval for use. It emphasizes that validation documentation must be structured and logically connected. The validation process for computerized systems requires a variety of documents—such as the IRA, Functional Risk Assessment (FRA), URS, QP, IQ, OQ, PQ, and qualification Report (QR), which must be interrelated throughout the project. Consistent document structure and thoughtful naming conventions are essential for traceability and efficient management of changes or updates. This organizational approach helps ensure proper oversight and facilitates faster access to necessary documentation. GAMP guidelines elaborates on several key documents involved in computerized system validation:

1. User Requirements Specification: URS document outlines the requirements set by the user for the equipment, covering general, functional, design, safety, automation, DI, and regulatory requirements. These requirements must be clear, testable, and relevant to ensuring the system's functionality and compliance with regulatory standards [4].
2. Supplier Assessment: Prior to purchasing equipment, the supplier's ability to meet the specified requirements is evaluated. Different levels of supplier assessments are performed based on the criticality of the system, ranging from baseline assessments to audits at the supplier's location [4].
3. Initial Risk Assessment: The IRA is conducted before qualification activities to assess the risks associated with the system, including its impact on patient health, product quality, and DI. The IRA helps determine the appropriate GAMP 5 category and the necessary qualification approach.
4. System Specifications: Once a system is selected, the manufacturer provides detailed system specifications, including Configuration Specification (CS), Functional Specification (FS), Hardware Design Specification (HDS), and Software Design Specification (SDS). These documents describe in detail the structure and functionalities of the selected system.
5. Functional Risk Assessment: Because IRA does not fully assess certain risks, a more detailed FRA is performed. This assessment focuses on critical requirements related to DI, quality and patient health, using methods like Failure Modes and Effects Analysis (FMEA) to mitigate potential risks [4].
6. Qualification Plan: The QP outlines the strategic plan for validating the system, including the necessary activities for each phase of the implementation process. It provides a roadmap for ensuring that all validation steps are completed in accordance with regulatory guidelines. Figure 1, shows the architecture of the documentation for the project phase leading up to the start of using the computerized system. The QP document can be prepared by either the supplier or the customer.
7. Installation Qualification: IQ tests verify that the system is installed and functioning correctly. This includes testing system components, access rights, and integration with other systems [5]. Automated testing methods can be used as long as they ensure DI [4].
8. Operational Qualification: OQ tests ensure that the system's key functions are operating as expected. Calibration tests and operation func-

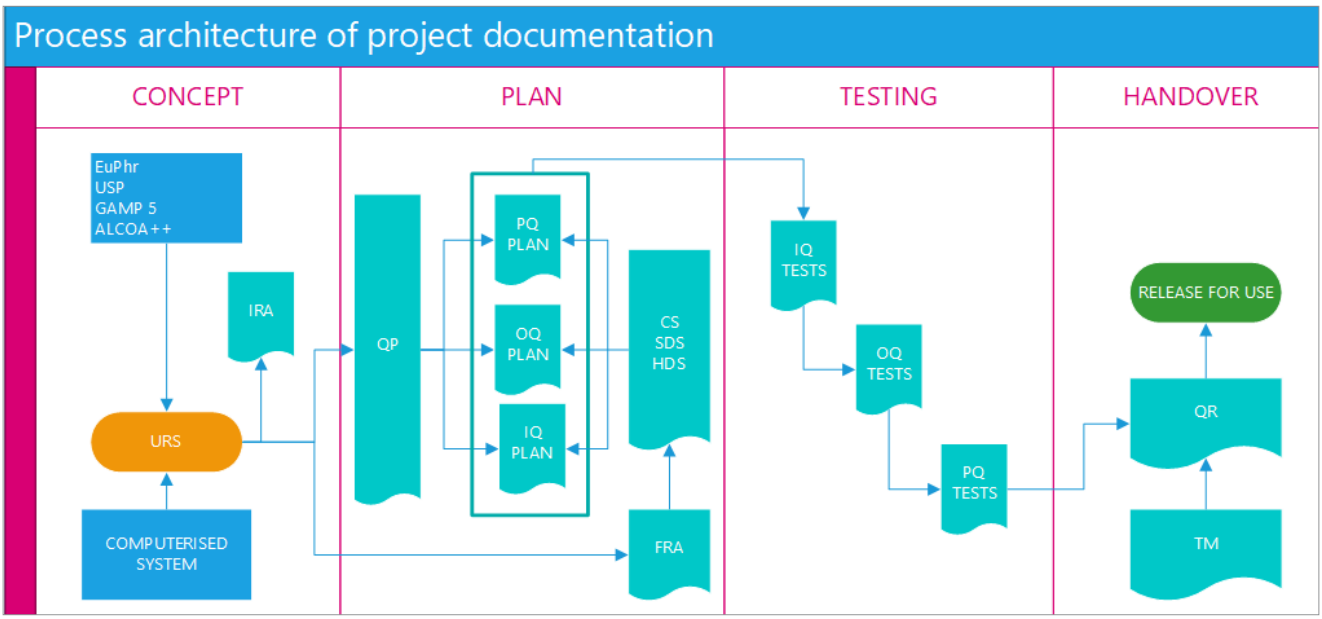

Figure 1 : *Process architecture of project documentation*

tionalities tests are performed to confirm the system's readiness for operational use [3].
9. Performance Qualification: PQ confirms that the system meets the user's requirements in its intended environment. It involves testing the system under real-life conditions, and any deviations must be documented and addressed [5]. With PQ testing we confirm that the system is suitable for performance of the desired process.
10. Traceability Matrix: The TM ensures the traceability of all requirements through the validation process. It links each requirement in the URS to the corresponding system specification and test case, providing a comprehensive overview of coverage [4].
11. Qualification Report: The QR summarizes the results of the validation process, including any deviations found during testing. Once all deviations are resolved, the system is deemed qualified and ready for use [5].

4 Results

Through a review of legislation, pharmacopoeias, and relevant guidelines, we identified the necessary steps and documentation for introducing a computerized system into a pharmaceutical laboratory. Following GAMP 5 guidelines, we explored potential simplifications of the validation process while ensuring compliance with regulatory standards. Our analysis revealed that European and US regulations, such as Annex 11 in EudraLex and 21 CFR Part 11, mandate comprehensive validation for computerized systems in both GLP and GMP environments. While neither regulatory framework differentiates laboratory and production systems in terms of validation requirements, the criticality of URS and FRA varies. GMP systems demand heightened scrutiny due to their potential direct impact on patient health, requiring more extensive testing and procedural adjustments to ensure system security.

Although necessary, the validation process is complex and time-consuming. Leveraging best practices outlined in GAMP 5 can streamline efforts. Innovations such as merging IQ and OQ phases into a single IOQ phase, incorporating random testing for broader coverage, and applying leveraging methods to minimize requalification testing are proposed to optimize the process. Additionally, AI offers opportunities to simplify workflows, enhance efficiency, and improve test coverage.

During our research, we observed that modern technologies, including AI, ML, and advanced analytics, not only present challenges for validation but also hold immense potential to assist in the process. These technologies can automate key validation aspects, such as documentation, test execution, and real-time system monitoring. AI and ML can enhance test coverage by identifying critical areas requiring validation, ensuring a more comprehensive approach. Automated tools further address complexity by reducing manual effort, minimizing errors, and providing actionable insights. This dual role of modern technologies, both a challenge and a solution-underscores their transformative potential in achieving efficient and compliant validation processes. The GAMP 5 guidelines often direct the simplification of processes using the leveraging method. Of course, when using this approach, the risks to which the pharmaceutical company could be exposed must be assessed. Through the study, the usefulness of the tactic is recognized, especially in transferring the responsibility of creating project documents and test specifications, which can be transferred to the supplier, instead of writing them internally. Combining IQ and OQ documents into IOQ is part of the leveraging method [4]. In practice, we already use the leveraging method when validating identical systems or identical families of systems. Thus, upon implementation, full validation is performed only for the first system (e.g. IQ, OQ, PQ), and for all subsequent ones, only IQ and a small part of PQ are performed. The method of leveraging can go even further. We could also use a supplier evaluation that was already made by another company, if of course that company was willing to share this information with us and we have a similar approach for evaluating suppliers. When using the leveraging method, we are concerned about the confidentiality of the information of the pharmaceutical industry. It is this secrecy that largely prevents cooperation between these companies and the sharing of good practices.

In the case of Slovenian pharmaceutical companies, from the point of view of the method of leveraging, the cooperation of Novartis and Sandoz could be very welcome, because until recently, these two companies had the same quality assurance system. At the same time, the companies are not competitive in terms of the portfolio of products they produce [6].

4.1 Modern challenges

The GAMP 5 guidelines have recently been revised because of the emergence of new technologies, such as AI, ML, chaining of data blocks (Blockchain), open source software, cloud computing [4]. The latter clearly indicates an increase in the use of the aforementioned technologies and their inclusion in the concept of Pharma 4.0. The purpose of Pharma 4.0, like Industry 4.0, is to improve efficiency and ensure a higher level of quality through the use of digital technologies and automation.

Digital maturity and DI design enable an effective digitization strategy and are supported by well-managed automated and information systems. GAMP 5 guidelines aim to ensure that GxP com-

puterised systems are fit for their intended use and that GxP electronic records and data are properly managed throughout the data lifecycle to ensure DI [4]. In the future the use of blockchain technology could improve efficiency, transparency and data security in the pharmaceutical industry [7]. Its inherent immutability ensures that once data is recorded, it cannot be altered or deleted, thereby safeguarding against unauthorized modifications and preserving data integrity. This feature is particularly beneficial in clinical trials and regulatory submissions, where tamper-proof records are essential [8].

With the help of AI and ML, the processes currently carried out by operators in the laboratory could be simplified and even improved [9]. Modern technologies can enhance the detection and prediction of malfunctions or trends before they occur. AI, for example, could operate continuously and compare data over time, unlike human operators who perform tasks less frequently. This would save operator time and improve efficiency. However, the challenge lies in developing complex algorithms and validating the system to ensure consistent performance throughout its lifecycle. AI and ML systems evolve over time, which may conflict with regulatory requirements for controlled changes and revalidation. A potential solution is allowing the system to learn, but having a system administrator implement changes through a controlled protocol, followed by partial validation. Over time, this process would help the system evolve, but each update requires a team for implementation and validation.

Zestful testing of the software is the main part of the computer system validation [10]. The new version of GAMP 5 describes and recommends the use of random testing as a new testing technique, which should lead to a higher level of testing scope, greater detection of possible malfunctions and, consequently, a higher level of system reliability. From a practical point of view, with computerised systems, all processes are very clearly defined in the instructions for the use of computerised system, which the company prescribes and which, as a regulatory requirement, must be adhered to without deviations. If the operator does not act in accordance with the work instructions, he breaks the rules and thus performs the analysis inconsistently with the procedure, which means that the result of analysis is not adequate. We describe this because the scenario of using the instrument is already very clear and defined in advance. Moreover, the analysis flow process is validated and should not be performed differently than defined in the work instructions. This process is fully tested as part of the PQ phase, so the usefulness of random testing is questionable. We also consider whether the time we will spend on random testing is justified, given that the entire analysis process is very rigid and regulated. We can see the sense in using automated random testing. However, when we automate something, it becomes prescribed and is no longer random. Random testing is thus only applicable in combination with AI and ML, which could lead to truly random situations.

Cloud validation plays a transformative role in pharmaceutical manufacturing, balancing compliance challenges with strategic benefits. While cloud technologies offer scalability, cost-efficiency, and real-time collaboration, they introduce unique validation complexities, particularly in regulated environments. Frameworks such as FDA's 21 CFR Part 11 and EMA's Annex 11 demand rigorous system validation, audit trails, and quality assurance, which are complicated by shared responsibilities, data sovereignty, and vendor dependencies inherent to cloud systems. A risk-based validation approach ensures that critical components impacting product quality and patient safety receive priority, leveraging modern techniques like automated testing and continuous validation. Beyond compliance, cloud validation enhances operational agility, fosters innovation, and supports global standardization, empowering pharmaceutical companies to adapt to diverse regulatory environments and remain competitive in an evolving digital healthcare landscape [11].

Maintaining DI is essential in pharmaceutical manufacturing to ensure product quality, safety, and regulatory compliance. The transition to Industry 4.0, with its focus on automation, smart manufacturing, and advanced analytics, has added complexity to DI management. Adherence to principles like ALCOA++ ensures compliance and minimizes regulatory risks, while robust validation protocols, regular audits, and a shift to electronic systems mitigate challenges posed by complex computerized systems. Industry 4.0 technologies, such as ML, multivariate data analysis, and cloud-based platforms, enhance efficiency but require strong cybersecurity measures. Future strategies include adopting blockchain for secure and transparent data management, improving traceability with independent logins, and leveraging advanced electronic systems. Ensuring DI not only supports regulatory compliance but also drives innovation and efficiency in an increasingly automated pharmaceutical landscape [1].

Technical Debt (TD) in automated production systems arises when interdisciplinary engineering decisions prioritize short-term benefits at the expense of long-term risks. Validation processes under frameworks like GAMP 5 are critical for ensuring safety and compliance, but they also present challenges associated with validation-related TD. Using a systematic meta-analysis approach, the study analysed engineering documents to identify and classify TD. 25 new sub-types were identified including Documentation TD, Risk Assessment TD,

and Manufacturing TD, which are common areas in pharma industry. Practical use cases and expert validation highlight the importance of addressing TD to enhance operational efficiency, ensure compliance, and improve lifecycle management [12].

To meet diverse internal and global requirements, pharmaceutical companies today must address the following eight key challenge areas in the validation of computerized systems: (1) Standards, (2) Interpretation, (3) Organization and Governance, (4) Efficiency Across Sites and Departments, (5) Execution, (6) Tools, (7) Training and (8) Personnel [13]. Validation must be based on risk identification. Such an approach, however, requires a thorough understanding of the system's functions, its position in manufacturing, and the potential repercussions of system failures or data integrity breaches. Companies can improve validation efficiency without sacrificing quality or compliance by concentrating on system criticality [14].

5 Conclusion

A previous study [15] found that the implementation of computerized systems in the pharmaceutical industry must ensure compliance with regulatory requirements, a high level of data integrity, and product quality. The present study confirms these results and adds new findings and recommendations. In conclusion, validating computerized systems in the pharmaceutical industry demands structured documentation, adherence to regulatory guidelines, and clear communication to ensure functionality, compliance, and data integrity. Regulatory frameworks such as GAMP 5, Annex 11, and 21 CFR Part 11 provide the foundation for comprehensive validation processes in both GLP and GMP environments. The process is complex, requiring robust validation documentation like TM and QP to ensure traceability and change management. Key elements, such as leveraging methods and risk assessments (e.g., IRA and FRA), help streamline validation efforts by reusing validated data and focusing on system criticality, especially for systems impacting patient health. Modern technologies, offer substantial potential to automate and enhance key validation tasks, from qualification documentation to test execution, improving efficiency, and accuracy. The use of leveraging methods can further optimize validation by reducing testing efforts for similar systems, provided risks are carefully assessed and confidentiality concerns are addressed. However, confidentiality of pharmaceutical documentation remains a significant obstacle, particularly when sharing good practices between companies. The pharmaceutical industry's reliance on secrecy limits opportunities for cooperation, which could be alleviated by companies like Novartis and Sandoz, given their similar quality assurance systems. Ultimately, while validation remains a complex and time-consuming task, strategies like leveraging, simplification, and the integration of modern technologies hold the key to achieving efficient, compliant, and innovative validation processes in the pharmaceutical industry.

The ongoing evolution of pharmaceutical manufacturing is heavily influenced by advanced technologies, such as AI, ML, blockchain, and cloud computing, as outlined in the revised GAMP 5 guidelines. These innovations support greater efficiency, quality, and automation, while also introducing challenges in validation, regulatory compliance, and data integrity management. The integration of these technologies within the Pharma 4.0 framework requires robust systems to manage GxP computerized systems and electronic records effectively. Maintaining DI is critical for ensuring product safety and regulatory compliance in the face of complex systems and the transition to Industry 4.0. Moreover, addressing TD in automated systems is vital for long-term operational efficiency and compliance. By prioritizing critical components and leveraging modern validation techniques like automated testing and continuous validation, pharmaceutical companies can navigate regulatory complexities, foster innovation, and drive sustainable growth in a rapidly evolving digital pharmaceutical landscape.

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Sodobni izzivi implementacije in validacije računalniških sistemov v farmaciji 4.0

Povzetek:
Validacija računalniških sistemov v farmacevtski industriji je zapleten in zahteven proces predvsem zaradi naraščajoče kompleksnosti sistemov in strogih regulativnih zahtev. Zagotavljanje skladnosti z dobrimi proizvodnimi praksami (GMP), dobrimi laboratorijskimi praksami (GLP) in zahtevanimi visokimi standardi zagotavljanja integritete podatkov (DI) zahteva strukturiran in učinkovit pristop. Ta študija preučuje strategije za optimizacijo validacijskih procesov z metodo uporabe obstoječih preverjenih podatkov v skladu s smernicami GAMP 5. Poseben poudarek je namenjen ključni dokumentaciji, potrebni za implementacijo sodobnega računalniškega sistema. Poleg tega študija pri oblikovanju prihodnosti implementacije in validacije računalniških sistemov raziskuje vlogo nastajajočih modernih tehnologij, kot so umetna inteligenca (AI), strojno učenje (ML), veriženje blokov (blockchain) in računalništvo v oblaku. Čeprav te tehnologije prinašajo nove izzive, hkrati ponujajo pomembne priložnosti za izboljšanje učinkovitosti delovnih procesov, avtomatizacijo testiranja in povišano stopnjo regulatorne skladnosti. Ugotovitve poudarjajo prednosti strukturiranih validacijskih pristopov, ocenjevanja dobaviteljev in učinkovitega upravljanja dokumentacije pri poenostavljanju validacijskih postopkov brez ogrožanja zagotavljanja kakovosti. Študija izpostavlja potrebo po uravnoteženem pristopu, ki združuje inovacije in regulatorno skladnost, s čimer podpira preobrazbo farmacevtske industrije v dobi farmacije 4.0.

Ključne besede:
Validacija računalniških sistemov, farmacevtska industrija, GAMP 5, metoda izkoriščanja, regulativna skladnost, integriteta podatkov, umetna inteligenca, strojno učenje, veriženje blokov, računalništvo v oblaku, farmacija 4.0