# Validating Enterprise Resource Planning (ERP) Systems in the Pharmaceutical Industry: A Literature Review

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## ABSTRACT
Enterprise Resource Planning (ERP) Applications control and manage complex business processes. The validation for such applications is very important due to the very high failure rate for ERP Applications. Any error made during the implementation of ERP leads to business failure. The objective of this study is to investigate the current ERP validation models and techniques to validate ERP systems in the pharmaceutical industry. This paper intends to serve two goals. First, it will be useful to researchers who are interested in the recent trends in ERP Validation. Second, it will identify the research gaps in the current ERP validation models with the aim of developing a new approach to validate ERP systems in the pharmaceutical industry. In the new approach, the focus will be on challenges in ERP applications validation, the impact of Critical Success Factors (CSFs) on ERP applications validation, the integration of risk assessment and ERP validation, the test rating and criticality during ERP validation, and the dependencies during ERP validation to improve the test evaluation.

## General Terms
ERP Validation, Computerized system Validation, V-model, Risk management, Data Integrity.

## Keywords
Good Automated Manufacturing Practice (GAMP), Good Manufacturing Practice (GMP), Critical Success Factors (CSFs).

## 1. INTRODUCTION
An ERP Applications are configured to comply with business requirements [1]. Many major industries use software applications to carry out business activities, and one of these industries is the pharmaceutical industry. There are many applications available for this industry such as Oracle ERP Applications, SAP ERP Applications, Microsoft Dynamics, Infor ERP, and Epicor ERP [2]. All such applications must be validated based on ISO, GAMP and 21 CFR part 11 guidelines before they can be used in production [3-5]. ERP Applications control and manage complex business processes. Validation for such applications is very important due to the very high failure rate of ERP Applications. Any error that occurs during the implementation of the ERP leads to business failure.

Software validation is a subset of computer system validation [6]. It is very important to deploy Software validation for any existing systems [4]. Computerized systems that support manufacturing operations in regulated business must be compliant with regulations and validated. Validation is mandatory when the application has a direct impact on the product and affects the quality of the product [3]. It is very important to determine the scope of validation that complies with the requirements of regulation [6]. To complete the validation process and the documentation it is important to be guided by company policies and GAMP instructions [5].

On the other hand, the Critical Success Factors (CSFs) are the factors necessary to ensure the successful implementation of ERP systems [7]. CSFs factors considered and managed to ensure validation project success and explain differences in project outcomes [7]. Therefore, it is important to assess the impact of the CSFs (independent variables) on the ERP validation (dependent variable).

The Risk assessment is important in implementing ERP, Risk weight is important areas for Improvements in ERP system. Risk led to difficulty in integration and technology fit for ERP system. [7]. Therefore, it is important to integrate risk assessment and ERP validation.

It's important to assess the criticality analysis using Risk Assessment based on all phases during the project [8]. Test case rating and prioritization to arrange test cases based on higher priority test cases execute earlier than test cases of lower priority [9]. Therefore, it is important to test rating and criticality during ERP validation.

Test case prioritization is based on the inherent structure of dependencies between tests, which is called dependency prioritization. Given that these dependencies reflect the dependencies of the system itself, it is important to order test executions based on the complexity of interactions between tests can increase the fault detection rate. [10]. Therefore, it is important to consider the dependencies during ERP validation to improve the test evaluation.

## 2. METHODOLOGY
This section describes the methodology followed through to answer the following research questions.

RQ1: What are the challenges in ERP Applications Validation?

RQ2: What are the existing approaches or models used in ERP Applications Validation?

RQ3: What are the Research gaps in the current validation models?

The articles that included for this study between 2012 and 2023 for the query technique. 27% of articles between 2012 and 2016, and 73% of articles between 2018 and 2023. For inclusion criteria the researcher takes into consideration all the papers that are significant to study.

This study will be adopted for Validating ERP Systems in the

Pharmaceutical Industry; each phase is described as the following, phase 1 "Background" provide ERP for Pharmaceutical Industry, ERP validation, Computerized system Validation failure Common Causes, and challenges, The advantages of validation in pharmaceutical companies. phase 2 "Literature review" provide, Decision tree Validation model, Validation life cycle, CSV procedure for GAMP category 3 model, CSV procedure for GAMP category 4 model, CSV procedure for GAMP category 5 model, Software validation flow chart, V-model for validation, Quality risk management process, Validation models comparison, Risk management, Automating the Validation Process, International Standards, regulatory authorities, and Guidelines, Auditing Frameworks, Data Integrity. phase 3 "Conclusion and Future work" a new approach to validate ERP systems in the pharmaceutical industry will be proposed.

Regarding the research gaps in the current validation models, the focus will be on challenges in ERP applications validation, the impact of Critical Success Factors (CSFs) on ERP applications validation, the integration of risk assessment and ERP validation, the test rating and criticality during ERP validation, and the dependencies during ERP validation to improve the test evaluation.

# 3. BACKGROUND

## 3.1 ERP for Pharmaceutical Industry

The pharmaceutical industry discovers, develops, produces, and markets medicines for use as medications to patients, with the goal of treating, vaccinating , or relieving symptoms. Pharmaceutical companies are subject to a variety of laws and regulations that govern the patenting, testing, safety, efficacy and marketing of drugs [11]. The increasing role of ERP systems to maintain a balanced supply chain to meet the demand for required medical and healthcare products. Hence, it is the call of time to reduce the hurdles in ERP systems to improve the efficiency of the pharmaceutical industry [12]. ERP systems consist of a set of modules related to manufacturing, financial, sales, CRM, purchasing, inventory, and others [As Figure 1].

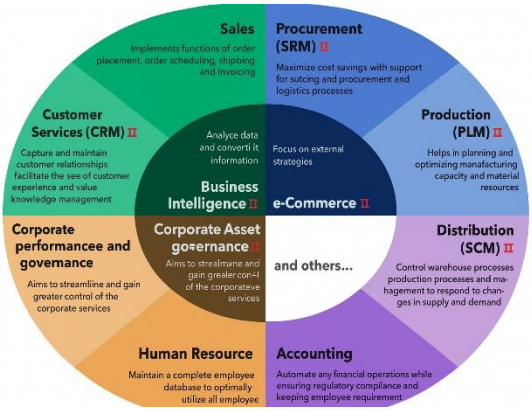


**Fig. 1. Functional Aspects of an ERP [13] [14].**

## 3.2 ERP validation

ERP applications must be validated based on GAMP 5, GMP, 21 CFR part 11, FDA Guidance, and ISO guidelines before they can be used in production. [15-17] Computerized system validation should be designed in accordance with GMP Annex 15 with URS, FAT, SAT, DQ, IQ, OQ and PQ tests as necessary. [18]. The protocol should contain all information such as scope, principles, objectives, procedures, operations, user manuals, documents, roles and responsibilities, specifications, risk management access, test criteria and acceptance limits [19]. Computer system validation can encounter several problems, which lead to Validation failure [16]:

### *3.2.1 Inadequate documentation of plans.*

### *3.2.2 Insufficient definition of what constitutes a computer system.*

### *3.2.3 Inadequate definition of expected results.*

### *3.2.4 Insufficient specification of software.*

### *3.2.5 Software that does not meet its specifications.*

### *3.2.6 Unavailable source code for software.*

CSV should establish a level of confidence that the system consistently meets requirements user requirements. As most methodologies require specifications and test protocols to be written, and approved by qualified personnel, it is possible to adapt the validation methodology to most situations, if system requirements and functionality can be tested, and demonstrated, and that system development, implementation, and operation are under control [20]. Validation judgement is a necessity in the pharmaceutical industry to ensure compliance with pharmaceutical cGMP guidelines, and to help companies maintain consistent quality [21]. The main purpose of computer system validation is to assure accuracy, consistency, reliability, and integrity of system data according to predefined specifications [21]. Vogel's diagram presents SQA consisting of V&V and software testing and identifies the existing relationships between these activities [22].

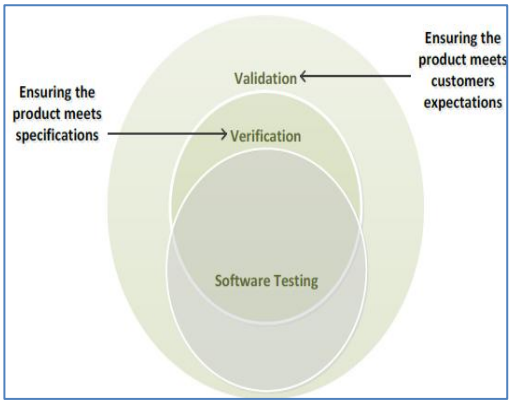


**Fig. 2. SQA Encompassing Verification & Validation - adapted from Vogel [22]**

## 3.3 Computerized system Validation failure Common Causes, and challenges:

There are many reasons for CSV failure [20]:

### *3.3.1 Inadequate documentation of plans.*

### *3.3.2 Insufficient definition of what constitutes a computer system.*

### *3.3.3 Inadequate definition of expected results.*

### *3.3.4 Insufficient specification for the software.*

### *3.3.5 Software that does not meet its specifications.*

### *3.3.6 Unavailable source code for software.*

The following common computer system validation problems Challenges [21]:

- *Challenge one Standards: Policies, Action Plan, work instructions, SOPs, ISPE and ICH*
- *Challenge two Interpretation: Most regulations include very high-level statements that define objectives, but do not specify how controls will be implemented or how much controls is enough.*
- *Challenge three Regulation and Governance: Many companies still have decentralized governance and uncontrolled execution.*
- *Challenge four Efficiency Across Sites and Departments: There are many cases where multiple sites develop complete validation packages for the same system they are using in the same way, because there is no sharing of inventory and project information.*
- *Challenge five Execution: As mentioned earlier, there is excessive rework being done by validation teams. Most often, the rework is the result of different opinions and styles of project team members and inconsistent quality of work performed by unqualified personnel.*
- *Challenge six Tools: System life cycle assets, such as templates, outlines, forms, and guidance documents are often inconsistent across departments and are not targeted to drive value.*

## 3.4 The advantages of validation in pharmaceutical companies [23]:

Several pharmaceutical companies have recognized the advantages of validation, and these advantages included the following.

### *3.4.1 Reduced rejections, rework, and retests*

### *3.4.2 Fewer complaints about process failures*

### *3.4.3 Reduced in-process testing and finished drug products*

### *3.4.4 Reliable start-up of new equipment*

### *3.4.5 Easier equipment maintenance*

### *3.4.6 Improved employee awareness of processes*

# 4. LITERATURE REVIEW

For an overview of the most important IS/ERP Validation models, the researcher refers to the reader to the research paper [24], which also includes a comparison of different Validation models. In this section, the researcher will summarize the advantages and disadvantages of the current validation models.

## 4.1 Decision tree Validation model:

discussion how, why, and when to use a validation decision tree that helps determine whether a process needs to be validated or not and is one of the easiest models under consideration. Each process must have specifications that describe both the process parameters and the desired output [25].

## 4.2 Validation life cycle:

When a system is setup for validation to verify that it meets the required operational and quality standards, the validation lifecycle ensures the integrity of system validity and process, and the Validation quality plan contains a Risk management plan, configuration management plan, and Quality assurance plan. According to the plan, the drug validation process should consider the development life cycle with quality [25].

## 4.3 CSV procedure for GAMP category 3 model

In GAMP category 3, software functionality is not modifiable, Requirement Testing (RT) verifies requirements, Requirements Relationship configuring in Design Testing (DT), RT is performed by developing a Requirements Traceability Matrix (RTM). Software configuration is described by the Installation Qualification (IQ) [24] [26].

## 4.4 CSV procedure for GAMP category 4 model

A URS that describes software requirements and a Functional Specification (FS) that describes the functions necessary to fulfill the requirements have been developed. In GAMP category 4, software functions are customizable and described by Functional Specification (FS), procedure also contains Configuration Specification (CS), Configuration Test (CT), Functional Test (FT) Requirement Test (RT), Design Qualification (DQ), and Installation Qualification (IQ) [26].

## 4.5 CSV procedure for GAMP category 5 model

In GAMP category 5 the software functions described by a Functional Specification (FS), the procedure also contains a detailed Specification (DS), Module Test (MT), Functional Testing (FT), Requirements Testing (RT), Design Qualification (DQ), and Installation Qualification (IQ). Software in category 5 is individually developed software, functions are verified by FT, and the requirements are verified by RT. [24] [26].

## 4.6 Software validation flow chart:

Software validation focuses on reviewing, accuracy, double checking, access, record retention, documentation, and showing the complete set of application usage, and protocols used in software validation such as FS, IQ, OQ and PQ. Points to consider are consistency in performance, functionality, repeats, documentation, and revalidation [27].

## 4.7 V-model for validation:

According to IEEE, validation is the process of evaluating a system or component during or at the end of the development process to determine whether it satisfies specified requirements. V-model contains User Acceptance, User requirement specification (URS), Functional Specification (FS), Configuration Specification (CS), Installation Qualification (IQ), Operation Qualification (OQ), Performance Qualification (PQ), and Change control. Computerized system achieved by GAMP5 and comply with regulation requirement [15].

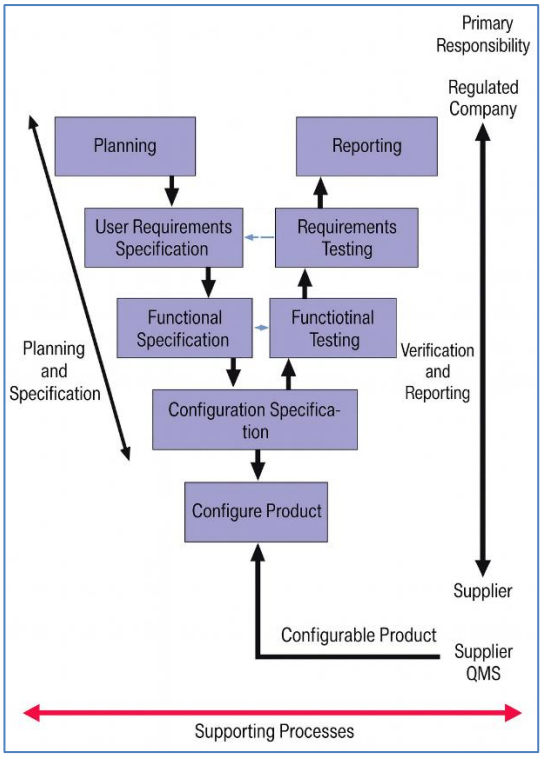


**Fig. 3. V-model flow chart [26]**

## 4.8 Quality risk management process:

The new GMP Annex 20 complies with ICH Q9 guideline on Quality Risk Management. It provides guidance on a systematic approach to quality risk management facilitating compliance with GMP and other quality requirements. used when applying a formal quality risk management approach. Risk management principles are used effectively in many areas of business. Although there are some examples of the use of quality risk management in the pharmaceutical industry, they are limited and do not represent the full contributions that risk management has to make. In addition, the importance of quality systems in the pharmaceutical industry has been recognized and it has become evident that quality risk management is a valuable component of an effective quality system.

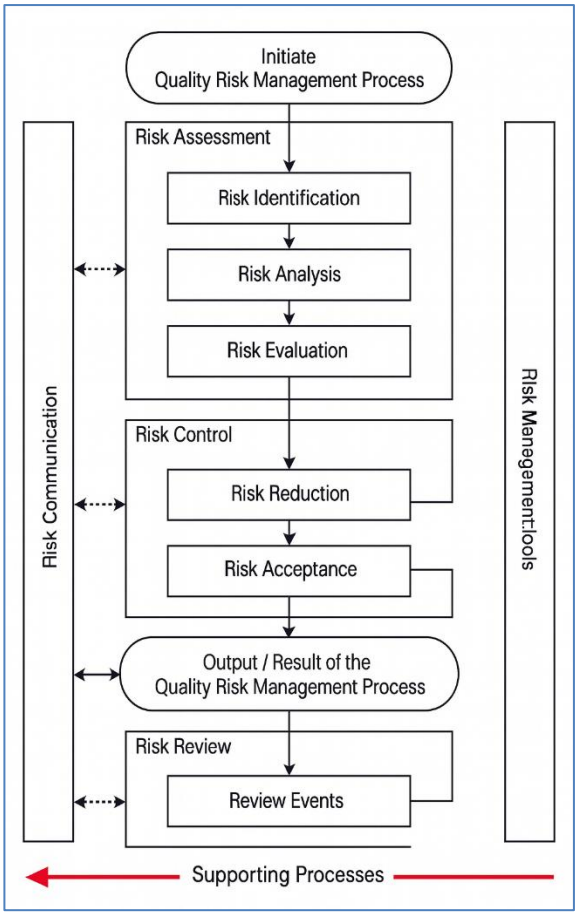


**Fig. 4. Overview of typical Quality risk management process [28].**

## 4.9 Validation models comparison

Table 2 illustrates the most important Validation models, including advantages and disadvantages for every model.

**TABLE I.** COMPARISON OF VALIDATION MODELS

| Model | Area | Advantage | Disadvantages | Phases for Validation |
|---|---|---|---|---|
| Decision tree Validation model [25]. | IS | Help determine whether the system needs to be validated or not. | Not going through the validation phases. | Use before starting validation. |
| Validation life cycle [25]. | IS | Maintaining the integrity and validity of systems * Verify that system meets the required criteria of operation and quality standards. | Risk assessment only in prior phase. | Multi stages. |
| CSV procedure for | IS | The URS is verified through a | Software functions cannot be | Multi stages. |

| | | | | |
|---|---|---|---|---|
| GAMP category 3 model [24]. | | requirement test.<br>* Ensure that the program is installed with the appropriate version. | modified in Category 3.<br>* Risk assessment is not applied in the model | |
| CSV procedure for category 4 model [24]. | IS | The URS is verified Through a Requirements Test.<br>* Confirm the correspondence between the requirements, functions, and configurations by developing a Requirements Traceability Matrix (RTM).<br>* Functional, and configuration in category 4 software is customizable. | Risk assessment not applied in the model | Multi stages. |
| CSV procedure for category 5 model [24] [26]. | IS | Detailed Specification (DS) describes algorithms to realize the functions that have been developed.<br>* Confirm correspondences between requirements, functions, configurations by developing a Requirement Traceability Matrix (RTM). | Risk assessment just in prior phase. | Multi stages. |
| Flow chart of Software validation: [27]. | IS | Consistency in performance. | Risk assessment not applied in the model | Multi stages. |
| V-model for validation [15]. | IS & ERP | For Infrastructure and Software. | Risk assessment just in prior phase. | Multi stages. |
| Quality risk management [28]. | IS & ERP | Valuable component of an effective quality system | They are limited and do not represent the full contributions made by risk management | Preliminary the stage |

These models have special perspectives for systems validation, some models have been developed to integrate with some previous models, and other models have been developed with new approaches. The researcher summarizes the advantages and disadvantages of the models. The researcher analyzes these models according to some characteristics:

- *Used in specific area of Application or used in general area.*
- *Is the model used in one phase or used in multi-phases of ERP validation?*
- *Maintaining the integrity and validity of systems*
- *Verify that the system meets the required operation and quality standards.*
- *URS is verified through the Requirement Test*
- *Ensure that the software is installed with the appropriate version.*
- *Confirm correspondence between requirements, functions, and configurations by developing a requirements traceability matrix.*
- *Functional and configuration are customizable.*
- *Consistency in performance*
- *Use for both Infrastructure qualification and Software validation.*
- *Dealing with all issues and risks related to Enterprise Resource Planning (ERP).*
- *Integrate Risk assessment into all phases of validation.*

Based on the above table, the researcher did not find a common and regular model to be used in the validation of different ERP systems, and the researcher contributed that the proposed new model for the validation of ERP systems in pharmaceutical industry should consider the following characteristics:

- *Used to validate multiple application domains.*
- *Use for validation at multiple phases of ERP implementation.*
- *Maintaining the integrity and validity of systems.*
- *Verify that the system meets the required operation and quality standards.*
- *URS are verified by the Requirement testing.*
- *Ensure that the software is installed with the appropriate version.*
- *Developing a Traceability Matrix.*

- *Functional and configuration are customizable.*
- *Consistency in performance.*
- *The model can be used to validate Infrastructure qualification and Software validation.*
- *Dealing with all issues and risks related to Enterprise Resource Planning (ERP).*
- *Integrate Risk assessment into all phases of validation.*
- *The model calculates the weight of the test ranked by criticality.*
- *The model is integrated with CSF.*

## 4.10 Risk management

Multiple risks can affect the implementation phases of an ERP system. Risk management techniques are very useful in the phases before, during and post the implementation of an ERP system. ERP system validation ensures proper control of functional risks and operational risks and ensures user satisfaction and ensures that the ERP system meets user requirements and expectations. There are different risk assessment tools that measure risk, and each tool has its own features, characteristics, or criteria [29].

## 4.11 Automating the Validation Process:

ERP, LIMS, QAMS, and Documentum systems must be validated based on GAMP5 and 21 CFR part 11 guidelines, which are essential because they "provide a framework to protect public health and ensure safety and quality of the product". To perform and complete validation, a large amount of documentation must be done. Automating the Validation process eliminates manual efforts in preparing validation documents, saving a significant amount of time, resources, and money [30].

## 4.12 International Standards, regulatory authorities, and Guidelines

To ensure regulatory compliance, as well as that the computer system operates within required specifications, it is important to consider the life cycle of the computer system [31].

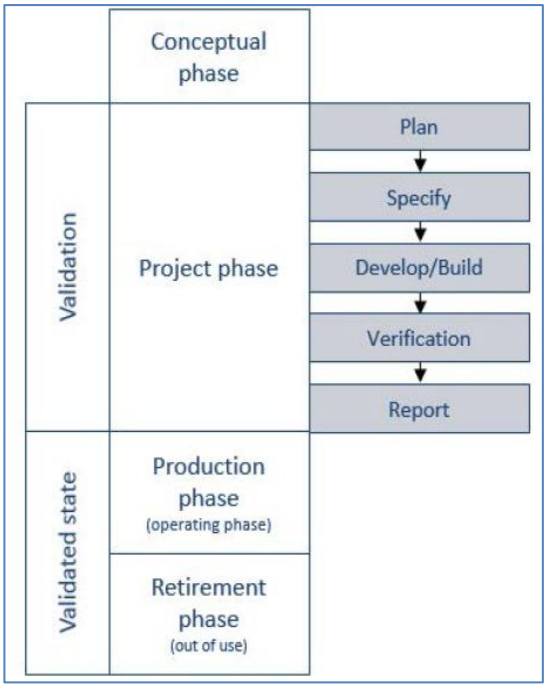


**Fig. 5. Computer system life-cycle model [31].**

Regulatory Requirements are grouped according to the following regulatory topics [20]:

- *Quality System: related to the Quality System and its associated documentation.*
- *Security: Related to the general features of System security and the security of the organized electronic record managed by the system*
- *Integrity: Related to the integrity of the structured electronic record managed by the system and its associated validation documents.*
- *Traceability: Related to the Traceability of the regulated electronic record managed by the system*
- *Accountability: related to Regulated electronic signatures managed by the system*

Many Guidelines and Regulations govern the pharmaceutical industry such as the Rules Governing Medicinal Products in the European Union "Eudralex" Vol.4 responsible for human sector, the following are several guidelines [32]:

- *Eudralex Vol.4 Annex 11: Rules governing medicinal products in the European Union contain guidance for principles and guidelines for good manufacturing practices for medicinal products.*
- *ISPE GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems is regarded as the definitive industry guidance on GxP computerized system compliance and validation*
- *FDA 21 CFR part 11: The regulations in this part are used to validate computerized systems, electronic records, and electronic signatures.*
- *PIC/s: The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme provide international instruments between countries and pharmaceutical inspection authorities in the field of Good Manufacturing Practice (GMP)*

- *ALCOA: ALCOA standards address data integrity.*
- *GMP (GOOD MANUFACTURING PRACTICE) Regulations: Regulations issued by the US Food and Drug Administration.*
- *GXP: Data Integrity Guidance and definitions.*
- *GAMP: Good Automated Manufacturing Practice the concept of potential validation following the life cycle model, evolving FDA and other regulatory agency expectations for computerized system compliance and validation.*
- *ICH Q10 principles: The International Conference on Harmonization -US FDA (ICH Q10) describes a comprehensive model for an effective pharmaceutical quality and Change Management system that is based on ISO quality concepts, includes applicable good manufacturing practice (GMP) regulations, and complements ICH "Q8 Pharmaceutical Development" and ICH "Q9 Quality Risk Management".*

There are several standards and frameworks that govern and control the security of an information system as follows:

- *NIST Cybersecurity Framework [33]: The National Institute of Standards and Technology helps organizations understand and combat cybersecurity risks. It provides the basis for preventing cyber-attacks and resolving negative consequences.*
  - *NIST SP 800-36, Guide to Selecting Information Technology Security Products.*
  - *NIST SP 800-61, Computer Security Incident Handling Guide.*
  - *NIST SP 800-83, Guide to Malware Prevention and Incident Handling for Desktops and Laptops.*
  - *NIST SP 800-86, Guide for Integrating Forensic Techniques into Incident Response.*
  - *NIST SP 800-92, Guide to Information Security Log Management.*
  - *NIST SP 800-94, Guide to Intrusion Detection and Prevention Systems (IDPS).*
  - *NIST SP 800-101, Guidelines on Mobile Devices.*
- *ISO 27001: monitoring, reviewing, maintaining, and improving a company's information security management system.*
- *REN-ISAC: Research and Education Networking Information Sharing and Analysis Center, aid and promote cyber security operational protection and response within the higher education and research (R&E) communities.*
- *SANS Security Awareness: Managing Human Cyber Risk identifies and benchmarks how organizations are Managing Human Risk.*

## 4.13 Auditing Frameworks [34]:

*4.13.1 ISACA "the Information Systems Audit and Control Association", demonstrate your understanding of cyber-related risk and ability to prepare, global portfolio of IT certifications – CISA, CISM, CRISC, CGEIT, CDPSE, CET, ITCA – not to mention the COBIT framework.*

*4.13.2 COPIT "Control Objectives for Information and Related Technologies" is a framework that aims to help organizations that are looking to develop, implement, monitor, and improve IT governance and information management. COBIT was established by ISACA, which stands for Information Systems Audit and Control Association. Both ISACA and the IT Governance Institute (ITGI) publish it.*

Many regulatory guidelines responsible for Data Integrity governance as shown in Figure 6

| Date of Issuance Timeline | Guidance Document |
|---|---|
| March 2015 | MHRA: GMP Data Integrity Definitions and Guidance for Industry (Draft) |
| September 2015 | WHO: Good Data and Record Management Practices (Draft) |
| April 2016 | FDA: Data Integrity and Compliance with CGMP (Draft) |
| June 15, 2016 | WHO: Good Data and Record Management Practices |
| July 2016 | MHRA: GxP Data Integrity Definitions and Guidance for Industry (Draft) |
| July 18, 2016 | PIC/S: Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments (Draft 1) |
| August 10, 2016 | PIC/S: Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments (Draft 2) |
| August 17, 2016 | EMA: Questions and Answers: Good Manufacturing Practices—Data Integrity |
| March 2018 | MHRA: GxP Data Integrity Guidance and Definitions (Revision 1) |
| November 30, 2018 | PIC/S: Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments (Draft 3) |
| December 2018 | FDA: Data Integrity and Compliance with Drug CGMP Questions and Answers |

**Fig. 6. Milestones of the Data Integrity Regulatory Guidance Documents Issuance [35].**

The next set was published by IEEE organization and the U.S. Food and Drug Administration (FDA) presented Figure 7. This set covers verification and validation activities in both generic and medical device domains.

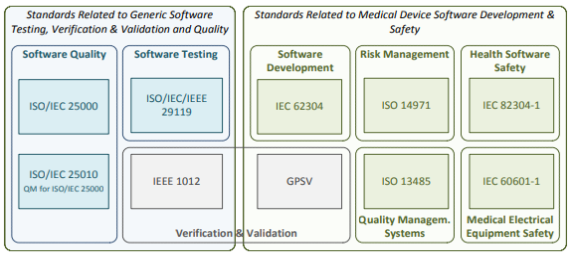


**Fig. 7. International Standards related to Medical Device Software Testing and SQA [36].**

## 4.14 Data Integrity

Regulatory authorities want to ensure data integrity through reliable systems that detect and expose errors. To ensure data integrity, regulatory authorities require computer systems to be validated according to their requirements [31]. The main conclusion of computer system validation is to maintain consistency and accuracy in the final product. It also prevents data integrity due to an error in the computer system. From time to time, it detects an error in the software and that is why it prevents data integrity issues that occur during FDA inspection [21].

Prevent data integrity failures in pharmaceutical manufacturing

through risk-based computerized systems validation [23]:

- *Reduced rejections, reworks, and retests*
- *Fewer complaints about process-related failures*
- *Reduced testing during process and finished drug products.*
- *Reliable startup of new equipment*
- *Ease of equipment maintenance*
- *Improve staff awareness of operations.*
- *Obtain data in electronic format including the full audit trail [37].*
- *It should not be possible to edit audit trail data or deactivate the audit trail functionality for normal or super users working on the system [37].*

**TABLE II. THE CURRENT GABS IN THE LITERATURE REVIEW**

| Serial | Gaps |
|---|---|
| 01 | Impact of Critical Success Factors (CSFs) on ERP applications validation. |
| 02 | Integration of risk assessment and ERP validation. |
| 03 | Test rating and criticality during ERP validation. |
| 04 | Dependence during ERP validation to improve the test evaluation. |

# 5. CONCLUSION AND FUTURE WORK

The pharmaceutical organizations must be very competitive to survive. EPR system implementation seems to be the current method of using technology as a competitive advantage. On the other hand, the validation for ERP applications is very important due to the very high failure rate for such Applications. This study examined the current ERP validation models and techniques to validate ERP systems in the pharmaceutical industry, with the aim of identifying the research gaps in validating ERP systems. The literature is inadequate with respect to assessing the impact of the CSFs on ERP Applications Validation, integrating the Risk Assessment in all ERP validation phases, rating the ERP Validation tests, determining the criticality for every test, and assessing dependencies during ERP Validation.

In the future work, a new approach to validate ERP systems in the pharmaceutical industry will be proposed. The new approach aims to assess the impact of CSFs on ERP Applications Validation, integrate the Risk Assessment in all ERP validation phases, rate ERP Validation tests, determine the criticality for every test, and assess the dependencies during ERP Validation to improve the test evaluation.

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