BENEFITS FROM PAPERLESS COMPUTER SYSTEM VALIDATION IN PHARMACEUTICAL INDUSTRY

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INTRODUCTION

Computer Systems Validation (CSV) is a process used to ensure that a computer-based systems will produce information or data that meet a set of defined requirements. If a system meets these requirements, it can be assumed that it is consistently performing in the way it was intended. Computer system validation checks the effectiveness and the efficiency with which the system is meeting the purpose for which it was designed.

The concept of validation was first proposed by Ted Byers and Bud Loftus in the mid-1970s to improve the quality of pharmaceutical products. Currently, in the pharmaceutical manufacturing industry, validation plays a vital role in producing high-quality pharmaceutical products that meet good manufacturing practice (GMP) guidelines.

Paperless validation is an electronic process of ensuring that a computer-based systems are compliant to the requirements. All steps of the validation process are registered in digital documents, or items, rather than on paper. By not using a single sheet of paper, the paperless validation presents many benefits to companies, professionals, and the environment. One of them is to convert a most common, system validation such as ERP (Enterprise Resource Planning), which usually uses almost 2,500 sheets of paper, converting it into 'zero paper'.

MATERIALS AND METHODS

This short paper presents literature data, which is analyzed and compared with a real case of paperless computer system validation in the pharmaceutical industry.

DISCUSSION

Paperless validation brings benefits in different areas of defined requirements while performing CSV.

On the topic of computer system validation in the pharmaceutical industry, it's important to go over the basics of Good Documentation Practice (GDocP). Data integrity is the cornerstone of GDocP in any kind of records - paper or electronic. Data Integrity in a validation project refers to ensure that the data inserted in those documents, are attributable, legible, contemporaneous, original and accurate. If one conducts their project using a paperless validation software, the chances of a break of GxP compliance are smaller.

Traceability matrix is a document that links GMP requirements with their tests over the validation lifecycle. This deliverable ensures that all requirements defined for a system, software, and process validation are linked with their respective risk scenarios and tests. In a traditional way, based on paper, a responsible person needs to link all requirements with their test protocol items manually. With a paperless validation, the traceability matrix is built in automatically, reducing time and avoiding mistakes.

The digital possibility to carry out a validation project, in just one software, also translates to financial benefits for industry and laboratories in the Life Science market. In addition, using a paperless validation software reduces team efforts to finish the project, saving 65% of company's validation costs.

It reduces repetitive and mechanical activities, leaving the thinking activities like Risk Assessment and testing strategies for the validation specialist to decide. However, the validation specialist has possibility to decide if these items adhere with the process and the project, taking advantage of an enhanced, pre-existing expertise database, not starting from scratch with every new project, saving a lot of time, producing validations at least three times faster.

By eliminating critical data manual management, paperless validation drastically reduces the danger of non-compliance, as well as being designed to allow not only management, but the preparation of documents with greater agility and safety, from the beginning of the project until the Final Validation Report.

In 2020, during the pandemic with COVID-19, a process of upgrading the ERP system was started in Alkaloid AD Skopje. A paperless validation method was used during the process of validation of the system. GO!FIVE™ platform (Validation Lifecycle Management Software – VLMS, that is cloud-based, fully paperless, with features that increase compliance) from FIVE Validation was used for conducting and documenting of the validation process. Due to the extraordinary conditions in which the work was done during the pandemic, this way of validation enabled an uninterrupted course of the validation process of the computer system. With the use of the paperless validation system from different locations and the ability to use electronic signatures, all processes and documents were completed on time. After the completion of the system verification phase, the documentation is available at any time to any authorized person who has an access to the system.

The validation project was structured to meet national and international standards and guidelines, such as:

- ▶ GAMP5® Good Automated Manufacturing Practice;
- ▶ FDA 21 CFR Part 11 American Standard for the Use of Electronic Signatures and Electronic Records;
- ▶ Annex 11 Good Manufacturing Practice – Medicinal Products for Human and Veterinary Use: Computerized Systems, EMA (European Medicine Agency). (https://fivevalidation.com/sap-hana-erp-validation/, 2022).

CONCLUSION

There is no doubt that as validation documentation becomes more complicated, methods to achieve more efficient and leaner execution than a compliance database system that takes a document-centric approach will be required. Choosing a paperless validation with an established track record can aid in the technology's effective adoption, replacing the paper-based approach's outgoing weight.

When implementing paperless computer system validation, the benefits to the project and the system are:

- ▶ Higher level of compliance, because of decreased risks of data integrity flaws;
- ▶ Enhanced speed of validation projects, to do the validation from start to finish in just one software;
- ▶ Decreased validation costs: faster work, avoided paper work, no printers, no physical space to store documents, no documentation scanning;
- ▶ Possibility of running the project remotely, online management and connecting of teams between several locations;
- ▶ Easier maintenance of the validation status, with decreased time of keeping the validation status with constant changes and periodical reports;
- ▶ Easier for auditors or inspectors, the data is available immediately;
- ▶ Sustainable documentation with no paper use, no printers and cartridges, which benefits the environment.

(+) MORE COMPLIANCE (-) LESS TIME

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