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Short communication

Creating and management of stability studies in AlkaSAP system

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Introduction

The stability of a drug substance or a drug product refers to their ability to remain within established shelf-life specifications or identity, strength, quality and purity till the specified period of time. Stability testing is the mechanism to obtain stability information and to demonstrate that the drug substance/drug product will meet the predefined acceptance criteria all through the defined storage period (EudraLex, 2014; ICH, 2003). Careful management of stability study is a core principle behind excellent outcomes in stability testing. Stability testing must consider proper planning, as well as sample and data management. The careful documentation of sample storage, sample management and the stability data is critical (Bajaj et al., 2018; EudraLex, 2014). AlkaSAP system helps automate this monitoring and documentation ensuring reliability and efficacy. Effective stability study management is vital to ensure ongoing product integrity and safety.

The aim of this work is to demonstrate how the on-going stability studies are created and managed in AlkaSAP system.

Materials and methods

SAP is software that enables management of different business processes and developing solutions that facilitate effective data processing and information flow across the organization. The stability study can be created and managed in AlkaSAP system by defining all the main features, the creating mode for a stability study plan, assigning a strategy (defined frequency for creating a sampling plan and inspection lot) defining the SAP transactions that are used, as well as the subsequent steps to conduct this process.

The AlkaSAP system ensures the data integrity in the database by protecting data against unauthorized changes. Also, all users have their own system login/password to represent their electronic signature.

The purpose of creating stability studies in AlkaSAP system is to provide a defined, standardized and automated mode for the procedures for stability study monitoring, through automatic release and printing of inspection lot with a predefined frequency, as well as recording and monitoring stability studies results in the AlkaSAP system.

Results and discussion

Creating a specification

The first step at the beginning of the stability study in the AlkaSAP system is creating a specification for product monitoring during stability testing. The specifications are created in separate SAP transaction and each specification is defined by unique combination of number and letters. The specification in AlkaSAP system contains different sections for physico-chemical, microbiological and biological testing. Besides entering specification parameters and specification limits, the transaction for specification of AlkaSAP system enables entering the number of samples required for one analysis of physico-chemical, microbiological and biological testing. For each stability study two specifications are created: specification for the starting point of stability testing and shelf-life specification (ICH, 2003).

Assigning a testing frequency

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After defining the specification, it is necessary to assign the testing frequency, i.e. a strategy of the stability study of the designated products. Testing frequencies are connected to the shelf-life specification. The testing frequencies can be entered in months, weeks or days.

Creating a stability study

After defining the testing frequency, the stability study is created by designating unique name following the naming convention. In the stability study, the necessary data for the product are entered – batch No, primary and secondary packaging, storage conditions, number of samples and the location in the stability chamber. The AlkaSAP system enables printing labels for proper labeling of the products placed on stability testing. The labels contain information about the name of the product, batch number, manufacturing date, storage conditions, name of the stability study and electronic signature of the person who created the study.

The shelf-life specification is entered in a separate field in the stability study, which enables connecting of the stability study with the assigned frequencies of the specification.

The creation of inspection lot for each testing frequency of the defined product is provided on appropriate date, according to the manufacturing date of the product which is considered as starting point of stability testing. Inspection lots are automatically printed.

In accordance with the monthly planning of the performance testing frequencies there is possibility for manually releasing the inspection lot for the current frequency on a different date.

When the testing frequency of the product is finished, the obtained data of the inspection lot are entered in appropriate transaction.

Sample management

The change in number of samples for stability testing for each frequency in AlkaSAP system is performed automatically, by creating the inspection lot for the suitable test frequency. The number of samples which is subtracted for every testing frequency is based on the number of samples in the appropriate specification separately for physico-chemical, microbiological and biological tests. The specifications are created in the separate SAP transaction, with a defined field for entering the number of samples necessary for performance of one analysis. The number of samples necessary for one analysis is defined for each product.

If additional number of samples is required, the change can be performed manually, in separate transaction, where the number of subtracted samples and the number if remained samples are entered with suitable comment.

The AlkaSAP system enables audit trail for sample management, where all the necessary data are displayed. The audit trail shows the number of samples before and after the subtraction, location of the samples, name of the person who managed the samples, and date and time for sample management.

The AlkaSAP system allows creating monthly and annual plan for stability testing which automates and facilitates the planning process of stability testing. It ensures correct planning procedures upfront. The data entered for all testing frequencies can be summarized in a stability report for each batch of the products subjected to stability testing.

Conclusion

Centralization and automation of the management of stability studies with AlkaSAP system allows more effective sample and study management. This makes the management process more effective, by reducing the possibility of human error and allowing for more detail via automation. Integration and implementation of AlkaSAP system for management of stability studies, helps improving efficacy and reliability of stability studies.

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