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Webinar on

2 Usefull Webinars On Pharmacovigilance, Stability Studies And Estimating Shelf Life

Webinar Description

The 2 webinars in this bundle will quickly review and update the Pharmacovigilance Systems. It will also explain the recent new published modules of the Good Pharmacovigilance Practice and the new GVP module VI "Collection, management and submission of reports of suspected adverse reactions to medicinal products", the new GVP module V "Risk Management Systems" and GVP module IX "Signal Management" require for update to Safety Databases/electronic interchange systems, processes/working instructions, contracts with Third Parties affected from such legislative changes. It will also discuss the steps to set-up a stability study and analyzes the results to estimate the product's shelf life. It will provide useful methods and techniques for conducting a stability study and analyzing the resulting data for the purpose of estimating shelf life.

The webinar format is 1-1.5 hours of audio-visual presentation, including a brief Q&A session.

This webinar bundle includes below 2 recorded webinars:

Pragmatic Approach to Pharmacovigilance/Drug Safety System Update Against the Latest New Requirements

Stability Studies and Estimating Shelf Life with Regression Models

Pragmatic Approach to Pharmacovigilance/Drug Safety System Update Against the Latest New Requirements

Presented by Marco Sardella

In the last year/recent months, there have been a lot of changes in the pharmacovigilance requirements especially impacting the reporting to EudraVigilance, the Signal Detection Management (e.g. inclusion of EudraVigilance Data Analysis System as part of the Signal Detection Management, etc.) and the Risk Management activities. The course is aimed at providing some practical examples of the application of the new requirements to PV Systems.

The recent new published modules of the Good Pharmacovigilance Practice (GVP) and in particular the new GVP module VI "Collection, management and submission of reports of suspected adverse reactions to medicinal products", the new GVP module V "Risk Management Systems" and GVP module IX "Signal Management" require for update to Safety Databases/electronic interchange systems, processes/working instructions, contracts with Third Parties affected from such legislative changes, etc. The review and update of Pharmacovigilance Systems as a result of the new requirements must take into account the type of medicinal products covered by the systems. Any update required to meet new local requirements from a specific territory will have to be performed in a way that does not generate conflicts with the functionalities of the system in place to meet the requirements of other territories.

Stability Studies and Estimating Shelf Life with Regression Models

Presented by Steven Wachs

Manufacturers of foods, drugs, consumer goods, and other products must determine the shelf life of their products so that customers know when the product can be expected to perform as intended. Many approaches are available to quantify the "shelf life" and the method(s) chosen often depend on the testing time available.

This webinar discusses the steps to set-up a stability study and analyzes the results to estimate the product's shelf life. The use of regression models to model the relationship between the response variable(s) and time are presented. Models useful for describing non-linear degradation over time are also presented. Additionally, methods for handling non-normal response data are also discussed. Finally, the use of accelerating variables to shorten the study time and the models required are introduced. The webinar includes several examples to illustrate the methods discussed.

The webinar will provide useful methods and techniques for conducting a stability study and analyzing the resulting data for the purpose of estimating shelf life. Participants should be able to immediately apply the methods presented. Also, the interpretation and communication of results will be stressed.

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