Enhanced Incurred Sample Reanalysis (ISR) in Watson LIMS

Joel I. Usansky, Marc Krug and Mike Small
Thermo Fisher Scientific, Philadelphia, USA

Introduction

During drug development programs, bioanalytical assays are validated and used to quantify drugs and their metabolites in samples from a variety of different biological matrices. Incurred Sample Reanalysis (ISR) has recently become an accepted way to assess the quality of bioanalytical assays and is widely used within the pharmaceutical industry and by contract research organizations for this purpose. ISR ensures that samples selected from an incurred study and are re-analyzed to demonstrate that the assay is reproducible.

The concept of incurred sample reanalysis was articulated in the third AAPS/FDA bioanalytical workshop/report1 where it was stated that performance of spiked standards and QCs may not adequately mimic that of study samples from dosed subjects, that is, incurred samples.

ISR in Watson 7.4

Thermo Scientific Watson LIMS is the most commonly used bioanalytical data system in the pharmaceutical industry. Watson™ users have been able to conduct incurred sample reanalysis and reporting for some time, but the enhancements introduced in Watson™ 7.4.1 provide an additional layer of functionality designed to improve workflow and reproducibility in the way that ISR samples are added to a Watson worklist. In addition, reporting features have been substantially improved providing more functionality and ease of use.

New features of ISR in Watson 7.4.1 are:

• Ability to have ISR samples within same run as regular bioanalytical samples
• Separate Mandatory Repeats run is no longer required
• Mandatory Repeats run type has been discontinued
• New sample type called “Incurred Sample Repeat” type (analogous to Reassay tagging)
• New feature called: “Incurred Sample Repeat” flag is added to assay parameters in the Assay Processes reports

ISR in Watson 7.4.1

New features of ISR in Watson 7.4.1 are:

• Ability to use incurred Repeatable Injection (IRI) samples as ISR samples
• Ability to report on Concentrations, IRM or both types of samples
• Ability to pre-define the default reporting template to be used
• Ability to report on Mandatory Runs, ISR samples, or both

Conclusions

The Incurred Sample Reanalysis features of Watson have been extended to allow for reporting of ISR samples as a separate reporting component. Processing and reporting of ISR data by Watson has been made faster and even more flexible.

References


All trademarks are the property of Thermo Fisher Scientific Inc. and its subsidiaries. This information is not intended to encourage use of these products in any manners that might infringe the intellectual property rights of others.