ECA Academy
Your GMP/GDP Information Source

Live Online Training

Speaker

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Handling OOT Results

Live Online Training on 13 October 2020

Highlights

- Regulatory Importance of Trend Analysis
- A Statistical Tool Box as Basis for Selection
- Trending for Process Control of Variables and Attributes
- Investigation of Trending using CUSUM
- AQLs & Sampling for Attributes
- Control Charts for Attributes

Objective

This new online Training Course participants will get practical advice on how to identify OOT Results. You will get to know how to use the statistical tool box for detecting OOT data. During the training the following aspects will be discussed:

- Regulatory concern for the control of processes
- Data types and distributions
- Variations and statistical control
- Statistical tool box
- Process stability versus process capability
- Recommendations for process control of variables and attributes

Participants will get a worksheet document and a preparation document for pre-reading upfront. During the training feedback related to the worksheet is requested which will be discussed by the speaker. Possible solutions will be suggested and recommendations will be provided.

Background

Laboratory tests are performed on active pharmaceutical ingredients, excipients and other components, inprocess materials, and finished drug product. In these tests a trend can occur and a trend analysis has to be performed by applying techniques for detecting an underlying pattern of behaviour in a time or batch sequence which would otherwise be partly or nearly completely hidden by noise.

There are two distinct types of trend situations:

- No trend is expected, for example for production or analytical process data which are known or assumed to be under statistical control.
- A trend is expected, for example in stability testing.

There is a fundamental difference between these two situations in that the variance increases with time in the second situation. Trend analysis is of regulatory relevance and a key aspect in both in EU guidelines (e.g. Annex 15, EU GMP-Guide) and FDA Guidances (e.g. Guidance for Industry, Process Validation: General Principles and Practices).

The **ECA Working Group on Analytical Quality Control** decided to address these aspects and developed a harmonised **guideline SOP** on managing analytical deviations within the laboratory including OOS, OOE and OOT results. It encourages the application of a consistent and scientifically sound approach to trend analysis as part of a QMS. The current Version 2 is available for all ECA members on the ECA members area.

Target Audience

This training is recommended for all levels of technical staff and managerial personnel dealing with out-of-trend results, including analytical laboratories, contract laboratories, and Quality Assurance/Quality Control personnel.

Programme

09.00 – 09.15 h Introduction

09.15 – 09.45 h
Regulatory Importance of Trend Analysis

- Expectations
- Process capability and performance
- Regulatory references
- Future requirements

09.45 – 10.30 h
An Introduction to the Statistical Tool Box; Distribution of Data and its Characterisation

- Specifications and processes
- Data types and models
- Populations and samples
- Data distributions
- Errors and confidence intervals

10.30 – 10.45 h
Questions & Answers

10.45 – 11.00 h Break

11.00 – 12.00 h
Trending for Process Control of Variables

- Statistical Process Control
- Individual and moving range charts
- Process capability indices
- CUSUM & EWMA charts
- Investigation using CUSUM

12.00 – 12.15 h
Questions & Answers

12.15 – 13.15 h Break

13.15 – 13.55 h
Workshop 1 on Variables

SPC of continuous individual and grouped monitoring data using the moving range and mean and range methods

- Interpretation
- Conclusions

13.55 – 14.15 h
Feedback from Workshop 1

14.15 – 15.15 h
Trending for Process Control of Attributes

- Basic differences between attributes and variables
- Distributional requirements
- AQLs & sampling for attributes [OOE attributes with a batch]
- Control charts for attributes; an overview

15.15 – 15.30 h
Questions & Answers

15.30 – 15.45 h Break

15.45 – 16.25 h
Workshop 2 on Attributes

ATP bioluminescence is used to provide a rapid and simple method to monitor the microbiological cleanliness of a process plant at a Critical Control Point (CCP). The data, in the form of discrete Relative Light Units (RLU), measure the amount of microbial ATP.

- Interpretation
- Conclusions

16.25 – 16.45 h
Feedback from Workshop 2

16.45 – 17.00 h
Overall Questions & Answers Session

17.00 h End of training

Speaker

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

He is a Chartered Chemist and has more than 40 years' experience in the pharmaceutical industry initially with Glaxo in Quality Assurance and Analytical R&D and then in international consultancy. He is a "Qualified Person" in the European Union and a member of the European QP Association advisory board. He was appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and re-elected 2015 to 2020 for and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Executive committee of European Compliance Academy. He is also a member of the USP Expert Panel on Validation and Verification entrusted to revise General Chapters <1224>, <1225> and <1226>.

Your Benefit:

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.


CERTIFICATE

Mr John Doe

has completed a two day ECA-Course on 5 to 6 December 2019 in Barcelona, Spain covering the following subject

ECA - Lab Data Integrity - Meeting FDA & EU Concerns Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

Contents of the course:

- Introduction to Course
- Data Integrity Self Inspections and Audits for Hybrid and Electronic Systems
- Workshop I: Risk Assessment and Prioritisation
- Workshop II: Audit of an Excel Spreadsheet
- Workshop III: Auditing a Hybrid Standalone System
- Workshop IV: Auditing a Networked Laboratory System – Audit Trail Review
- Workshop V: Electronic Signature Auditing
- Workshop VI: Preparing for the Data Integrity Audit
- Workshop VII: Observations and Findings During a Laboratory Audit and Planning the Closing Meeting
- Workshop VIII: Feedback to the Auditees
- Review of the Course and Key Learning Points

Heidelberg, 6 December 2019

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Reservation Form (Please complete in full)

Handling OOT Results, Live Online Training on 13 October 2020

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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If you cannot attend the conference you have two options:
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German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Tuesday, 13 October 2020, 09.00 – 17.00 h CEST

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 890
APIC Members € 950
Non-ECA Members € 990
EU GMP Inspectorates € 495
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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