



## Speaker



**Dr Christopher Burgess**  
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*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>.*

# Handling OOT Results



Live Online Training on 24 November 2021



## 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

At this Live Online Training 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 Guidelines (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 Live Online 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

### Regulatory Importance of Trend Analysis

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

### An Introduction to the Statistical Tool Box; Distribution of Data and its Characterisation

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

### Trending for Process Control of Variables

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

### Workshop 1 on Variables

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

- Interpretation
- Conclusions
- Feedback from Workshop 1

### Trending for Process Control of Attributes

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

### Workshop 2 on Attributes

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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
- Feedback from Workshop 2



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## Date of the Live Online Training

Wednesday, 24 November 2021, 09.00 – 17.00 h CET

## Technical Requirements

For our Live Online Training Courses and 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](http://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.

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.

## Organisation and Contact

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

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