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GMP Certification Programme
Certified Quality Control Manager

Speakers

Dr Raphael Bar
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Analytical Methods for Cleaning Validation

Development, Validation & Control

Live Online Training on 31 May - 02 June 2023

Highlights

- Cleaning Method Characteristics
- Calculation of MAC
- Sampling Techniques of Cleaning Residues
- Method Validation for Cleaning Residues
- Documentation of Method Validation
- Demonstrations with examples and practices

With practical Excel exercises

Objective

This live online training consists of two parts. The first part revolves around the development of suitable analytical methods. The characteristics of these methods (HPLC, HPTLC, TOC, conductometry, pH, total protein, visual inspection etc...) will be discussed in the light of their capability of detection and quantitation of residues. In particular, the advantages of the TOC method in accurately detecting and quantifying low levels of nonspecific residues (such as detergents, drug excipients and active ingredients) which may not be determined by HPLC, will be highlighted. Prior to this, the concept of Maximal Carry Over (MAC) limits according to PIC/S, FDA and WHO guides will be presented along with the new EMA approach based on toxicity thresholds. Finally, a prerequisite requirement for a well-developed analytical procedure is an efficient sampling recovery and therefore, the first part of the course will highlight the various techniques of sampling recovery.

The second part of the live online training will address a systematic validation of the analytical method for cleaning residues. Performance characteristics of the analytical method (accuracy, precision, linearity, robustness, sensitivity and sampling recovery) will be systematically presented.

This Live Online Training combines presentations and practices with Excel, which allows all delegates t**o apply the presented theory directly into practice**. Therefore, a device with installed Excel programme is required.

Background

Initiating a manufacturing of pharmaceutical in shared equipment requires demonstrating that no cross-contamination from previous product takes place. Optimally, residues from previous manufactured product or API or residues from the cleaning agent itself should be absent or very low. The validation of any cleaning process relies heavily on the validity of the test results provided by the analytical procedure for cleaning residues. However, here lies the challenge facing an analytical chemist: the need to develop and validate an analytical method that is sensitive enough to detect and reliably quantify well recovered trace amounts of chemicals and practical enough to rapidly deliver results.

Target Audience

The addressees of the event are analytical chemists testing the residues, quality control personnel, quality assurance personnel, regulatory affairs professionals, GMP auditors and inspectors and validation personnel also involved in cleaning validation.

Programme

Introduction Cleaning Validation and Regulatory Requirements

- Regulations (FDA, EU, PIC/S, APIC, WHO)
- Cleaning process
- Life cycle of cleaning process from development to validation

Understanding the Allowable Carryover (MAC)

- Common MAC limits (PIC/S, FDA and WHO guides)
- New approach of EMA guide (NOAEL and PDE)
- Residues limits on swab and rinse samples and in analytical samples
- Formulas for calculating MAC

Cleaning Method Characteristics

- Types of cleaning residues and their identification
- Analytical methods for cleaning residues: specific versus non-specific (HPLC, HPTLC, TOC, Conductometry, pH, total protein, visual inspection etc...
- Methods for validation and for monitoring
- Limit test versus quantitative test
- Correlation between specific and non-specific methods
- Methods for cleaning residues

Sampling Techniques of Cleaning Residues

- Swab and Wipe Sampling
- Requirements from Swab
- Rinse Sampling
- Solvent Sampling
- Placebo Sampling
- Product Sampling
- Visual examination of cleaned equipment

HPLC, TOC and Conductivity Methods for Residues

- HPLC procedure for residues
- Procedure for Total Organic Carbon
- Procedure for conductivity
- Testing methods for cleaning agents

Roadmap of Development and Validation of Analytical Procedure of Cleaning Residues

- Cleanability studies
- Development of an analytical method for residues
- Requirements from a method ready for validation
- Validation strategy of analytical methods for residues
- Role of statistical tools in method validation
- Overview of the roadmap from development to formal validation of analytical procedures

Specificity of Measurement Method

- Interference with excipient residues, degradation product, and cleaning residue
- Interference with swab extractables
- Interferences in analytical samples
- Quantitative aspect of specificity

Accuracy (incl. demonstration with examples and practices)

- Swab Recovery Studies on coupons
- Rinse Recovery Studies on coupons
- Solvent Sampling from hoses
- Accuracy of the Measurement Method

Precision of Measurement Method (incl. demonstration with examples and practices)

- Method Repeatability
- Intermediate Precision
- Combined analysis of Repeatability/Intermediate Precision with One-way ANOVA

Detection and Quantitation Limits of Measurement Methods (incl. demonstration with examples and practices)

- By ICH, EP and USP methods
  - of TOC method
  - of HPLC method
- Visual detection Limit (VDL)

Linearity of Measurement Method (incl. demonstration with examples and practices)

- ICH requirements (Correlation coefficient, residual SS, residuals plot)
- Considerations (number of data points, of repeats, quality of fit to linearity, etc.)
- Analysis of plot of measured vs. actual concentrations
- Correlation between Cleaning Validation and Monitoring: Relative TOC response factor of Target Residue/ Reference Standard in TOC method

Range

- Range on swab and rinse samples
- Range of analytical samples

Robustness

- Robustness factors for sampling recovery
- Robustness factors for measurement method
- by DOE matrix Solvent Sampling from hoses

Validation of Sampling Recovery

- Validation of swab and rinse sampling recovery
- What Spiking levels?
- How many replicates?
- Acceptance criteria
- Should you correct for recovery?
- Validation of Visible Residue Level (VRL)
- Examples of statistical recovery data analysis

Documentation of Method Validation

- Writing a protocol
- Writing a report

Speakers

Dr Raphael Bar
BR Consulting, Israel

Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and subsequently the analytical QC Laboratory at Pharmos. For the last twelve years, Raphael Bar has been a pharmaceutical consultant for the Pharma and Bio-Pharma industries.

Walid El Azab
STERIS Cooperation, Belgium

Walid El Azab is an Industrial pharmacist, a Qualified Person and Lean Six Sigma green belt. He provides technical support related to cleaning, disinfectants and sterility assurance.

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Reservation Form (Please complete in full)

Analytical Methods for Cleaning Validation
Live Online Training on 31 May - 02 June 2023

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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Date of the Live Online Training

Wednesday, 31 May 2023, 09.00 - 16.45 h
Thursday, 01 June 2023, 08.30 - 14.00 h
Friday, 02 June 2023, 08.30 - 12.00 h
All times mentioned are CEST.

Technical Requirements

We use Webex Events for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference 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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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