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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 from 11-13 June 2025

Highlights

- Cleaning Method Characteristics
- Calculation of MAC
- Sampling Techniques of Cleaning Residues
- Method Validation for Cleaning Residues
- Documentation of Method Validation
- Demonstration of examples and practices
- Validation in the light of the new ICH Q14 and Q2(R2) guides

With outlook on ICH Q2(R2) and ICH Q14

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.

Moderator

Dr Raphael Bar

Programme

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 for cleaning residues

Introduction Cleaning Validation and Regulatory Requirements

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

HPLC, TOC and Conductivity Methods for Residues

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

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

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

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
- The approach to development and validation of analytical procedures according to the new draft ICH Q14 and Q2(R2) guides

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

Precision of Measurement Method (incl. demonstration)

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

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

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

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

Robustness

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

Linearity and Range of Measurement Method (incl. demonstration)

- 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 on swab and rinse samples
- Range of analytical samples

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 Laboratory at Teva Pharmaceuticals and the QC Laboratory at Pharmos. He has been involved with the Pharma industry for the last 30 years and served as a member of the Scientific Advisory Board of global PDA (USA). In Addition he is past president and now a member of the Israel PDA Chapter as well as a member of the organizing committee of Israel Society of Analytical Chemistry. For the last fifteen years, Raphael Bar has been a pharmaceutical consultant for the Pharma and bio-Pharma industries.

Walid El Azab
QP Pro Services, Belgium

Walid is a senior consultant, specializes in GMP and GDP activities, with a focus on contamination control, sterility assurance, and inspection readiness. Acting as a Qualified Person and Responsible Person, he possesses expertise in non-sterile and sterile processes, including drug substance and product manufacturing. Walid's auditing proficiency covers CMOs, API manufacturers, and suppliers. Engaged in professional organizations, he contributes to conferences, and industry guidelines. Committed to education, he is a professor at Brussels and Liège University and co-founded the QP Academy. He provides consultancy support through QPM Consulting and QP Pro Services, acting as a strategic partner for pharmaceutical industry business continuity.

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Reservation Form (Please complete in full)

Analytical Methods for Cleaning Validation
Live Online Training from 11-13 June 2025

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

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Date of the Live Online Training

Wednesday, 11 June 2025, 09.00 - 16.45 h
Thursday, 12 June 2025, 08.30 - 15.30 h
Friday, 13 June 2025, 08.30 - 12.15 h
All times mentioned are CEST.

Technical Requirements

We use Webex 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 € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21872. To avoid incorrect information, please give us the exact address and full name of the participant.

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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