ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified API Production Manager

Speakers

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Handling of Foreign Particles in APIs and Excipients

Live Online Training on 25/26 January 2022

Risk analysis, preventive measures and incident management

Highlights

- Key preventive measures to minimise foreign particles
- How to deal with technically unavoidable particles in excipients
- Acceptance criteria for particles in APIs
- How to identify the source of insoluble matter
- Analytical control methods for particle detection
- How to minimise the presence of particles – strategies for cleaning and detection
- Foreign particles in excipients and finished product quality and safety

Objectives

During this Live Online Training all relevant aspects regarding the control of particles in APIs and excipients will be discussed.

You will learn

- How potential sources of insoluble matter can be identified
- Which acceptance criteria for particles can be applied
- How good practices to minimise the presence of particles in APIs can look like
- What has to be considered regarding control of particles during plant and equipment maintenance and cleaning
- How a particulate contamination profile can be established.

Background

Visible particles, insoluble particles or matter or foreign particles in Active Pharmaceutical Ingredients (APIs) and pharmaceutical excipients are topics of great interest and of importance to the pharmaceutical industry.

A number of inspectional observations from various Regulatory Authorities related to visible particles in Drug Products and APIs has risen considerable concern. Moreover inappropriate methods of investigation, controls and preventive and corrective actions were all subjects of citations by authorities and observations by API and excipient customers.

Particles have always been present in APIs and excipients but guidance from health authorities (EMA, FDA, others) or Pharmacopoeias (e.g. EP, USP) about particles is very limited. The APIC Guidance on Insoluble Matter and Foreign Particles in APIs and the IPEC Guide on "Technically Unavoidable Particle Profile (TUPP)" are the only best practice documents so far providing guidance for a standard approach towards an appropriate control of foreign particles in APIs and pharmaceutical excipients.

Target Audience

This Live Online Training is addressed to employees and senior staff of pharmaceutical companies and manufacturers of APIs and excipients. The course is of particular interest to all those working in Quality Assurance, Quality Control, production and purchasing departments.

Programme

Particles and Insoluble Matter in API Manufacturing: Why is it a Topic of Great Interest?

- Definition of particles
- Types of particles
- Possible reasons for the elevated presence of visible particles
- Hints in guidances on how to deal with visible particles
- Inspectional observations
- Expectations of API manufacturers, API users, API suppliers and supervisory authorities regarding visible particles in APIs

Foreign Matter in Pharmaceutical Excipients – How to Deal with "Technically Unavoidable Particles" (TUPs)

- Understanding the nature of contaminants
- Establishing the target profile to support risk assessment
- Establishing the risk profile of unavoidable foreign particles
- Understanding the source and mitigation to minimise the foreign particles

Incident Management – How to Identify the Source of Insoluble Matter

- Potential sources of insoluble matter
- Root cause analysis – examples of investigation techniques and aids
- Risk assessment: topics to be considered during the investigation/disposition decision

Acceptance Criteria for Particles in APIs

- Types of dosage forms and routes of administration
- Typical limits for particle size seen via a filter test
- Proposal for limits

Case Studies: Deviations Caused by Foreign Particles

How Can Routine Cleaning Procedures Detect or Minimize the Presence of Particles in API Production?

- Guides and Industry Standards regarding cleaning
- Equipment cleaning
- Production environment cleaning
- Equipment design considerations
- Detection/removal methods of particles
- Preventive measures

Analytical Control Methods for Particle Detection

- Design of appropriate analytical techniques
- Understanding the operational and investigative analytical methodologies

Foreign Particles in Excipients and Finished Product Quality and Safety

- Contamination Profile of Excipients meets Finished Product Quality Target Product Profile
- Excipient Process Risk Analysis and TUPP/ Particulate Contamination Profiling

Speakers

Dr Uwe Löffler
HELM AG, Germany

Dr Löffler is founder and leader of Uwe Löffler Consultancy and started his business just recently. Before that he worked 30 years in different positions in the pharmaceutical industry. His last position has been at HELM AG Hamburg where Dr Löffler held a position as Head of Department of a unit being responsible for the scientific Life-cycle-Management of generic drugs - beside that he held the function as a Quality Assurance Manager.

Dr Martin Melzer
gempex GmbH, Germany

Dr Melzer is Principal Consultant at gempex GmbH, Germany. Before that he was consultant for GMP/ GDP aspects, GMP -Inspector in a German Field Inspectorate in Germany, QA/ QC manager at a production site for AP/ and finished products, and head of laboratory for plant medicinal products.

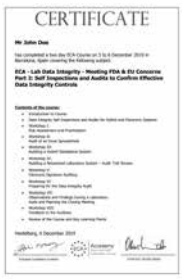
Peter Mungenast
Merck KGaA, Germany

Mr Mungenast studied Biology and Chemistry at the University in Karlsruhe. Then he worked in different functions for Merck KGaA. Since 1996 he is responsible for cleaning validation, training and different projects in the Quality Assurance department.

Dr Dirk Overrödder
Janssen, Schaffhausen, Switzerland

Dr Overrödder joined Cilag AG in 1995 and was employed in various positions in R&D and Compliance. Since May 2014 he is Head of QA Small Molecules (API & Drug Product) at Janssen's site in Schaffhausen, Switzerland.

Your Benefits


CERTIFICATE

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.

This Live Online Training is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org.

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Reservation Form (Please complete in full)

Handling of Foreign Particles in APIs and Excipients, Live Online Training on 25/26 January 2022

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

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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

Tuesday, 25 January 2022, 09.00 – 17.00 h CET
Wednesday, 26 January 2022, 9.00 – 13.00 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 e-mail 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 € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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 Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

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

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