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

4/5 February 2020 | Prague, Czech Republic

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 course 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 course 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)

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

Good practices to minimise the presence of particles in APIs – key preventive measures

- Typical construction materials in API manufacturing plants as source of particles
- Effective cleaning procedures
- Pretreatment of equipment/product contact utilities
- Inspection of equipment before and after production
- Cleaning after repairs
- Essential written procedures covering maintenance and cleaning procedures Environmental conditions during open handling in final stages of API manufacturing
- Effective training of operators

Analytical control methods for particle detection

- General conditions: design of an appropriate sampling process
- Application of different inspection techniques: filter test, visual inspection etc.
- Metal detectors, metal separators
- Weighing and/or visual inspection of pieces of equipment
- Periodic review of security sieves and/or filters

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

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 Rajnish Chhabra
QAR Solutions, The Netherlands

Dr Chhabra is founder and leader of QAR Solutions B.V. and started his business in September 2018. Before that he worked at DSM Sinochem Pharmaceuticals where Dr Chhabra held a position as Sr. Manager and Director Quality & Regulatory Affairs.

Dr Martin Melzer
Chemgineering Business Design GmbH, Germany

Dr Melzer is Senior Consultant GMP Compliance. Before that he was GMP -Inspector in a German Field Inspectorate in Hannover. During that time he was representing the German inspectorates in EMA and PIC/S Working Groups for the preparation of the new GDP-Guidelines.

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.

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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GERMANY

Reservation Form (Please complete in full)

Handling of Foreign Particles in APIs and Excipients, 4/5 February 2020, Prague, Czech Republic

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
Tuesday, 4 February 2020, 10.00 – 18.00 h
(Registration and coffee 9.30 – 10.00 h)
Wednesday, 5 February 2020, 9.00 – 13.00 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
Email prague@corinthia.com

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 and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

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

Conference language
The official conference language will be English.

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

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