ECA Academy
Your GMP/GDP Information Source

Handling of Foreign Particles in APIs

Preventive measures, analytical controls and incident management

SPEAKERS:

Nils Dickfeld
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Peter Mungenast
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Spain

18-19 May 2017, Barcelona, Spain

HIGHLIGHTS:

- Key preventive measures to minimise foreign particles
- Acceptance criteria for particles in APIs
- Analytical control methods for particle detection
- Good cleaning practices to minimise the presence of particles
- Particles in Packaging Materials
- How to identify the source of insoluble matter
- How to avoid the presence of foreign particles and insoluble matter – risk assessment and CAPAs

This education course is recognised for the ECA GMP Certification Programme „Certified API Production Manager“.
Please find details at www.gmp-certification.eu

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Objectives

During this course all relevant aspects regarding the control of particles in APIs 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 particles in Raw Materials and Packaging Materials can be minimised or avoided

Background

Visible particles, insoluble particles or matter or foreign particles in Active Pharmaceutical Ingredients (APIs) and related intermediates is a topic of great interest and 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 customers.

Particles have always been present in APIs but guidance from health authorities (EMA, FDA, others) or Pharmacopoeias (e.g. EP, USP) about particles in APIs is very limited. The APIC Guidance on Insoluble Matter and Foreign Particles in APIs is the only document so far providing guidance for a standard approach towards an appropriate control of foreign particles in APIs.

Target Audience

This course is designed for all persons involved in the manufacture of APIs. In particular, the seminar will be of interest to personnel from quality assurance, quality control and production.

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.

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

Analytical control methods for particle detection and identification

- 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

Incident management

- 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
- 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

How can routine cleaning procedures detect or minimise the presence of particles in API production

- Routine cleaning activities to reduce cross contamination and particle contamination
- Pretreatment of the equipment train before use
- Rinsing of the equipment to detect particles
- Inspection of equipment before and after production
- Cleaning after repairs
- Cleaning of packaging materials (drums, IBCs)

Case Study: Automatic detection and removal of visible foreign particles in APIs

- Foreign particles removal in powders and granules
- Types of foreign particles materials
- Concept of automated foreign particles detection and removal

Particles in Raw Materials and Packaging Materials

- Potential particles in raw materials/packaging materials
- Standard checks by QC
- Qualification of raw materials suppliers
- Communication with suppliers

Speakers

Nils Dickfeld
Meliscout
Nils Dickfeld studied Optical Technology and Image Processing. He has been working for PCE as development engineer and headed the department for Printing Verification. In 2012 he founded Melibokus Startup Scout (Meliscout) focusing on image processing for the chemical and pharmaceutical industry.

Dr Jörg Gampfer
Hovione, Portugal

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

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

Luisa Paulo
Hovione, Portugal
Luisa is Compliance Director at Hovione and Chair of APIC's Quality Metrics Task Force.

Dr Jordi Ruiz-Combalia
Spain
Dr Ruiz-Combalia has 30 years experience in the Active Pharmaceutical Ingredient Industry, where he has had different responsibilities. In his current position he has been working as R&D Director. Since 1992, he is a member of the Organic Chemistry Expert Group of the Real Farmacopea Española. Since 1994, he is member of the Groups of Experts of the European Pharmacopoeia, currently chairman of Group 11S and collaborates with the APIC (Active Pharmaceutical Ingredients Committee) in the GMP Working Group.

Easy Registration

Reservation Form:
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P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

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Date

Thursday, 18 May 2017, 10.00 – 18.00 h
(Registration and coffee 9.30 – 10.00 h)
Friday, 19 May 2017, 9.00 – 13.00 h

Venue

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 (93) 503 53 00
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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 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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