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GMP Certification Programme
Certified API Production Manager

## Speakers

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# Handling of Foreign Particles in APIs and Excipients

## Live Online Training on 10/11 February 2026

*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

All participants get free access to the current version of APIC's document "Guidance on Handling of Insoluble Matter and Foreign Particles in APIs".

## 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.

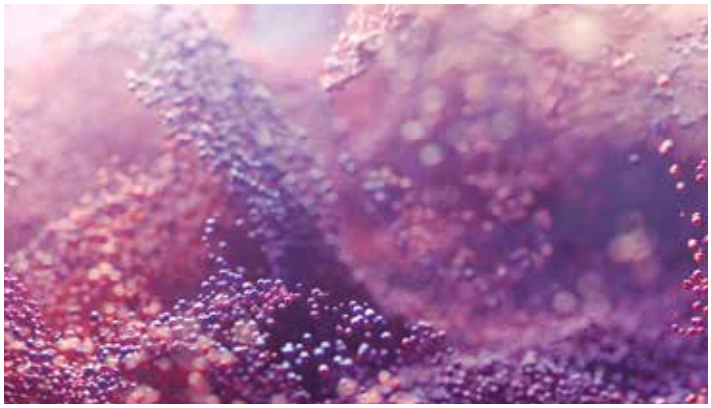
## Programme

### 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



### Foreign Particles – Quality Assurance Aspects

- 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 Cleaning can Minimize the Presence of Particles?

- Particles and Cleaning in GMP-Guidelines
- Equipment Cleaning vs Cleanroom Cleaning
- No Particles or low Particles? – Removal, Detection and Residuals

## Analytical Control Methods for Particle Detection

- Design of appropriate analytical techniques
- Understanding the operational and investigative analytical methodologies
- Case studies to identify the contaminants

## 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

### Your Benefit


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.

# Speakers

### Karl Heinz Freitag
Takeda Manufacturing Austria AG

Mr Freitag joined Takeda in 2014 and was responsible for quality oversight for visual inspection and secondary packaging processes at a multi-product manufacturing facility in Vienna, Austria. Since 2022, he has been acting as Product Quality Lead for plasma-derived therapies.

### Dr Rajnish Kumar
QAR Solutions, The Netherlands

Dr Kumar 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 Kumar held a position as Sr. Manager and Director Quality & Regulatory Affairs.

### 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.

### Robert G. Schwarz
GXP-TrainCon e.U., Austria

Robert G. Schwarz studied bioengineering and biotechnological quality management. After working as an EM-team leader at Baxter, Vienna from 2001 until 2005 he joined the validation department focusing on cleaning validation, also being the cleaning validation SME from 2016 until 2018. Additionally, since 2010, he has been a university lecturer in the field of biotech. In 2019 he became freelancing trainer and founded his consulting company GXP-TrainCon in 2022.

NEWS

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Reservation Form (Please complete in full)

## Handling of Foreign Particles in APIs and Excipients
## Live Online Training on 10/11 February 2026

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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## Date of the Live Online Training

Tuesday, 10 February 2026, 09.00 - 17.00 h
Wednesday, 11 February 2026, 09.00 - 13.00 h
*All times mentioned are CET.*

## Technical Requirements

We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings 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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The 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 22174.

## 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

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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