20 YEARS | ECA Academy
Your GMP/GDP Information Source

Sampling Strategies in the Pharma Industy

FDA/EU GMP compliant Sampling Plans with Efficient Procedures and Reduced Sampling

SPEAKERS:

Dr Raphael (Raphy) Bar
BR Consulting, Israel

Dr Gerald Kindermann
F. Hoffmann-La Roche, Basel, Switzerland

Philip Lienbacher
Shire, Vienna, Austria

12 – 13 June 2019, Copenhagen, Denmark

LEARNING OBJECTIVES:

- Regulatory and compendial requirements around sampling
- Acquaintance with basic sampling distributions
- Classification of non-conformities and allocating AQL to classes
- Acceptance Sampling Plans in ISO-2859-1/ANSI Z1.4
- Understanding the risks of producer and consumer associated with the sampling plans
- Sampling for visual inspection of particles in drugs
- How to effectively reduce the amount of samples to be tested?
- Sampling of powders (APIs and excipients) / Sampling according to the WHO Guide
- Tools for sampling in a pharmaceutical plant
- Sampling and inspection of packaging materials
- Charting and trending non-conformities and non-conforming items
- Good quality practice around sampling plans
- √N rule: its uses and misuses

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

Sampling Strategies in the Pharma Industry

12 – 13 June 2019, Copenhagen, Denmark

Objectives

The aim of this course is to discuss the process of the statistical sampling by attributes of units of finished drug products, of packaging materials (primary and secondary) and of medical devices as well as sampling of starting materials (APIs and excipients) and to define the prerequisites for implementing a system for reduced sampling and reduced testing for these products.
This course is also intended to give a practical training on the use of the most common sampling standards: ISO 2859-1:1999 and ANSI/ASQ Z1.4. These Standards are widely employed in various types of industries which are required by Regulatory Authorities to follow a statistically sound sampling plan. Starting with regulatory and compendial requirements around sampling, this course will also address charting and trending non-conformities and non-conformant items and good quality practice around sampling plans.

Background

Sampling of materials is one of the most important processes in pharmaceutical companies. Today there are **more and more detailed questions during regulatory GMP Inspections,** both in Europe and in the US (FDA) **about the amount of samples to be taken**.

Sampling by Attributes is a process of inspecting a representative sample of identical product units of product for presence or absence of non-conforming units or non-conformities before accepting or rejecting the whole lot of product. Regulatory agencies require a sampling plan that utilizes basic elements of statistical analysis or provide a scientific rationale for taking a representative sample according to the lot size.
In the light of these regulatory requirements, one may wonder whether the Square Root of N is a statistically valid sampling plan.

According to the revised Chapter 6 of EU GMP Guide, the sampling plan used should be appropriately justified and based on a risk management approach.
Representative samples should be taken and recorded in accordance with approved written procedures.

FDA requires as well in the Code of Federal Regulations (21 CFR Part 211.84), that sampling should be done upon statistical criteria.

In the past the Military Standard 105 D was commonly used in the pharmaceutical industry, but this standard has been withdrawn and is now obsolete. Today, either the ISO Standard 2859:1-1999 or the ANSI Z1.4 are applied and the course participants will thus learn how to read and to use this standard for selecting a sampling plan with an understanding of the associated producer and consumer risks.

Target Audience

This GMP Education Course is directed at all those employees from quality control units and production units in the pharmaceutical industry who are competent or responsible for sampling, testing and release of starting materials (APIs and excipients), packaging materials (primary and secondary) as well as finished pharmaceutical products. This course is also of interest to personnel from quality assurance and to those employees from API, excipient or packaging material suppliers who want to inform themselves about the requirements of the pharmaceutical industry on the testing of these materials.

The course does not require prior knowledge in sampling and statistics. It teaches the participant how to use the multiple tables and plots of the Standard for designing a sampling plan.

Relevant tables from the ISO Standard
ISO 2859-1:1999
Sampling procedures for inspection by attributes
Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection –

will be made available to the course participants for the purpose of practicing.

Programme

Regulatory and compendial requirements around sampling

- History of sample taking and sampling
- Sampling plans
- Regulations: US GMPs, EU GMPs, WHO, PIC/S
- Articles sampled in pharma and bio-tech (discrete units vs. granular or liquid materials)

Acquaintance with basic sampling distributions

- What is Acceptance Sampling:
- Sampling Attributes vs. sampling by variables
- Nonconforming items and non-conformities
- Hypergeometric distribution
- Binomial distribution
- Poisson distribution
- Normal distribution
- Concept of probability of acceptance

Classification of nonconformities and allocating AQL to classes

- Classification schemes
- Classification of non-conforming items (Class A, B, C...)
- Classification of non-conformities (Class A, B, C...)
- Examples of non-conformities in pharmaceutical preparations (Optional)
- Allocating AQL to various classes

Acceptance Sampling Plans in ISO-2859-1/ANSI Z1.4

- Structure of the Standards
- Single sampling Plan
- Double sampling Plan
- Multiple sampling Plan
- Switching rules between Normal-Tightened-Reduced inspections
- Producer and consumer risks
- Acceptance sampling of an isolated lot using ISO-2859-2

WORKSHOP I: Step-by-step use of ISO-2859-1/ANSI Z1.4

- Procedure for a Single sampling Plan (Exercises)
- Procedure for a Double sampling Plan (Exercises)
- Procedure for a Multiple sampling Plan (Exercises)
- Exercise in using tables of sampling

Risks in sampling with ISO-2859-1/ANSI Z1.4

- Probability of acceptance
- Producer risk
- Consumer risk
- Operating Curve
- Misconceptions of sampling
- Determining product and consumer risks in a sampling plan

Sampling for visual inspection of particles in parenteral drugs

- Regulations for sampling for visual inspection
- Types of sampling
- AQL for sampling
- Policy of sampling and inspection

How to effectively reduce the amount of samples to be tested?

- Reduced Testing concepts
- Internal testing vs. external testing
- Using the suppliers CoA instead of in-house testing
- Use of devices to reduce amount of samples (Rapid ID testing, Rapid Mibi Testing)

WORKSHOP II Implementing Reduced Testing

- Exercise implementation of reduced testing concepts on real life examples

Sampling according to the WHO Guide

- Sampling of starting materials
- Full testing vs. testing for identity
- Qualified supplier vs. unreliable supplier
- n, p and r plans
- Criticism of the sampling plans

Sampling of Powders (APIs and Excipients)

- Regulatory requirements
- Risk assessment for sampling
- Sampling plans / sampling schemes
- Training for sampling
- Retention / Reference samples
- Starting material Identity testing
- Sampling for the purpose of Assay
- Sampling of raw materials (WHO guide, n/r/p-sampling plans)

Tools for Sampling in a pharmaceutical plant

- Techniques of drawing samples
- Prerequisites / Requirements for correct sampling
- Sampling devices and containers

Sampling and inspection of packaging materials

- Regulations and guidance for packaging and labeling control
- Primary packaging: containers and closures:
  - What is inspected?
  - AQL for sampling
  - Defects in PPMs
- Secondary packaging: labels, leaflets and folded boxes:
  - What is inspected?
  - AQL for sampling
  - Sampling in printing house
  - Sampling in manufacturer's site
  - Defects in labels

Charting and trending non-conformities and non-conforming items

- Run chart and control chart
- Charting the number of defectives
- Charting the number of non-conformities
- Detecting a trend in your inspection quality
- Determining your process average
- Does your inspection data confirm your AQL?
- Deriving statistically your allowed percent defectives

Good quality practice around sampling plans

- How to document the sampling system within the company?
- How to incorporate it into specifications (FDP/raw materials)?
- How to incorporate it into the LIMS system?
- What you should discuss with the supplier! (tailgate samples, pre-delivery shipment samples, statements of homogeneity)

√N rule: its uses and misuses

- Origin of the rule
- Uses and misuses
- How confident is it?

Speakers

Dr Raphael (Raphy) Bar

BR Consulting, Israel

Raphael Bar is presently a pharmaceutical consultant for the Pharma and bio-Pharma industries. He is consulting various companies and provides development and analytical support to investigational, generic, new drugs as well as combination device-drug products and CMC project management. With a doctorate in Chemistry (1984), Dr. Bar joined (1995) Teva Pharmaceuticals and headed for three years the Analytical R&D Laboratory. He was involved in preparation of ANDA files. He then joined Pharmos where he managed the quality control and R&D laboratory till 2007. As Senior Director of Analytical Development he was actively involved in preparation of CMC packages for clinical trial studies. From 2009 until June 2015, he was a member of the scientific advisory board of global PDA (USA).

Dr Gerald Kindermann

F. Hoffmann-La Roche, Basel, Switzerland

Dr Gerald Kindermann is Product Quality Manager at the Global Quality Group at Roche working on quality systems. Before that he was Group Leader Quality Control and Quality Manager for the Supply Center.

Philip Lienbacher

Shire, Vienna, Austria

Philip Lienbacher started his career within Shire (previously Baxter/Baxalta) in 2008 in Vienna. Since then he held a variety of roles inside quality. In 2014, he accepted the position of Manager Global Material Lifecycle Management Systems and is responsible for a team of process experts and project managers. His responsibility includes the global ownership for Receiving & Inspection as well as the general testing and method deployment-strategy in the company.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
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

Date

Wednesday, 12 June 2019, 09.00 h - 18.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 13 June 2019, 08.30 h - 16.30 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 (0)33 96 50 00
Fax +49 (0)33 96 55 00
Scandinavia.meetings.events@radissonblu.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 event. 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49-62 21/84 44-0
Fax +49-62 21/84 44 84
info@concept-heidelberg.de,
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Günter Brendelberger (Operations Director)
at +49-62 21 / 84 44 40 or per e-mail at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Rouwen Schopka (Organisation Manager)
at +49-62 21 / 84 44 13 or per e-mail at
schopka@concept-heidelberg.de.

Social Event

On the evening of the first course day, all participants and speakers are invited to a guided sight seeing tour and a nice dinner afterwards.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge.
More information about ECA Academy can be obtained on the Website https://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy

- free access to the members' area where you always find the latest update of the "GMP Guideline Manager" online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy. And as member you can also get to this detailed tree with the GMP WebApp on your smartphone or tablet PC.
- a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Sampling Strategies in the Pharma Industry

12 – 13 June 2019, Copenhagen, Denmark

☐Mr ☐Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **PO Number if applicable**

Street/P.O. Box

City | Zip Code | Country

Phone | Fax | E-Mail (please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
German law shall apply. Court of jurisdiction is Heidelberg.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012)

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.