



**PEC** PHARMA  
EDUCATION  
CENTER

March 7, 2023 - ONLINE  
March 10, 2023 - ONLINE

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# Pharmaceutical Risk Assessment techniques and applications

# Abstract

The introduction in recent years of the concept of Quality Risk Management inside GMP guidelines has caused a change in the regulatory requirements for the pharmaceutical industry.

Starting from the analysis of these important changes and the "ICH Q9 - Quality Risk Management" guideline, aim of the training "Pharmaceutical Risk Assessment: techniques and applications" will be to illustrate to the attendees the process of Quality Risk Management and all its phases: Risk Assessment, Risk Control, Risk Review and Risk Communication. The most widely used Risk Assessment techniques (Fishbone, Root Cause Analysis, FMEA, FTA, Risk Ranking and Filtering) will be examined and framed in the contexts in which they are most commonly applied. Emphasis will be put on making the attendee sufficiently familiar with these tools to help him tackle real life situations. To this end, the expert will showcase some case studies to better underline how to correctly put theory in practice.

## Who Should Attend

This training is addressed to professionals involved in Quality Assurance, Validation, Production, Quality Control, Engineering.

## Learning Objectives Of The Training "Pharmaceutical Risk Assessment: Techniques And Applications":

1. Understand how the application of Quality Risk Management has changed the regulatory requirements
2. Learn in detail all the steps that make up the Quality Risk Management process
3. Understand the main Risk Analysis Tools for an effective application in your own business reality
4. Identify the most appropriate Risk Analysis tools for each scenario
5. Learn which Risk Assessment models have been most applied to address regulatory requirements

# Speaker



## **Daniele Calzolari**

Graduated with a Master's degree in Chemistry of Biological Molecules from the University of Florence in 2016, Daniele Calzolari works at Pharma D&S, a consultancy company in which over the years has carried out various activities: supporting companies in drafting GMP documentation (SOP, PQR, OQ/PQ reports), in the preparation of inspections (gap analysis), in performing audits to suppliers, in the execution of GMP Quality System Training and, its main activity, in the development of Quality Risk Management methodologies concerning process validations, Cleaning Validation, Cross-Contamination, control of elemental impurities (ICH Q3D), control of the presence of Nitrosamines in APIs and pharmaceutical products.

# Program

Times are UTC +1 (Rome time)

9:00 am - 1:00 pm SESSION MARCH 7

9:00 am - 12:00 am SESSION MARCH 10

- QRM - GMP Update and Pharmaceutical Quality System
- ICH Q9 - Quality Risk management
- Overview of the main Risk Assessment Tools and focus on Fish Bone, Root Cause Analysis, FMEA, FTA and Risk Ranking and Filtering
- Examples of application of the tools with presentation of case studies:
  - Risk Assessment approach ICH Q3D (Elemental Impurities in drug products)
  - Nitrosamines Risk Assessment
- Supplier Risk Assessment (to determine audit frequency)
- Application of QRM in Cleaning Validation: definition of Cleaning Plan, Worst case product and calculation of limits



## **ENTRY FEE**

**800 €**

5% discount for enrollments within 1 month of the course

10% discount for enrollments within 2 months of the course

**Discounts are not cumulative**  
**VAT not included**

**For discounts on multiple enrollments, please contact [info@pharmaeducationcenter.it](mailto:info@pharmaeducationcenter.it)**

## **TERMS OF PAYMENT**

Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa - Firenze, IBAN IT81P0503402801000000007431, Bic/SWIFT BAPPIT21N25 made payable to Pharma Education Center S.r.l., Via dei Pratoni 16, 50018 Scandicci (FI), VAT number 02173670486, specifying event title along with name and surname of the participant enrolling. Attendance to the event will be allowed upon payment received. Invoice of payment will be issued after the second half of the month after the course.

**For further information and/or further assistance please contact (+39) 0550465181 or email: [amministrazione@pharmaeducationcenter.it](mailto:amministrazione@pharmaeducationcenter.it)**

# **PEC** PHARMA EDUCATION CENTER

## **COURSE/EVENT CANCELLATION**

If the minimum number of participants is not reached, Pharma Education Center reserves the right to cancel or schedule the event for another date. Formal communication will be given within 5 days before the event date. In this case Pharma Education Center will refund the registration fee in full and without additional charges. Alternatively, the participant can request a spendable coupon for participating in another PEC event scheduled in the current year.

## **CANCELLATION TERMS**

In order to cancel enrolment to a event, please email [info@pharmaeducationcenter.it](mailto:info@pharmaeducationcenter.it) within 2 weeks before the starting date of the event. Once this term will be expired, the entire fee will be charged.

## **PARTICIPANT REPLACEMENT**

It is possible to replace a participant attendance without additional cost, simply by contacting [info@pharmaeducationcenter.it](mailto:info@pharmaeducationcenter.it). It is asked to notify the participant replacement request within 5 days before the starting date of the course/event, specifying the full name and surname of the enrolled participant as well as the full name and surname of the substitute.

## **HOW TO REGISTER**

Please, fill the form on the web site <https://www.pharmaeducationcenter.it/>

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