PEC PHARMA EDUCATION CENTER

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Effective management of Annual Product Review (APR), Process Quality Review (PQR) and Corrective Actions-Preventive Actions (CAPA)

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Abstract

The training course "Effective management of Annual Product Review (APR), Process Quality Review (PQR) and Corrective Actions-Preventive Actions" is addressed to pharmaceutical professionals dealing with Quality Assurance that wish to deepen their knowledge on these pivotal documents.
The training is structured in two parts.
In the first part, the current regulatory requirements (EMA, FDA) for issuing APRs and PQRs are explained in detail for each single chapter. The organizational flow, timing, definition of the actors involved and the collection of supporting data to ensure the effective and timely issuance of the document, in compliance with regulatory requirements, will be examined. This theoretical explanation will be then followed by a practical example of a PQR, with detailed comments, helpful for the attendee, as well as hints aimed at pursuing "Continuous Improvement".
In the second part of the course, the CAPA Management System and the management of Deviations, as integral part of the Quality Management System, will be thoroughly illustrated.
Attendees will be actively involved during the discussion, so to address questions and doubts and help them gain the right tools to apply in their daily job routine.

Who should attend

This training is mainly addressed, but not limited to, professionals belonging to Quality Assurance, Quality Control, Compliance and Operations.

What you will learn

- Understand the role, importance, and learn in depth the contents of APR/PQR reports
- Be informed on the EU and US latest regulatory requirements for these documents
- Spot the actors involved and define a timely data collection
- Learn all about CAPA and deviations management system

Speaker

Filippa Lo Biundo, MSc
Graduated in Pharmaceutical Chemistry and Technology at the University of Pisa (Italy), she has started her activity in pharmaceutical consultancy covering the role of Compliance and Maintenance Consultant, she now covers the role of Quality and Process Consultant. Over the years she has carried out several activities: supporting companies in the preparation for GMP and medical device inspections according to MDR 2017/745 (gap analysis), development of Quality Risk Management and drafting risk assessments, performing trainings on GMP Quality Systems and supporting the drafting of GMP documentation, in particular SOP, APRs and RFPs and evaluation of RFPs drafted by third parties.

Program

Times are UTC +1 (Rome time)
Training session: 9:00 am – 1:00 pm

- EU, US and ICH regulatory requirements, definition of responsibilities and role of the APQR in the Quality Management System
- How to efficiently structure data collection, timing, definition of actors involved, merging criteria and rationale
- The chapters of the APQR: complete example of an APQR with comments on the main contents of the individual chapters
- CAPA Management System: overview of cGMP requirements and guidelines EMA/FDA
- CAPA: sources, critical steps, and example of a CAPA document
- Deviations: introduction and relationship between CAPA and deviations

ENTRY FEE
550 €

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VAT not included

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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

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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 refound 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 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 without additional cost, simply by contacting info@pharmaeducationcenter.it. It is asked to notify the participant replacement within 5 days before the starting 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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