QUINTESSENCE ENTERPRISES LTD
Vocational Training Centre

LABORATORY DATA INTEGRITY

Synchronous Remote E-learning

Identify the principles of data integrity, how laboratory data are generated, processed and reported and work with the data review and audit processes.

16 & 17 November 2020
08:30 - 17:15

Course's fee:

HRDA Beneficiaries[1]:
€70,00 + VAT[2]
More than 3 participants:
€600[3] +VAT

Non HRDA Beneficiaries:
€900[4] + VAT

ROBERT MCDOWALL
Pharmaceutical Consultant

Training Method: Blended learning with synchronous and asynchronous electronic learning.

Course Content

Day 1

How did we get here?
A Data Integrity Model
Principles of data integrity
EU and FDA GMP Regulations Impacting Laboratory Data and Results
Overview of DI guidance documents
MHRA and WHO Data Integrity Guidances, FDA and PIC/S data integrity guidance documents, APIC data integrity guidance document, GAMP and PDA data integrity guidance documents
Principles for the Generation of Data
A flexible analytical data life cycle, Static and dynamic laboratory data, Observational tests and instrument tests, Qualified analytical instruments and validated software, Integrity issues
WORKSHOP I:
Generation of Data
What are the requirements for data integrity?
Three scenarios covering
a paper system, a hybrid system, a client server electronic system
Processing and Reporting of Data
Paper / hybrid based systems, Networked systems with electronic records and signatures,
Calculations and transformation of data manually and by computer applications, Application of ALCOA+ principles to the process. Calculating the reportable value and comparison with the specification, Paper processes versus electronic processes

Day 2

Presentation: Understanding complete data and raw data (FDA & EU terms)
WORKSHOP II:
Processing and Reporting of Data
Reviewing an analytical record, Scenario covering paper based records and an electronic system
Reviewing Data
Role of the second person review, Determination that the reportable result is correct, Identification and correction of errors for paper and electronic systems, Audit trail review
WORKSHOP III: Three Data Review Mini Workshops
Data Review of a Paper Record, Audit trail review, Spreadsheet printout, Chromatographic integration and data integrity violations, Ten Compliance Commandments
WORKSHOP IV: Facilitated Discussion
Paper, Hybrid and Electronic Reporting Processes, Discussion of the strengths and weaknesses of reporting processes

Benefits in attending:

- Identify the data integrity requirements of a GMP regulated laboratory in Pharmaceutical organizations and contract labs
- Ensure compliance with the EU and FDA Good Manufacturing Practice Regulations Impacting Laboratory Data and Results
- Explain the ALCOA+ Principles
- Apply the ALCOA+ Principles to Laboratory Data
- Act in a "second person review" process to ensure that data issues are picked up and resolved in a thorough and effective manner
- Collate and report results
- Perform Self Inspections and Audits to Confirm Effective Data Integrity Controls
- Defend the laboratory positions on data integrity policy and procedures

Βεβαιωθείτε για τις ανάγκες και προσδοκίες σας:
Πολιτική Ποιότητας Quintessence Enterprises Ltd

Δείτε την Πολιτική Απορρήτου της Quintessence Enterprises Ltd

Quintessence Social Networking:

(1) The VAT is calculated over the amount of the total fee (including the subsidy (€1.600,00))
(2) Company visit not included

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ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ

Οργανισμός: ……μM* ☐ M* ☐

Οικονομική Δραστηριότητα ……Κίνητρα Συμμετοχής** 1 2 3

Τηλ:…… Φαξ:…….. Email:……..
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Επώνυμο και Όνομα Συμμετεχόντων: email: Κιν. Τηλ.:***
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* μM: Μικρομεσαία Επιχείρηση, M: Μεγάλη Επιχείρηση
** Κυκλώστε: 1. Προσωπική Ανάπτυξη, 2. Νομοθετική Συμμόρφωση, 3. Επιχειρησιακή Αριστεία
***Για σκοπούς άμεσης επικοινωνίας, αποστολής μηνυμάτων SMS κτλ. σχετικά με το σεμινάριο

Οι προδιαγραφές των προγραμμάτων εγκρίθηκαν από την ΑνΑΔ.

Αρχή Ανάπτυξης Ανθρώπινου Δυναμικού Κύπρου