Good Documentation Practice and Record Keeping Regulations (FDA & EMA)

Date : May 03, 2018 - 08:30 AM

Event URL : http://www.BostonEventsList.com/events/good-documentation-practice-and-record-keeping-regulations-fda-ema-may-2018-1521119252

Organizer : NYMT

Venue :

Location : TBA Boston, MA United States,
Boston, MA, US, ZIP: 02128

Good Documentation Practice and Record Keeping Regulations (FDA & EMA)

Good documentation Practices (GDP) is an essential factor that needs to be closely followed by the personnel in any regulated environment as a process for a successful project completion including observations of unanticipated responses that are required to be accurately recorded and verified. This one-day workshop covers the essentials of GDP, its definition, purpose, and importance. Then expands on general rules and principles of GDP (US & EU), General tips for Laboratory Notebook documentation and finally discussing GDP enforcement by regulatory bodies in different countries with some examples of FDA citations and warning letters for different points presented in the session. In several occasions, group activities will be presented to find errors in documents based on the information provided in the class.

Learning Objectives:

In this seminar you will gain a basic to moderate knowledge of definition, purpose, importance of GDP, General rules of GDP, GDP as applies to laboratory notebook documentation, US Pharmacopeia General Chapter introduction "Good Documentation Guidelines", A very brief introduction to European Union (EU) GDP, and finally its enforcement along with some observation samples from FDA.

Areas Covered:

-
    - Definition, Purpose, and Importance
    - General Rules and Principles of GDP
        - Requirements of Records
        - General Tips in GDP:
            - Signature / initial and the meaning
            - Copying records
            - Document maintenance
            - Recording the time and date
            - Correction of errors
            - Rounding rules
            - Back dating
            - Missing data
            - Voiding / cancelling records
            - Recreating / rewriting records
            - Deviations
        - General Tips for Laboratory Notebook Documentation:
            - Assignment of Lab notebook
            - How to properly document in lab notebooks
            - How to include tables / graphs
            - How to attach instrument print outs
            - How to include metadata
            - How to reference lab notebook
            - How to store the completed lab notebooks
        - US Pharmacopoeia General Chapter
        - Rules Governing Medicinal Products in the European Union (Vol. 4: Documentation)
            - What is new in the Latest Version?
            - Outline of EU GDP Regulations
        - GDP Enforcement (examples from FDA warning letters)

Who Will Benefit:

-
    - Anybody who works in a regulated environment
    - Manufacturing & Production Personnel / Managers
    - Research and Development Personnel (R&D) / Managers
    - Quality Assurance & Quality Control Personnel / Managers
    - Laboratory Personnel / Managers
    - Validation Specialists
    - Clinical trial personnel

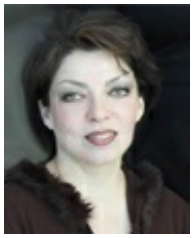
- Project Managers

DAY 01(8:30 AM - 4:30 PM)

- 08:30 am – 08:59 am : Registration and Meet & Greet.
- 09:00 am – 11:00 am
  - Seminar objectives review, expectations and scope.
  - Definition of GDP
  - Purpose of GDP
  - Importance of GDP
  - Requirements of records
  - General rules of GDP:
    - Signature / initial and the meaning
    - Copying records
    - Document maintenance
    - Recording the time and date
    - Correction of errors
    - Rounding rules
    - Back dating
    - Missing data
    - Voiding / cancelling records
    - Recreating / rewriting records
    - Deviations
- 11:00 am – 12:00 pm
  - General Tips for Laboratory Notebook Documentation
  - Assignment of Lab notebook
  - How to properly document in lab notebooks
  - How to include tables / graphs
  - How to attach instrument print outs
  - How to include metadata
  - How to reference lab notebook
  - How to store the completed lab notebooks
- 12:00 pm - 01:00 pm Lunch
- 01:00 pm – 02:00 pm
  - US Pharmacopeia General Chapter introduction “Good Documentation Guidelines”
  - History of the Chapter
  - The purpose of the Chapter
  - Outline of the Chapter
  - Rules Governing Medicinal Products in the European Union (Vol. 4: Documentation)
  - History of the Regulation in the EU
  - The 2011 Update
  - The list of changes in the 2011 update
  - Outline of the EU GDP guideline
  - Discussion into the guideline

- 02:00 pm – 03:00 pm
    - GDP Enforcement
    - How to avoid getting warning letters
    - Examples from FDA warning letters
- 03:00 pm - 04:00 pm 21 CFR 11 (electronic records and electronic signatures)
- 04:00 pm - 04:30 pm Question & Answer session

Speaker



Dr. Afsaneh Motamed Khorasani
Vice President of Medical Affairs, Easy Global Training

Dr. Afsaneh Motamed Khorasani, PhD, is a Medical and scientific Affairs expert and a Senior Scientist with a strong background in biomedical science and clinical trial/research. She has a tenured and diverse range of experience in medical affairs, basic and industrial clinical research and development, clinical trials, Medical and regulatory writing and intellectual property. She is currently the Vice President of Medical Affairs at Easy Global Training, which is a US-based firm providing global regulatory, quality and medical affairs training backed by consulting. Before joining this company, Dr. Motamed Khorasani has served as an independent consultant, director of medical affairs, senior medical sciences liaison, senior scientist and senior medical analyst at Merck (MDS), Johnson & Johnson, United States Pharmacopeia Convention (USP), Amgen, Baxter International, Covidien (eV3), Radient Pharmaceuticals, AMDL Diagnostics, Microbix Biosystems, Neometrix Consulting, Mount Sinai Hospital, Princess Margaret Hospital, and Vancouver General Hospital.

She has more than 20 years of experience and many National and international certificates in GLP, GMP, ICH-GCP and global regulatory compliance for clinical trials and is a member in a number of professional associations, including: American Association of Cancer Research (AACR), American Medical Writers Association (AMWA), Regulatory Affairs Professional Society (RAPS), American Society of Quality (ASQ), Project Management Institute (PMI), and Intellectual Property Institute of Canada (IPIC). Dr. Motamed Khorasani's research has focused on high throughput approaches in the context of cancer informatics with a particular interest in the use of comparative analysis for the mining of integrated oncology datasets that include protein-protein interaction and gene expression profiling. She has published and presented more than 50 papers, abstracts and articles in highly regarded scientific journals and high profile conferences and scientific meetings.

Please contact the event manager Marilyn (marilyn.b.turner(at)nyeventslist.com) below for: www.BostonEventsList.com

- Multiple participant discounts
- Price quotations or visa invitation letters
- Payment by alternate channels (PayPal, check, Western Union, wire transfers etc)
- Event sponsorship

NO REFUNDS ALLOWED ON REGISTRATIONS
Prices may go up any time. Service fees included in pricing.

This event is brought to you by:
MetricStream, Inc. - NewYorkEventsList
http://www.NyEventsList.com
http://www.BostonEventsList.com
http://www.SFBayEventsList.com

VIO180109CEV JOA180315CEV

Event Categories :