

## **2018 Data Integrity Seminar : FDA/EU Requirements and Implementation**

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**Date :** Apr 17, 2018 - 08:30 AM - Apr 18, 04:30 PM

**Event URL :** <http://www.BostonEventsList.com/events/2018-data-integrity-seminar-fda-eu-requirements-and-implementation-apr-2018>

**Organizer :** Chinmoy Roy

**Venue :** San Diego CA

**Location** Homewood Suites by Hilton San Diego-Del Mar 11025 Vista Sorrento Parkway, San Diego CA 92130.,  
Hollywood, FL, US, ZIP: 33021  
Phone: 347 282-5400

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**Ticket Price: Seminar One Registration \$ 1095 |Special Group Discount Register for Four attendees \$ 3995**

### **Description**

Data Integrity audits project a moving goal post. Issues that were top warning letter vote getters have made way for newer ones to include Cybersecurity etc. Our Data Integrity courses which are offered around the world are renowned for addressing such evolving trends. Consequently, they have attracted record attendances. Attendee feedback suggests the uniqueness of our offerings. Particularly significant is the feedback from those who attended similar courses offered by other companies.

Chinmoy Roy, our course instructor, is one of the world's first to design, implement and obtain "fit for use" certification for the world's largest paperless biologics manufacturing facility in the late 1990s. He is a practicing Data Integrity auditor. Former FDA inspectors include him on their 3rd party and mock audit teams. He also continues to provide consulting services in the design and implementation of Data Integrity infrastructures to major multinational companies. His lucid and pragmatic presentation style and interaction with the trainees/conference attendees, has earned him the "Speaker of the year" award from attendees of the world's prestigious conference on Data Integrity.

## **Areas Covered**

- What is Data integrity
- Data Life Cycle design and controls
- Elements of a Data Integrity Assurance program
- Roles and responsibilities of different groups in ensuring data integrity
- What data integrity SOPs do auditors expect to see during audits
- Validating Data Integrity

## **Who will Benefit**

- Pharmaceutical industry / Medical device industry / Healthcare industry personnel
- Developers of software for use in Life Sciences industry
- Validation service providers, IT service providers
- Manufacturing personnel, Manufacturing Automation system vendors and system integrators
- Regulatory Affairs group, Quality Unit
- Laboratory personnel
- Users of Cloud
- Clinical Trial Sponsors

## **Learning Objectives**

- Some advanced Data Integrity topics include:
  - Data Integrity triad
  - Data Integrity Maturity Model
  - Developing critical thinking skills
  - Data Integrity Audit trends

## **Event Categories :**