GMQA Data Integrity Webinar Agendas:

The summary of the content of each of the upcoming data integrity webinars are as follows:

Data Integrity Overview—Good Documentation Practices for Electronic Data

This 90-minute webinar provides an overview of the key principles for assuring data integrity in GXP- regulated organizations and provides detailed examples of the foundational principles of Good Documentation Practices and how to apply these to both paper and electronic records. Examples will be presented for GMPs (laboratory and production), GCPs, GLPs, and Medical Devices. The webinar provides an additional 30 minutes for Q&A from 12:30-1:00pm ET for those interested.

Example topics include:

- What is "Data Integrity"?
- Regulatory Update & Focus
- Key Quality Management System Controls
- Data Life Cycle
- Paradigm Shift—paper to electronic
- 21 CFR Part 11 as "Good Documentation Practices for Electronic Data"
- US FDA & EU Observations
- Q&A

Reviewing Electronic Data & Metadata, such as Audit Trails

This 90-minute webinar provides an overview of the GXP requirements for review of original records, including source electronic records and meaningful "metadata". The discussion will include defining "metadata" and "critical" data, including data that is essential to assuring patient safety, product quality, and the reliability of regulatory submissions. We will discuss the application of holistic Quality Risk Management principles to conduct risk-based reviews that add value and strengthen the confidence of our decision-making. The case study presented will provide participants the opportunity to review both paper and electronic data sets, as well as metadata, such as audit trails. This hypothetical scenario raises important questions regarding our historical data review approaches and calls us to modernize our data review strategies to design the most efficient and effective techniques to assure patient safety and product quality. The webinar provides an additional 30 minutes for Q&A from 12:30-1:00pm ET for those interested.

Example topics include:

- Data Review—General Concepts
- What is "Data" and "Metadata"?
- Audit Trails & Review? Which Ones? How Often?
- Where should review take place in context of the Data Life Cycle?
- Critical Thinking Skills to Identify Patterns
- US FDA & EU Observations
- Case Study
- Q&A

Management Culture & Data Integrity Governance Plans

This 90-minute webinar discusses the potential root causes of intentional and unintentional lapses in data integrity and how a robust Management Governance Program and healthy Quality Culture may be designed to prevent, detect, and respond to these risks. The discussion will include developing plans to remediate existing gaps and designing and integrating data integrity controls into current Quality Systems, Enterprise Risk Management, and 'end-to-end' Corporate Data Governance program frameworks. We will also discuss ideas for monitoring and ensuring the effectiveness of the data integrity program through Quality Metrics and Management Review. The webinar provides an additional 30 minutes for Q&A from 12:30-1:00pm ET for those interested.

Example topics include:

- Management & Quality Culture to Assure Data Integrity
    - – Falsification vs Bad Practice
    - – Cressey's 'Fraud Triangle'
    - – Managing Behavior
    - – Fixing 'the System' to Foster Data Integrity
- Possible Governance Models for Data Integrity
    - – Risk-Based Plans and Organizational Structures
    - – Quality Management System enhancements, such as
        - Managing Out-Sourced Relationships
        - Introducing Data Life Cycle
        - Forensic Auditing
    - – Metrics and Reporting to SLT
- Q&A

Data Process Mapping & Data Life Cycle

This 90-minute webinar discusses the exciting new program of "Corporate Data Governance" that is being implemented within and outside the GXP-regulated industries as all organizations increasingly appreciate the importance and value of accurate, consistent, and reliable data for effective decision- making. To achieve this, many companies are developing data process maps as "useful tools" (ref: ICH Q10) in their Corporate Data Integrity Governance Programs. The exercise of mapping data processes, assessing data integrity risks, reducing risks by implementing mitigating controls, continuously reviewing risks, and reducing residual data integrity risk applies to all GXP-regulated activities across the entire product life cycle. This webinar will discuss these principles and potential pitfalls associated with various approaches to building reliable 'end-to-end' data life cycles for effective knowledge management. The webinar provides an additional 30 minutes for Q&A from 12:30-1:00pm ET for those interested.

Example topics include:

- Where does Data Life Cycle fit into the Quality Management System?
- Quality Risk Management of Data Life Cycle

- Process Mapping Tools
- Defining "Critical" Data and "Meaningful" Metadata
- Assessing Controls to Prevent & Detect Data Integrity Issues during Inspections of Data Processes
- Case Studies
- Q&A

Data Process Mapping Case Study Examples

This 90-minute webinar continues the discussion from the previous day's webinar on CGxP Data Process Mapping by reviewing several examples, approaches and case studies for data process mapping. Examples will illustrate varied methodologies for applying Quality Risk Management principles to reduce data integrity risks in critical data processes. Discussions will include ideas for approaches to assure that activities are value-added and cost effective. The webinar provides an additional 30 minutes for Q&A from 12:30-1:00pm ET for those interested.

Example topics include:

- Process Mapping Tools
- Case Studies
- Discussions & Idea Sharing
- Q&A

Costs for 90-minute Data Integrity webinars (with additional 30 minutes Q&A):

Individual - $399/webinar;
Groups of 2-4 persons - $699/webinar
Groups of 5-10 persons - $1625/webinar
Groups of more than 10 - $2500/webinar

**Please note*: Each registration fee provides for a single log-in link at a single site, so groups must participate in a classroom-like arrangement. Please do not forward the webinar link you receive; there are a limited number of links available in the GoTo Meeting system, and attendance and receipt of handouts are restricted only to paid participants with one link per payment received.

TERMS & CONDITIONS: Individuals registering for all GMQA training events are required to abide by the **terms and conditions** set forth by GMQA regarding photography & video permissions and non-disclosure agreement. GMQA strictly prohibits all other audio and video recording of GMQA training events.

CANCELLATION POLICY *Full refunds of registration fees will be made with cancellations received more than 24 hours prior to the webinar's start time. Refunds are not provided for no-shows nor for cancellations received after the webinar link has been provided, however, participant substitutions are permitted if requested via info@GMQA.net prior to the webinar's start time.*