Peter E. Baker
President
Live Oak Quality Assurance
pbaker@liveoakqa.com

LIVEOAK
QUALITY ASSURANCE

Quality Intelligence Workshops – AGENDA 2023

Day 1

Timing	Content
8:30 – 9:00	Refreshments & Networking
9:00 – 11:00	Introduction to Quality Intelligence: • Current Regulatory Framework • Introduction to Key Fundamental Concepts • What data should be included in our QI efforts? This session will feature an introduction to current regulatory expectations for the use of Quality Intelligence in GXP applications. For example, Data Integrity/Data Governance expectations when QI tools are used for decision-making. We will discuss how to ensure the use of our QI tools does not violate the existing regulatory framework.
11:00 – 11:20	Coffee Break
11:20 – 12:30	Introduction to Quality Intelligence Tools: • Dashboarding • Golden Batch • Natural Language Processing • Digital Twins This session will provide an introduction to a variety of QI tools, and how they can be used to enhance Quality decision-making.
12:30 – 13:30	Lunch

Peter E. Baker
President
Live Oak Quality Assurance
pbaker@liveoakqa.com

Timing	Content
13:30 – 15:00	Hands-On Exercise: • Building QI Dashboards in Power BI by Microsoft In this session we will focus on the data importation, cleaning & transformation. Participants will discuss safeguards to ensure the integrity of data throughout the process using existing regulatory guidance for risk management and computer system validation.
15:00 – 16:30	Hands-On Exercise: • Building QI Dashboards in Power BI by Microsoft In this session we will focus on transforming information to knowledge through data visualization. Participants will learn various low/no code techniques to enhance quality oversight through process knowledge.

Day 2

Timing	Content
8:30 – 9:00	Refreshments & Networking

Peter E. Baker
President
Live Oak Quality Assurance
pbaker@liveoakqa.com

Timing	Content
9:00 – 11:00	Reviewing and Approving QI Validation Strategies • What is Machine Learning? • AIML: The regulatory perspective • Robotic Process Automation (Bots) • Dashboarding • Cloud Applications (from IAAS to SAAS) In this session we will discuss the critical components of a QI validation strategy to ensure compliance with Part 11.10(a): validation for "consistent intended performance", and existing data integrity guidance. Examples of machine learning will be demonstrated, followed by a discussion on of similar models in a GXP environment.
11:00 – 11:20	Coffee Break
11:20 – 12:30	Exercise: Validation Plan for Machine Learning • Defining your validation strategy (data and process mapping) • Risk assessment exercises • Risk acceptance (ICH Q9)
12:30 – 13:30	Lunch
13:30 – 15:00	Case Study: GxP Quality Intelligence Hands On exercise with laboratory datasets • Addressing FDA's "Vigilant Operations Management Oversight" expectations using simple solutions In this session participants will work on laboratory datasets and identify high-level signals that require further investigation.

Peter E. Baker
President
Live Oak Quality Assurance
pbaker@liveoakqa.com

Timing	Content
15:00 – 16:30	The future of Quality Intelligence? • Hands-On Exercise using ChatGPT In this session we will focus on the currently hottest topic: Chatbots. Participants will discover some use-cases how to make a chat-bot an assistant to the quality department and figure out challenges and restrictions (data privacy). We might call this "artificial assistance" for GXP purposes.

www.liveoakqa.com

Page 4 of 4