PDA Parenteral Drug Association Canada Chapter

Web Event

DATA INTEGRITY

July 28, 2022 • 2:00 pm – 4:00 pm EST

PDA Technical Report 80

Data Integrity for Pharmaceutical Laboratories

PDA Technical Report 84

Integrating Data Integrity Requirements to Manufacturing & Packaging Operations

Event Description

Data integrity is one of the pillars of compliance. The regulated Life Sciences Industry heavily relies on data to demonstrate product safety, quality, identity, purity and potency throughout the developmental phases and commercial lifecycle. It is an integral part of the process and always assessed during inspections. This interactive web event will cover PDA's Technical Reports on the subject, both TR-80 on Data Integrity Management System for Pharmaceutical Laboratories and TR-84 on Integrating Data Integrity Requirements into Manufacturing & Packaging Operations.

Our speakers will look at the challenges the industry still faces today, and will address topics such as hybrid systems, laboratory techniques that still rely on non-automated data, and will introduce a risk matrix approach to get through these challenges and pitfalls. The webinar will also examine how industry regulators view data integrity and reflect on the most current feedback regarding this fundamental process.

Join us for this exciting web event with the contributing authors of TR-80 and TR-84. This interactive session will welcome a dialogue with participants and focus on addressing questions and concerns.

Event Pricing

$45 | PDA Member

$55 | Non-Member

Registered participants will receive a 15% discount code which may be used to purchase TR 80 & 84 and PDA membership.

** tickets sold in USD*

Denyse Baker

Contributing Author, **TR-80**
Senior Director, Global Regulatory Policy
AstraZeneca

Denyse is passionate about connecting and collaborating to promote the importance of science-based regulation and organizational quality culture as foundations for delivering high quality products to patients. Denyse brings a strong technical foundation to her policy work with experience in engineering, manufacturing, quality and regulatory for small molecules, biologics and devices.

Her work experience prior to AZ, includes US FDA, the Parenteral Drug Association, and Eli Lilly and Company. She is Vice Chair of PDA's Regulatory and Quality Advisory Board, Co-leader of the Quality Management Maturity Task Force, member of the Quality Culture Assessment ANSI Standard Working Group and has trained over 100 regulators on the PDA Quality Culture Assessment Tool. Denyse is also secretary to the FDA Alumni Association Board of Directors. Denyse earned a B.S in Mechanical Engineering from Northwestern University, is a licensed professional engineer, and holds RAC certifications in US and EU reg. affairs.

Susan Schniepp

Contributing Author, **TR-84**
Distinguished Fellow
Regulatory Compliance Associates Inc.

Susan has over 40 years of quality assurance experience in the pharmaceutical industry. She has earned several awards from the PDA, including Distinguished Service Award, and Gordon Personeus Award.

Sue's publications include the book, Understanding the United States Pharmacopeia and the National Formulary: Demystifying the Standards-Setting Process, for which she was awarded the 2007 PDA's Distinguished Author Award. She co-edited and contributed to the books Pharmaceutical Outsourcing: Quality Management and Project Delivery and SOPs Clear and Simple for Healthcare Manufacturers.

Sue has served on the PDA Board of Directors from 2011- 2013, 2016- 2019 and is currently the Chair of the BoD. She has served on the PDA/FDA Joint Regulatory Conference Planning Committee since 2002. She is currently part of the working group writing a technical report relating to manufacturing data integrity issues and participating in PDA's standard setting activity regarding purchasing controls.

Sue is an editorial advisory board member and columnist for Pharmaceutical Technology (since 2007) and BioPharm International Magazines. She holds a bachelor of science degree in Microbiology from Northern Illinois University.

REGISTER TODAY

https://store.pda.org/Meetings/Login.aspx?ID=6721

QUESTIONS?

Contact us at chapters@pda.org