

# Welcome to the Conference!

## Future Landscape in Pharma: Bridging Innovations for Sustainable Compliance

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**2024 Pharmaceutical Manufacturing and Quality Conference**

CONNECTING  
PEOPLE  
SCIENCE AND  
REGULATION®

# Defining Sustainable Compliance

## WHAT

- Compliance that adapts to changing regulations
- Incorporates ethical practices and corporate responsibility
- Ensures patient safety and product quality over time

## WHY

- Maintains public trust and company reputation
- Avoids legal and financial repercussions
- Aligns with global sustainability goals and practices

# Tying Sustainability with Innovation

## Emerging Tech Shaping Compliance

- AI and machine learning for predictive compliance
- Blockchain for secure and transparent supply chains
- Digital health technologies for real-time monitoring

## The Role of Data Analytics

- Big data for tracking quality metrics
- Advanced analytics for risk assessment and management

# The Regulatory Evolution

## Adapting to a Dynamic Regulatory Environment

- Global harmonization of standards (ICH, PIC/S)
- Tailored approaches for fast-track approvals (Orphan drugs, Breakthrough therapies)

## Collaboration with Regulatory Bodies

- Joint initiatives for innovation-friendly guidelines
- Public-private partnerships for agile regulation

# What did I ask AI?

- Prepare a couple of slides on the following topic: Future Landscape in Pharma: Bridging Innovations for Sustainable Compliance
- So, am I now redundant?
- Shall we just watch AI generated Conferences online?
- Shall we let AI watch AI generated Conferences online?

**Fraud Alert!**

**Yes, to all of the above!**  
**BUT (there's always a BUT!)**

# AI to enhance human intelligence

- AI made this presentation easier to write, but all the anecdotes and linkages I have talked about verbally came from my own Intelligence
- The importance of “Human in the loop” –
- (i) with Quality Events/Notifications, we must keep the human central in decision making, even if the analysis of data can be assisted by AI.
- (ii) For predictive compliance, we still need humans to think “outside the box” when considering all the consequences when taking action
- BUT – maybe our decisions will be better as they will be more informed
- **Ultimately, the human is Accountable – the buck stops with us when it comes to patient safety. That is never going to go away.**

# Lastly, and Most Importantly!

- Thanks to the organizing committee and PDA AsiaPac
- Thanks to you, for making the effort to be here amongst your peers at this Event
- Thanks, in anticipation, for your thoughtful engaging questions: this is a Conference, no one is here to “lecture” anybody! You are amongst friends, the community of the Parenteral Drug Association
- Rules of Engagement: No such thing as a “stupid question”. The only stupid thing is to not ask it!
- Most importantly, thanks to AI for helping me write this opening presentation!

# Before we start Conference – Logistics!

How things will work for the next 2 days including:

- Food and drink,
- Exhibits (thanks to our Sponsors),
  - Mingling / networking time,
    - fire egress



# Thank You!

Don't forget!

Thursday 9<sup>th</sup> May 2024 - 2024 PDA Sponsored Workshop -  
Environmental Monitoring: Science-based Decision Making