Transforming Regulatory Affairs with Generative AI: Practical Integration for Smarter, Faster Outcomes

Agenda

April 21, 2026   9:00 AM – 1:00 PM EST / 2:00 PM – 6:00 PM CET

9:00-9:20 AM   **Introduction & Purpose**

- Introduction
- Purpose and expectations for the day

9:20-10:05 AM   **Session 1: Introduction to Generative AI in a Regulatory Setting**

- Introduction to technology and potentials: expected productivity & quality gains
- Pitfalls, limitations and biases to be aware of when working with GenAI
- Specific considerations when using GenAI in a Regulatory setting including dos and don'ts
- Examples of practical application in Regulatory such as health authority interaction, quality check of e.g. SmPC and SPL and CCDS translation support

10:05-10:15 AM   **Break**

10:15 AM -12:00 PM   **Session 2: Practical Applications**

(There will be a 10-minute break halfway through this agenda point)

- Introduction to prompt engineering and prompting strategies
  - How to create good prompts that ensure reliable, high-quality outputs
  - How to work with structured data and documents like eCTD, SmPC, SPL, labelling and more
  - Generative AI in a Regulatory setting, based on real life use cases, exemplifying use, to inspire application in own daily work
- Guided hands-on work for participants: Overview of Regulatory practical applications and use cases, own work with examples based on standard and accessible GPT-based tools

12:00-12:10 PM   **Break**

12:10-1:00 PM   **Session 3: Engagement and Reflection**

- Individual work on regulatory case
  - Participants can use their own cases or choose from ones shared by instructors
- Reflections (e.g., process v. result, when to use and not to use GenAI for work)
- Making GenAI a habit in daily work and finding ideas of use
- Reflections and commitments on own work, such as, "What will you do differently, starting tomorrow?"