## Revolutionizing Biopharmaceuticals with AI: From Soup to Nuts

## Applications

Specific Problems to Anticipate

- What are the most exciting applications of AI across different stages of biopharmaceuticals (e.g., development, clinical, CMC, regulatory)?
- 2. And what tools and software are being used to develop applications?

**Best Practices** 

3. What areas of AI do you think present the highest potential risks or need the most caution in biopharmaceutical applications?

- 1. What specific problems have organizations encountered when implementing AI solutions, and how have they addressed them?
- 2. How do you balance the benefits of AI tools with the risks of over-reliance on automation in critical decision-making processes?

## Regulatory

- 1. What best practices have emerged for building AI systems in biopharma?
- 2. How can organizations ensure that their AI systems undergo rigorous testing, validation, and monitoring throughout their entire lifecycle to maintain high standards of quality and reliability (human-in-the-loop, new roles)?

- 1. What considerations are most important for integrating AI into the regulatory landscape, and how can companies work effectively with health authorities?
- 2. How might regulatory agencies adapt to the use of AI in the biopharmaceutical industry? What challenges could arise?
- 3. What metrics can be used to evaluate the safety, efficacy, and generalizability of AI models in the industry?