# SESSION V

# Application and Regulation of Artificial Intelligence (AI) in the Pharmaceutical Industry

PDA Parenteral Drug Association

2023 PDA Asia Pacific Regulatory Conference

CONNECTING PEOPLE SCIENCE AND REGULATION®

# AI and Parenteral Products

## What does this look like and how is PDA supporting industry

Lisa Bennett, SeerPharma & PDA RAQAB

PDA Parenteral Drug Association

2023 PDA Asia Pacific Regulatory Conference

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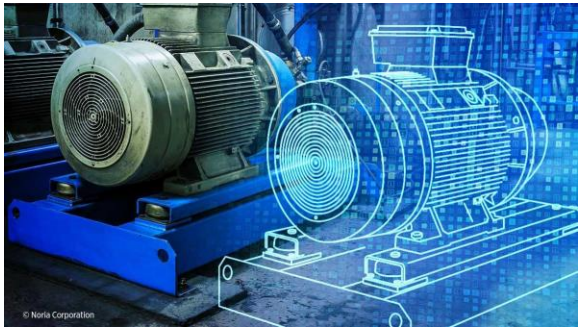


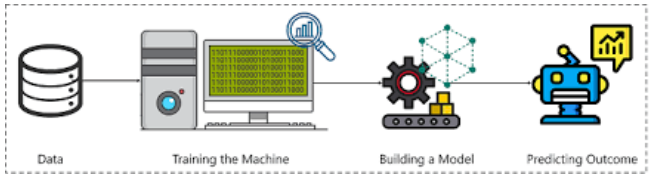


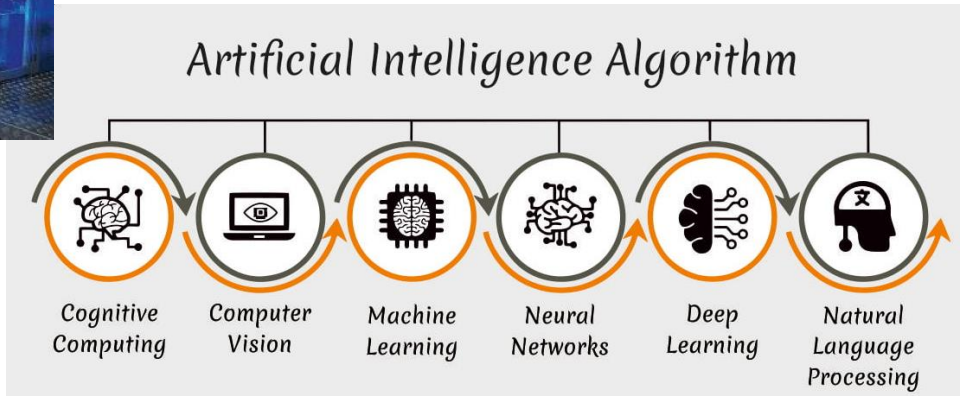

# HMA/EMA Big Data Task Force

- The **HMA/EMA Big Data Task Force** operated from 2017 until December 2019 to report on the challenges and opportunities posed by **big data** in medicines regulation

- Summary Report Published in February 2019

https://www.ema.europa.eu/en/documents/minutes/hma/ema-joint-task-force-big-data-summary-report_en.pdf

# Joint HMA/EMA Big Data Steering Group

Co-chaired by:

- Jesper Kjær, Director of Data Analytics Centre at the Danish Medicines Agency and
- Peter Arlett, Head of Data Analytics and Methods at EMA

- https://www.hma.eu/about-hma/working-groups/hma/ema-joint-big-data-steering-group/hma/ema-joint-big-data-steering-group.html

## Network capability to analyse

A proof-of-concept pilot will be performed to clarify the benefits and practicalities of access to individual patient data from clinical trials (raw data) in the scientific assessment of medicines. Learnings from the pilot will help the EU medicines regulatory network to make an informed decision on the place of raw data in regulatory decision-making. Data analysis for assessment and inspection of manufacturing data will be explored, while safety monitoring will benefit from enhanced EudraVigilance data analytics. The EMRN capacity and capability for computing will be reviewed and actions taken based on recommendations. A reflection paper on artificial intelligence (AI) for use in regulatory processes may lead to development of guidelines. Options for knowledge sharing within EMRN will also be explored to support network capabilities.

| | |
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| **Q4 2022** | Launch CHMP pilot on CT Raw Data |
| **Q4 2022** | Consult on reflection paper on AI (v-) |
| **2023 - 2025** | Scope knowledge sharing fora on advance analytics |
| **Q2 - Q3 2023** | Review EMRN computing capability to analyse Big Data (v-) |
| **Q3 2023** | Publish final AI reflection paper (v-) |
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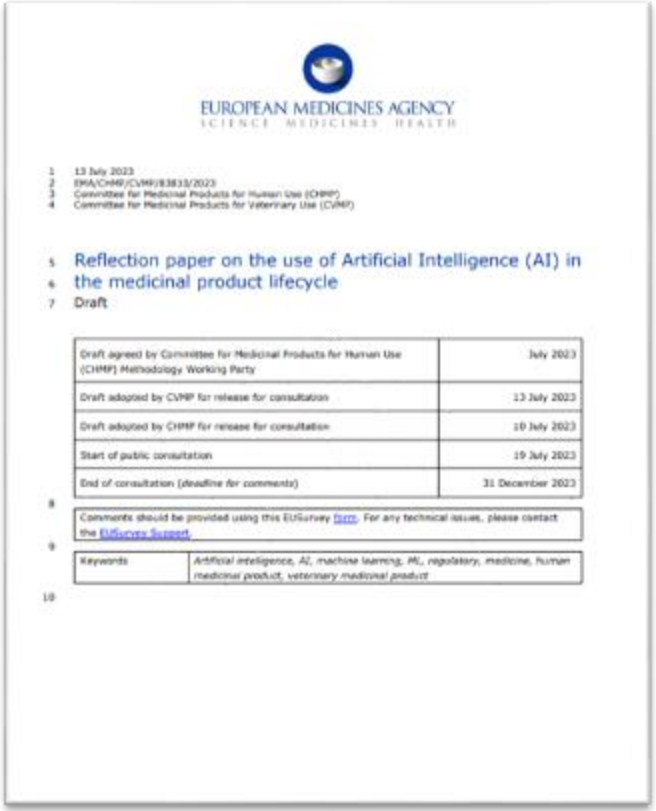
| **2024** | Develop AI guidelines |
| **Q4 2024** | Raw data workshop & final report |
| **Q4 2024** | Launch new EudraVigilance website |

- EMA Reflection Paper on use of AI in the medicinal product life cycle

- https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 July 2023
EMA/CHMP/CVMP/83833/2023
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Draft

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| Draft agreed by Committee for Medicinal Products for Human Use (CHMP) Methodology Working Party | July 2023 |
| Draft adopted by CVMP for release for consultation | 13 July 2023 |
| Draft adopted by CHMP for release for consultation | 10 July 2023 |
| Start of public consultation | 19 July 2023 |
| End of consultation (*deadline for comments*) | 31 December 2023 |

Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

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| Keywords | *Artificial intelligence, AI, machine learning, ML, regulatory, medicine, human medicinal product, veterinary medicinal product* |

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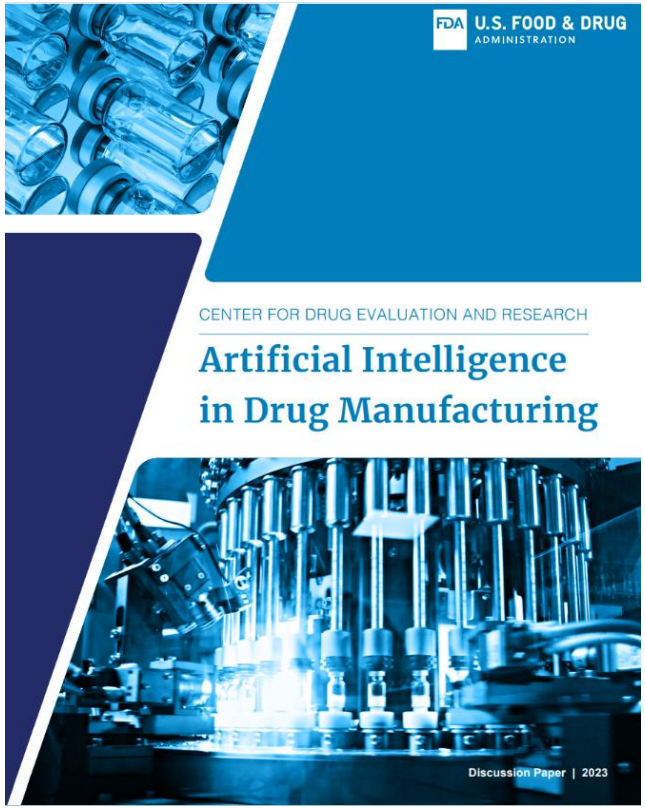
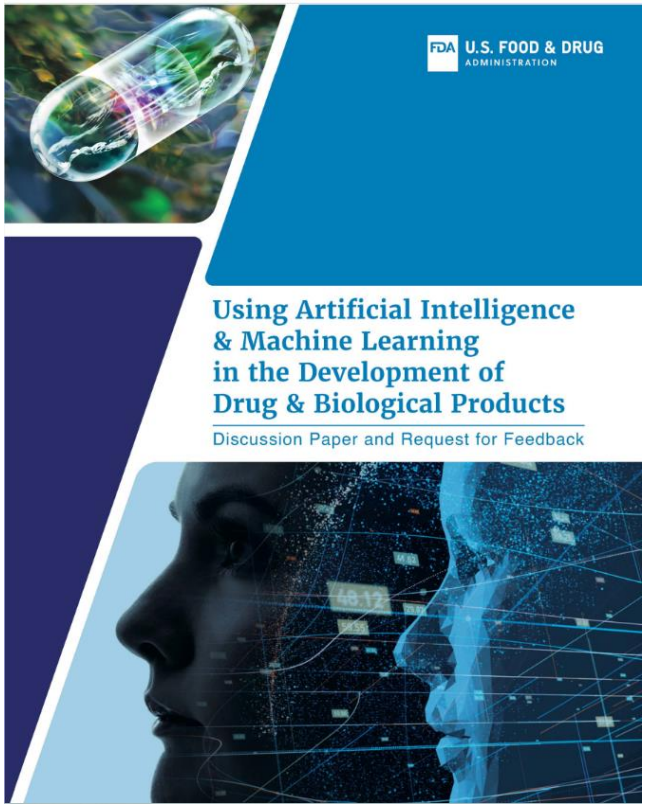


# How is PDA supporting industry

U.S. FOOD & DRUG ADMINISTRATION

VIRTUAL EVENT

PQRI Product Quality Research Institute

***FDA/PQRI Workshop on the Regulatory Framework for the Utilization of Artificial Intelligence in Pharmaceutical Manufacturing***

**An Opportunity for Stakeholder Engagement**

**Tuesday - Wednesday, September 26-27, 2023**

**Day 1 – Tuesday, September 26, 2023**
**10:00 AM – 3:00 PM US ET**

| | |
|---|---|
| **9:45 – 10:00 AM US** | Pre-Workshop Attendees Check Connections |
| **10:00 - 10:15 AM** | ***Welcome and Introductory Remarks***<br>**Glenn Wright**, Chair - PQRI Board of Directors; President and CEO, Parenteral Drug Association (PDA) |

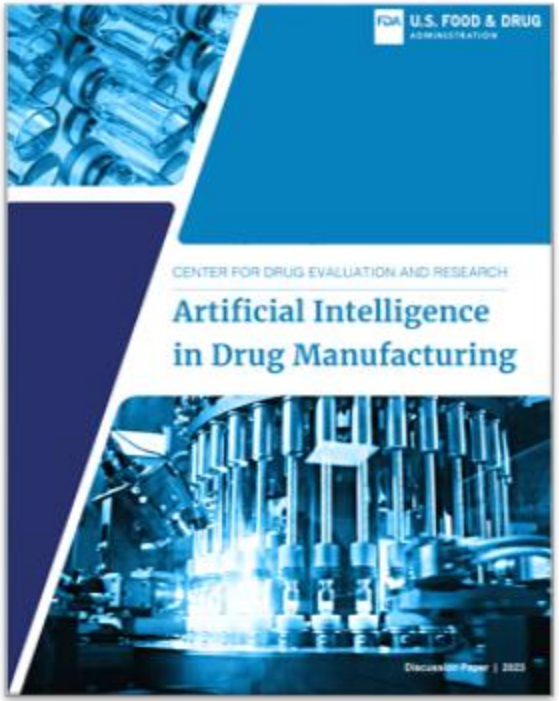
**SESSION 1: FDA Introduction to State of Artificial Intelligence Regulatory Framework**

Session 1 will discuss the state of AI in the pharmaceutical manufacturing space and explore the area of consideration for a potential framework to regulate AI technologies. An overview will be provided of how AI can be utilized to support other advanced manufacturing technologies. This session will also provide updates regarding feedback received on the discussion paper.

# Interest Groups

- Data Government Management Integrity and Digitalisation
  - Regulatory Affairs and Quality Advisory Board
- Advanced Manufacturing and Applied Process Digitalisation
  - Science Advisory Board
- https://www.pda.org/scientific-and-regulatory-affairs/pda-interest-groups

# Commenting & Feedback



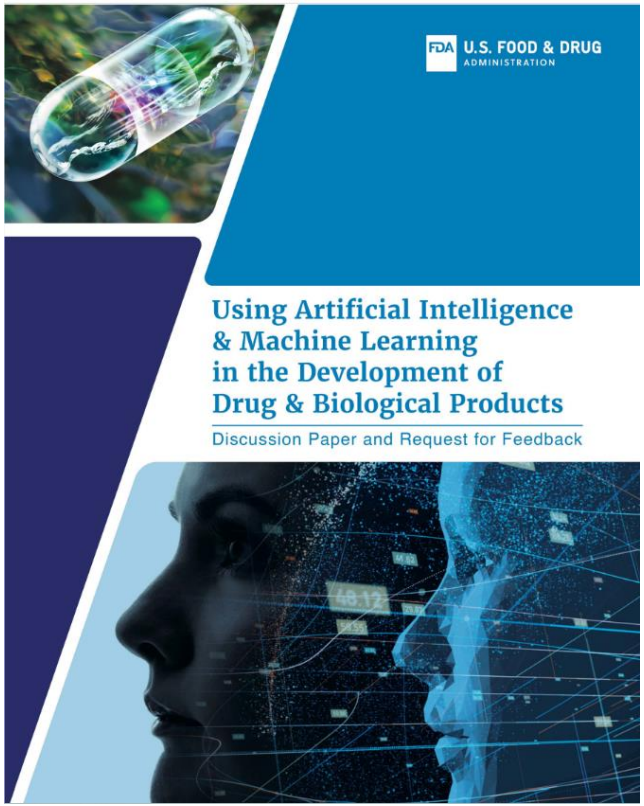

Discussion Paper: Artificial Intelligence in Drug Manufacturing 11

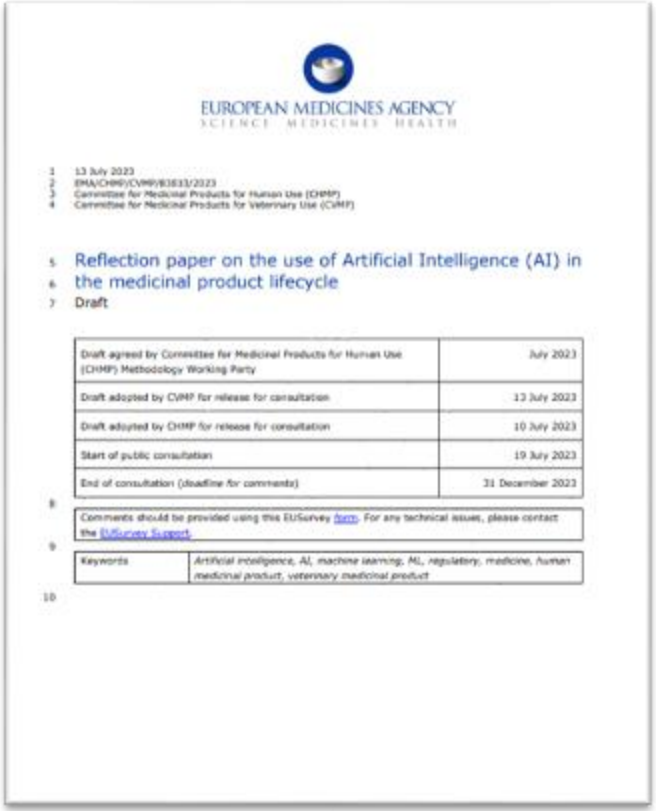
## AI Questions & Feedback Section

1. *What types of AI applications do you envision being used in pharmaceutical manufacturing?*
2. *Are there additional aspects of the current regulatory framework (e.g., aspects not listed above) that may affect the implementation of AI in drug manufacturing and should be considered by PDA?*
3. *Would guidance in the area of AI in drug manufacturing be beneficial? If so, what aspects of AI technology should be considered?*
4. *What are the necessary elements for a manufacturer to implement AI-based models in a CGMP environment?*
5. *What are common practices for validating and maintaining self-learning AI models and what steps need to be considered to establish best practices?*
6. *What are the necessary mechanisms for managing the data used to generate AI models in pharmaceutical manufacturing?*
7. *Are there other aspects of implementing models (including AI-based models) for pharmaceutical manufacturing where further guidance would be helpful?*
8. *Are there aspects of the application of AI in pharmaceutical manufacturing not covered in this document that FDA should consider?*

## Conclusion

This discussion paper presents areas for consideration and potential policy development that CDER identified based on evaluating the application of the existing regulatory framework to use of AI in pharmaceutical manufacturing. A regulatory framework for advanced manufacturing evaluation will address these areas while also considering how potential changes could affect existing technologies and facilities. CDER will use feedback submitted to the docket to inform future policy development. Please submit your comments regarding this discussion paper to https://www.regulations.gov, Docket No. FDA-2023-N-0467.





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# PDA Activities

- Interest Group discussions
- 3x Commenting efforts (2x FDA, 1x EMA)
- RAQAB held a focussed discussion on AI at September meeting

- → Glossary on AI

# Thank you