



5 October 2022
EMA/852563/2022
European Medicines Agency

First EMA – Parenteral Drug Association bilateral meeting 5 October 2022

Chair: Alexis Nolte (EMA)

1. Welcome and introduction

The meeting was chaired by Alexis Nolte (EMA) who opened the meeting. Alexis welcomed Parenteral Drug Association (PDA) participants who introduced PDA as a professional society committed to the professional education of its members in key scientific topics. The PDA also fosters joint Regulators and Industry events such as workshops and joint position papers. PDA's main focus is on parenteral (sterile dosage forms) and associated manufacturing and pharmaceutical topics.

2. EMA priorities

Alexis Nolte provided a high-level overview of EMA's priorities relevant to the PDA.

Veronika Jekerle complemented with more detail on the Agency's priorities relative to pharmaceutical quality:

- Innovative manufacturing approaches including decentralized/mobile manufacturing, personalized medicines, additive and continuous manufacturing, Pharma 4.0 (digitalization)
- Medical devices and digital health
- risk-based approaches in review of Mod 3 data packages to respond to public health needs including the EMA toolbox approach
- to continue capacity building on EMA/network expertise in areas of innovation (e.g. vaccines, ATMPs, combination products (ABDC, encapsulated mRNA products), gene editing and related technology to innovative manufacturing approaches (e.g. advanced analytical methods)
- Strengthening manufacturing supply chain resilience and reliance & international convergence (e.g. ICH + ICMRA)



3. Parenteral Drug Association (PDA) activities

PDA participants gave an overview of PDA and indicated priorities of future meetings. They also shared a summary of their Strategic Plan 2020-2026 incorporating four key pillars and key objectives for 2022:

- Continuing to meet the needs of their members
 - Offering leading conferences, returning to in person; Expanding training portfolio; Adding more technical guidance; Enhancing membership options
- Enhance opportunities for ECPs
 - Continued focus on improving manufacturing processes and operations
- Use social media more broadly to communicate to members and to engage ECPs
 - Created expanded opportunities for volunteers and improve entry process
- Create a hot topic/trend repository that can be maintained, and accessed across PDA
- Target opportunities to engage HAs and industry leaders on important topics to drive consensus
 - Begin development of a library of on-demand basic training modules
- Target technologies where regulatory acceptance is not harmonized to drive towards harmonization
 - Continue to drive towards diversity in all PDA activities
- Expand the activities of the PDA Foundation

7. AOB

No topics were raised.

Wrap up / end of meeting

Alexis Nolte closed the meeting by thanking all the participants for their time and for an open and constructive discussion.