Join us!

When?

Wednesday, 04 September 2024:	13:00-17:00 CEST
Thursday, 05 September 2024:	09:00-17:00 CEST
Friday, 06 September 2024:	09:00-12:00 CEST

Where?

Change Hub, Hardenbergstraße 32, 10623 Berlin

What to expect:

This interactive workshop brings experts from the pharmaceutical industry (Manufacturing/Quality and Governmental Affairs) and the legislative sector (politicians) together to discuss current challenges and best practices in the manufacturing of medicinal products following the latest developments in the regulatory environment. The workshop provides a platform for exchanging insights among industry, with regulatory and politicians on regulatory expectations, manufacturing realities, and compliance strategies crucial to the regulated pharmaceutical industry.

Participants will have the opportunity to follow round table discussions and ask questions to communicate practical solutions. There will also be the opportunity to

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analyze case studies and gain valuable insights from professionals in the field regarding implementing effective manufacturing processes in compliance with existing and upcoming legal requirements. The workshop promotes collaboration and communication between manufacturers, students, early career professionals, scientific experts, politicians, and government officials to ensure the safe, effective, and compliant manufacturing of medicinal products.

Legislation

The EU Pharma Strategy is part of an ever-evolving regulatory landscape. We are addressing the pressing issues that confront legislators, regulators, and our industry, and discussing effective solutions. By bringing together voices from industry, academia, and politics, we aim to foster a comprehensive dialogue that not only acknowledges the current challenges but also explores innovative strategies to overcome them. The output would be used to share a common understanding within the areas the representatives are involved. Be prepared to present your questions, needs, and concerns.

Regulatory Guidelines

While legislation is supported by guidelines, we will demonstrate new developments and discuss practical solutions on how to implement new and revised regulatory guidelines out of the legislative framework. The opportunities with the agile regulatory framework on topics like sterile manufacturing (Annex 1), AI and computerized systems (Annex 11), and Quality Risk Management aspects as of ICH Q9(R1) as an enabler will be worked out. This will support PDA’s position for topics to consider addressing within the EMA Inspector Working Group for their work in 2025.

Manufacturing

Manufacturing is a resource-intensive, long process. We will demonstrate which steps are taken, and how this is managed and regulated. We work on suggestions for solutions on how politics can support to ensure manufacturing remains in and is transferred to the EU. Innovative manufacturing solutions will be presented to allow spotting aspects of how manufacturing of the future could look to manage the prevention of drug shortages.

PFAS (Per- and Polyfluoroalkyl Substances)

Let us discuss how and by when to realistically achieve PFAS-free solutions: We will work on an alternative strategy as the European Community is considering a ban on PFAS in all industry branches. Recognizing the urgency and significance of this issue, the industry is committed and active to progressing innovative technologies and proven methods in manufacturing processes for active pharmaceutical ingredients and medicinal products. Researchers and component manufacturers from various disciplines will submit technical solutions and proposals addressing critical aspects of replacing PFAS. Politicians can understand what efforts are on the way to best achieve the goal.

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Who should attend?

- Representatives from pharmaceutical/biopharmaceutical companies
- Members of parliament
- Suppliers and vendors in the pharmaceutical sector
- Students, Academia, and Early Career Professionals
- Consultants

Submit your Topic!

Which topic does the PDA Community bring to the attention of policymakers / legislators and of the inspectors of EU Member States/EMA? Please provide the challenges and propose solutions.

Submit your topic or challenge relevant to the pharmaceutical industry. Upon selection and subsequent on-site discussion, we will forward it to the EMA Inspectors Working Party for further consideration.

Deadline: 20 June 2024

Submission Link