Innovations in pharmaceutical manufacturing on the horizon
A virtual dissemination workshop

Session III. Challenges and opportunities

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An agency of the European Union

EMA’s mission

- Decentralised agency of the EU
- Founded in 1995
- Reg. (EC) No 726/2004
- The mission of the European Medicines Agency is to foster **scientific excellence** in the evaluation and supervision of medicines, for the **benefit of public and animal health**.

To address our public health mission innovation is needed

- ✓ Medicines of the best quality – highly efficacious and good safety profile
- ✓ Address unmet medical needs
- ✓ Improve processes efficiency & reliability
  - ↑ Flexibility, agility
  - ↓ quality defects-> prevent shortages
  - ↑ Yields
  - ↓ environmental impact
  - …

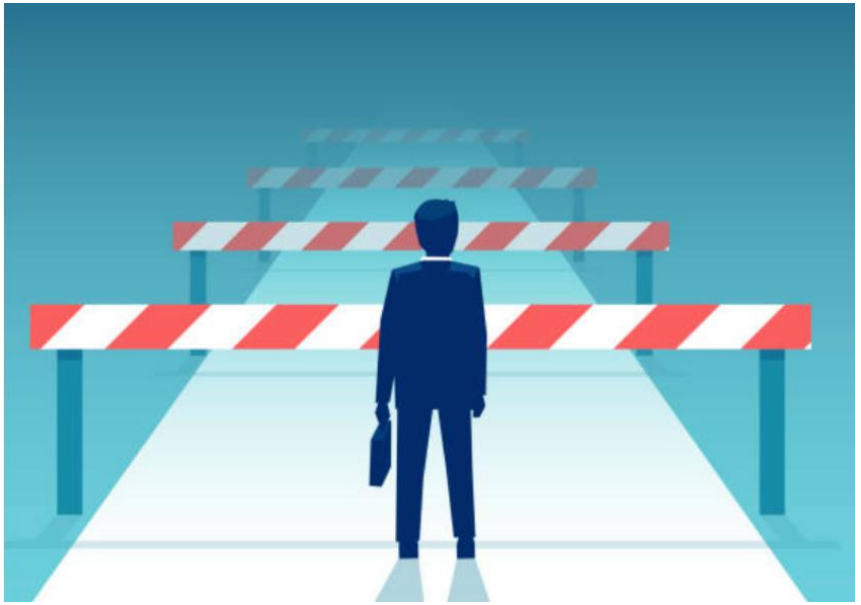
We are open forward and encourage innovation!

General challenges

	Regulators	Industry
	Traditional mindset	
	Early visibility of cy's developments to ensure preparedness	Uncertainty/fear of its acceptance by regulators
	Training	
	Potential need to adapt regulatory frameworks	Upfront capital investment

Technical/regulatory challenges

- More and more complex systems/technologies: additive manufacturing, platform technologies.
- Performance based approaches-advanced process controls & automation, AI
- Portable modular systems
- Bed side manufacturing & decentralized manufacturing e.g. ATMPs
- Companion diagnostics
- Borderline products, etc



What is EMA doing?

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

Goal 1: Catalysing the integration of science and technology in medicines' development

- Facilitate the implementation of novel manufacturing technologies
- Support translation of ATMPs into patient treatments
- Develop understanding of, and regulatory response to, nanotechnology and new materials in pharmaceuticals

Goal 5: Enabling and leveraging research and innovation in regulatory science

What is EMA/EC doing?

A pharmaceutical strategy for Europe | Public Health (europa.eu)

*…'aims at creating a future proof regulatory framework and at supporting industry in promoting research and technologies that actually reach **patients** in order to fulfil their **therapeutic needs** while addressing market failures. It will also take into account the weaknesses exposed by the coronavirus pandemic and take appropriate actions to strengthen the system'…*

Existing opportunities for dialogue with EMA on CMC innovation

Global dimension

- ✓ Industry to work together, in collaboration with academia/research institutions, and liaise with regulators as needed.
- ✓ Applicants to allow regulators to discuss their applications among themselves.
- ✓ National regulations to allow regulators to share & discuss CCI information.
- ✓ ….

Take home messages

- Innovation is needed for the benefit of public health.
- Industry and regulators share the responsibility to make it happen.
- All parties have challenges, but should work together to overcome them.
- Early dialogue is essential to pave the way and ensure there is a mutual understanding.