efpia

European Federation of Pharmaceutical Industries and Associations

Autonomous & Portable Manufacturing

Reflection Paper

March 2021

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Reflection Paper

- Pharma and biotech's key objective remains to ensure that medicines to save and improve lives are available to patients globally, preserving their safety, efficacy and quality.
- The industry is currently investing significantly in the modernisation of their manufacturing and supply operations leading to more agile processes and methods including 'Autonomous & Portable' solutions.
- Digital technologies such as 3D printing, support medicinal specialisation and the production of personalised medicines, which may require dispensing closer to patients.
- Agile manufacturing is becoming increasingly critical in addressing the number and frequency of natural disasters, the 'green agenda', and global pandemics, such as Covid-19 and future crises.
- All are dependant on an enhanced flexibility and speed in manufacturing operations combined with capacity production and an immediate investment in the process and facilities required for an accelerated execution

The EU Pharmaceutical Strategy

Communication from Commission to European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Pharmaceutical Strategy for Europe, 25th November 2020.

- Ensure preparedness for new manufacturing technologies
- Ensure a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards, and advance international harmonisation by proactively proposing topics in line with the latest scientific developments, at e.g. ICH2 and/or PIC/S3
- This supports the introduction of new manufacturing technologies, including 'Autonomous & Portable' units such as Portable On Demands (PODs)

"PODs" encompass:

- One or multiple units that house a defined set of pharmaceutical operations
- Unit(s) that can be placed within an existing facility or be fully autonomous
- A unit that can be replicated in an equivalent manner, is transportable including to different geographic regions
- Leads to increased consistency , higher production volumes and a greater patient responsiveness

ICH the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - https://www.ich.org/page/membersobservers

PIC/S the Pharmaceutical Inspection Co-operation Scheme https://picscheme.org

Considerations in line with adoption of Autonomous & Portable Manufacturing Processes

- Acceptance that a unit constitutes a site is either or both autonomous and mobile
- GMP compliance status of a unit be retained when replicated or relocated in another geographic site through reliance on the GMP compliance status of the inspectorate of the country where the equipment is originally located (e.g. where the inspectorate is a PIC/S member)
- The registered details of an establishment (eg address) remain valid when changing the unit's location by e.g. introducing a tracking system that would be referred to in the Site Master File
- Allowance is made for the risk-based reporting of stability and validation studies upon a change of location
- The insurance that the registered information be made compatible with mobile manufacturing

General recommendations

- Greater global alignment through building on existing inspections reliance and recognition principles, the development of ICH principles, via e.g. an addendum/Q&As to Q9 on Quality Risk Management, Q10 on Pharmaceutical Quality System
- In the EU, build on the EFPIA initiated dialogue with the EMA Quality office to engage on emerging technologies, especially with the Assessor and Inspectorate Teams