The monthly European Industrial Pharmacists' newsletter October 2022

Technology & Research

Drug substance supply in new product introduction processes

BioPhorum discusses an approach to the selection and validation of suppliers of raw materials. This process often proves critical to establish product lifecycle materials requirements from the very early clinical phase of development. The impact of incorrect forecasts may be high in terms of costs and possible delays of production. >>

Regulatory Affairs

MDCG, a position paper on the capacity of notified bodies

Insufficient capacity of notified bodies may cause delays in the certification of new medical devices and in vitro diagnostics that may result in a supply crisis. A position paper by the Medical Devices Coordination Group discusses the possible solution immediately available to increase NB's capacity. >>

Business & Policies

The current status of trade agreements

EU has signed or is negotiating a wide range of trade agreements with countries in other geographic areas to reinforce it competitiveness in the global markets. UK and India are also discussing a new free trade agreement.

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EU Focus

The FDA warns about manufacturing on the same equipment

FDA highlights issues connected to manufacturing of different types of products in shared equipment. In the EU, the current pharmaceutical legislation does not openly address the issue, giving more emphasis to the application of Quality Risk Management as the preferred tool to design and validate process. >>

News from EIPG

Webinar: The impact of pharmaceuticals on the environment

At the next EIPG webinar to be held on Wednesday 9th November at 17.00 CET (16.00 GMT) in conjunction with PIER and University College Cork, Bengt Mattson will present the impact of pharmaceuticals on the environment and what industrial pharmacists can do to help decrease the potential environmental impact. >>