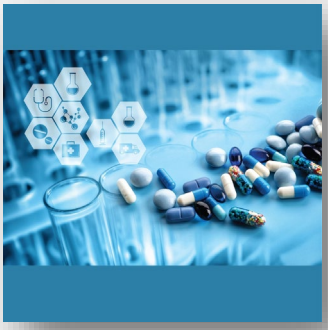
The monthly European Industrial Pharmacists' newsletter October 2021



Technology & Research

Automation of aseptic manufacturing

The presence of robots allows the elimination of human operators from cleanrooms, thus reducing the risk of contamination. The available technologies are now highly standardised and offer many opportunities for new designs of the manufacturing process.

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Regulatory Affairs

ICH Q13 guideline on continuous manufacturing

The guideline provides the general framework for the development and operation of a CM system, both under the scientific and regulatory perspective. It also offers examples to illustrate the main features to be considered under the different domains of pharmaceutical manufacturing.

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Business & Policies

First steps of the HERA Authority

Three different calls for tender on antimicrobial resistance and strategic stockpiling of therapeutics to treat Covid-19 are the first activities launched by the EU Commission to provide the basis for the new European Health Emergency preparedness and Response Authority to become fully operative.

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EU Focus

Reform of the European pharmaceutical legislation

The initiative launched by the EC is open for comments until December 2021. It aims to collect opinions from all the different stakeholders as the first step towards the review of the current pharmaceutical legislation to better reflect the state-of-the-art in technology, innovation and regulatory sciences.

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News from EIPG

IMP manufacturing in the era of the CT regulation 536/14

The next EIPG's and PIER's webinar to be held on Thursday 18th November 2021 (17.00 CET) will raise questions and provide preliminary answers to any differences between the current and new manufacturing and labelling requirements.

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