

## **Press Release**

Paris, October 13th, 2022

## Winner of the Roger F. Sherwood "Article of the Year" award announced by ISPE magazine Pharmaceutical Engineering®

As every year for the past 30 years, ISPE magazine Pharmaceutical Engineering® has just announced the winner of the Roger F. Sherwood prize, which recognises the best article of the year for excellent and quality content aimed at the pharmaceutical industry.

For this year's edition, no fewer than 35 articles were submitted to the jury, chaired by Michelle Gonzalez. The 2021 prize has been awarded to "Management of UDI components in medical devices in the European Union", co-written by twelve authors [1], including Christophe Devins, co-founder and CEO of Ackomas. It will be presented at the next ISPE annual conference in Orlando, Florida, on 1 November.

The winning article highlights the important of unit identification for medical devices and new traceability requirements set by regulatory standards. It discusses the European Union database Eudamed and components of the UDI system, such as Basic UDI-DI to identify product groups, UDI-DI for specific devices and UDI-PI for all of the device's production. The article also provides insight into serialisation and obligations that apply to medical device manufacturers.

"We are aware how complex the actions are that must be implemented in order to comply with MDR and IVDR. These regulations involve all levels of a company, from the sales department to IT, manufacturing to the QA/RA departments," says Christophe Devins. "But beyond the challenges that it represents, UDI not only provides a common language for the entire supply chain, but above all, a considerable improvement to the safety of medical devices for final users and patients. This is now a global development and stakeholders can no longer ignore regulatory changes."

## **About Ackomas**

Innovative and dynamic, Ackomas is a French company already involved with large groups. It is specialized in the design and development of software for industries subject to strict regulations. The most concerned are the medical device and pharmaceutical industries where the application of unit identification and traceability systems is required from the manufacturing of the product to its final utilization. Ackomas has developed KOA, a powerful tool that is the only level 4 solution capable of centrally managing the regulatory requirements imposed on the pharmaceutical industry. www.ackomas.com

## [1] Authors

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