

Joint Event

# 15<sup>th</sup> International Conference and Exhibition on Pharmacovigilance and Drug Safety

September 26-27, 2022

# 25<sup>th</sup> International Conference and Exhibition on Pharmaceutical Formulations

WEBINAR

Rimma Battalova, J Pharm Sci Emerg Drugs 2022, Volume 10

## **The global issues of ensuring the continuity and efficiency of the performing pharmacovigilance processes by Marketing Authorization Holders (MAH) during mortal low, based on the experience of Ukraine since 24.02.2022**

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In my report, as a QPPV, I would like to share the experience of functioning PhV system in Ukrainian MAH as one of the market leader. Also as well I would like to highlight the key points, challenges, solutions are faced during the performing Pharmacovigilance processes by Arterium Corporation since the beginning of a military invasion of Ukraine by the Russian Federation.

The company's motto is- "To be closer to the people", in PhV language it means- to ensure the appropriate level of safety for each product.

02/24/2022 - the date that brought new challenges for all MAHs, who operate on the Ukrainian market, such as:

- showed their breaking point of the current Pharmacovigilance system,
- identified new weak links and development zones for the MAH, which could not be predicted in peacetime,
- identified for managers what tools and approaches were effective, which have made contribution for ensuring the sustainability of the system,
- We were able to identify vulnerable points in matters of ensuring the safety of the Ukrainian applicant's drugs in foreign markets of presence, on which it is necessary to work together in nearest future with the Global pharmaceutical community, and develop approaches and rules for further actions in critical situations.
- In practice, we have faced and experienced in real condition the principles that at critical moments you are at the level of basic training, and it is important to understand this and continue to maintain a sufficient level of professionalism and managerial competencies.

### Summary

The author does not state the conclusion, but highlights the intermediate results according to the assessment:

- The readiness of System
- The detection of the margin of safety
- The ability to respond quickly

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This, in turn, will allow us in the future to:

- Stabilize and continue uninterrupted operation
- Identify weak links and areas of development
- Develop additional procedures within the system
- Raise global issues of patient safety to a higher level of communication in the industry in order to share experience and further develop joint approaches and solutions

## Biography

Rimma Battalova has more than 20 years experienced in pharmaceutical area. For over 12 years as QPPV take an active part as QPPV in maintaining and developing PhV System in Arterium Corporation, also as a member of working groups from MAHs took an active part in harmonization Ukrainian PhV legislation with EU standards. She is the Head of Subcommittee of Pharmacovigilance in European Business Association (Ukraine), certificated business trainer of PhV, Guest-lecturer from MAH in Medical and Biotechnological Universities of Ukraine.

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