

# SOPHARMA CASE STUDY

Ensuring Track & Trace  
compliance across  
multiple regions

## THE CHALLENGE

Sopharma, a leading pharmaceutical company in the Central and Eastern Europe ("CEE") region, needed an end-to-end solution that enables serialization, aggregation, and track & trace capabilities. The company's main challenge revolved around ensuring its compliance with existing track and trace requirements without having to go through any future expensive and time-consuming recalibrations related to ongoing regulatory updates.

Operating as a Marketing Authorization Holder ("MAH") and a Contract Manufacturing Organization ("CMO"), Sopharma was looking for an automated and secure solution to manage its numerous connections with supply chain partners while avoiding further significant IT investments.

Sopharma's need for secure, remote access to the serialization data from each of its production plants led their team to search for a more advanced serialization data management and reporting solution. Moreover, Sopharma's partners' requirements pushed the company to look for a flexible aggregation solution (pallet aggregation) for the company's different locations.

## INTRODUCTION

Sopharma is an industry leader and a key stakeholder in the pharmaceutical landscape across the CEE region.

The company has 7 production plants in Bulgaria and operates in the European, Uzbekistan, Kazakhstan, Kyrgyzstan and Russian markets. Additionally, Sopharma has several local representatives in foreign countries.

The company is widely regarded as one of the top industry players in the CEE region, working both as a MAH and CMO.



## SOLUTION SELECTION

Sopharma selected the SATT PLATFORM®, a comprehensive SaaS solution based on Microsoft Azure, to replace the company's serialization and regulatory compliance software which had been built in-house.

The SATT PLATFORM® proved to be the right choice for Sopharma, given its ability to guarantee future-proof regulatory compliance and address the CIS countries' frequently changing regulatory requirements. In addition, the SATT PLATFORM® Hubs provide a high level of security (e.g., elimination of possible mismatching of product pack data, data encryption, prevention of loss of serial numbers or serial shipping container code, etc.) while leveraging Microsoft Azure's security-first approach to the design and development of its cloud offering.

Furthermore, Sopharma adopted the SATT PLATFORM® Communication Cloud in order to effectively manage its IT department's daunting task of managing communication with more than 15 supply chain partners, thus significantly improving the level of transparency and visibility between internal and external stakeholders. This automated communication provides a reliable connection that minimizes the risk of human error while also limiting the risk of data loss and corruption.

Lastly, Sopharma adopted the cloud-based centralized management system (SATT PLATFORM® EBR) to significantly improve its control and visibility of serialization data in each of its production plants.

## SUCCESSFUL IMPLEMENTATION

Sopharma was able to implement a comprehensive cloud-based solution which allowed the company to ensure high availability of its production and to benefit from maximum security and seamless scalability while avoiding any disruptions to its existing processes.

Sopharma now has a future-ready cloud solution integrated into all of its production lines. It offers their QP seamless remote access and the secure review, publishing, and transfer of serialization and aggregation data between the company's partners and the Regulatory Authorities.

The service of the SATT PLATFORM® Web Aggregation capabilities to the company's operations minimized the investment needs towards new and complex aggregation equipment.

The capacity for pallet aggregation addressed the company's business partners' requirements by introducing a more straightforward process of traceability starting from batch creation all the way to its reporting.

## MICROSOFT AZURE'S ROLE

Hosted on the future-ready Microsoft Azure cloud environment, the SATT PLATFORM® provides premium reliability and performance metrics, scalability on demand, data backup, secure identity, and access management, which Sopharma can rely on and benefit from.

The system's efficient and cost-effective business model enables Sopharma to streamline its processes by eliminating additional investment in expensive hardware and IT maintenance costs while benefiting from rapid deployment, advanced insights, and automatic updates.



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