CASE STUDY

Huvepharma maintains quality and regulatory compliance to support rapid global growth

Key facts:

Company: Huvepharma

Industry: Pharmaceuticals

Country: Bulgaria

Octave products used: Reliance *(ETQ Reliance)*

Key benefits:

- Achieved compliance with global regulations (EU GMP, USDA, FDA) across multiple international sites
- Harmonized quality processes across manufacturing units in Bulgaria, Italy, France and the US
- Transitioned from paper-based quality culture to digital system with global oversight and standardized documentation

Headquartered in Sofia, Bulgaria, Huvepharma focuses on bringing human health and animal health and nutrition products to market. The company has gained a track record as a fast-growing global pharmaceutical company in the past ten years.

With independent manufacturing units in Bulgaria, Italy, France, and the US — and over 90 affiliates and offices worldwide — Huvepharma's ambitious growth demanded a strong focus on quality and implementing a global quality management system. Huvepharma's quality team realized it needed compliance management software to ensure the delivery of safe, quality products to its customers.

Meeting the need

When they decided to implement a QMS in pharmaceuticals, Huvepharma faced unique compliance and quality process challenges. Standardizing quality processes across many global sites was difficult as each location had to meet its own specific governmental and industry regulations. Developing and implementing standardized quality processes across many global sites was difficult, as processes needed to meet each location's specific governmental and industry regulations. In addition, Huvepharma's "paper quality culture" made staff reluctant to move away from tried-and-true manual processes to a compliance management system, and multiple languages complicated quality processes and made training across all production sites a tedious task.

The company was experiencing rapid growth, and its quality team understood that to provide the accurate analytics that would empower data-driven decisions, it must standardize its quality processes and documentation across the entire product lifecycle. The team also wanted to reduce nonconformance, improve supplier quality, work with suppliers on corrective actions, and reduce corrective action closure time. conformance, improve supplier quality, work with suppliers on corrective actions, and reduce corrective action closure time.

Quality journey

Standardization across disparate systems

Harmonization using one QMS for 12k users

Out-of-box implementation enabled rapid deployment

"Reliance was selected because it was flexible, highly configurable, easy to modify in house – and it was FDA and EU compliant, giving audit trail electronic signatures traceability. It had very good connectivity between modules, records and processes. Also, its intuitive interface looks similar across modules — very important for a multi-site company such as ours."

Mina Gavrilova
Quality Manager,
Huvepharma

Filling the gap

Today, Huvepharma counts on Reliance to comply with regulations across the globe, including regulations set forth by the European Union Good Manufacturing Practices (EU GMP), the United States Department of Agriculture (USDA), and the United States Food and Drug Administration (US FDA).

The company kicked off the use of Reliance by implementing change management, events, and CAPA applications across its sites in Bulgaria, Italy, and the US. Then, Huvepharma went live with document control and complaints management before implementing events, CAPA and change control for its French sites. Most recently, Huvepharma has migrated paper documents — including SOPs, policies, guidelines, templates, protocols, and reports — from their sites in Bulgaria, Italy, the US, and Belgium into Reliance.

Working with Reliance has provided Huvepharma with harmonization across all its entities, ensuring compliance for every international site. Able to use Reliance right out of the box with minimal customization, Huvepharma's quality team enjoys global oversight of quality compliance and process improvements, allowing them to maximize efficient use of the team's resources.

With early wins in document control, complaints management, change control and CAPA, Huvepharma plans to continue using Reliance to standardize and streamline the company's quality management processes. The quality team has plans to implement training management and supplier qualification applications.

About Huvepharma

Huvepharma is a fast-growing global pharma company (in terms of sales growth), focusing on developing, manufacturing, and marketing animal and human health and nutraceutical products. Its key strengths lie in large-scale fermentation and technical expertise developed over half a century at its European manufacturing sites. With the joint venture partnership, Huve Nutraceuticals brings expertise in microorganisms to produce ultra-high quality, very competitive algal-based ingredients and finished products for human, pet, and aquaculture nutrition applications. For more information, visit www.huvepharma.com.

About Octave

Octave is a leader in enterprise software, turning data into decisive action and intelligence into your edge. Our software solves for and simplifies complexity, from the design and build to operations and protection of people, property and assets – for any scope, at any scale. For decades, we've partnered with customers to sharpen performance, elevate efficiency and amplify results. From factory floors to entire cities, our solutions are tuned to scale up what's possible from day one onward.