



LYO **CHECK**

**DISRUPTIVE INNOVATION
IN THE VISUAL INSPECTION
OF LYOPHILIZED
PHARMACEUTICAL
PRODUCTS**



Horizon 2020



THE PROJECT

The aim of the LYO-CHECK project is to create two machines, one pilot machine and one fully automatic industrial machine, for the **visual inspection of lyophilized pharmaceutical preparations intended for injection**, based on the two elements of:

- an innovative vision architecture (dedicated software and optical layout);
- an ancillary technology (HSGA - head space gas analysis) for testing the sterility of the product via container integrity inspection.

The two machines will be used for demonstration in operational environment with trials on potential customer's products.

SCOPE

Pharmaceutical products intended for injection, also called **parenteralia**, are becoming more and more commonly found in lyophilized form and this trend appears to grow steadily, especially for anti-infectives, biotechnology derived products, and in-vitro diagnostics.

The main characteristics of lyophilized products are:

- Long term storage (more than two years), even at room temperature if stored properly
- Protection from pollution due to microorganisms activity
- Ease of transport and storage
- Rapid reconstitution of the product in contact with the appropriate solvent
- Preservation of the original product features

The **quality-control inspection** of products in lyophilized form poses peculiar challenges, thus creating the need for an innovative **dedicated system** which is totally different from the one so far applied to inspect parenteral products in liquid form.

During the **LYO-CHECK project**, the new pilot and industrial machines will be employed for demonstrations in operational environment with trials on potential customer's products.

IMPACTS

The worldwide pharmaceutical market is driven by two main necessities:

- a constant increase in product **quality** (in order to ensure patient safety and product compliance);
- a constant increase in production **output** (in order to decrease the overall costs of the pharmaceutical product thus making it available to a wider spectrum of users).

Given that **the lyophilized form is set to become the most widely used in the production of high added-value preparations for injection**, the increase in product quality and production output can be achieved only by the combination of different factors and improvement strategies, which are being taken into account in the development of the LYO-CHECK machine.

The new automatic inspection process performed with the LYO-CHECK machine will impact the lyophilized products sector in terms of:

- **extended shelf-life** for prolonged storage;
- higher quality of product due to **lower inspection errors**;
- **lower overall process cost** compared to manual inspection.



THE TEAM

Antares Vision's project for a disruptive innovation in the inspection technology for lyophilized products has been selected for funding within the European Union's Horizon 2020 research and innovation programme thanks to:

- A winning idea for a **substantial improvement** compared to the current technologies;
- The company's well-proven competence in **visual inspection**, and specifically in the advanced analysis on liquid products;
- A structured and dedicated **engineering team**;
- A solid **business plan** and project timing, in view of the medium and long term exploitation of the innovation.



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Automatic inspection of lyophilized preparations through innovative ICT control system



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