



## CASE STUDY

Challenges in day to day operations.  
The battle of performance in production

**How an inline vial management device is able to reject, retrieve for sampling, or reintroduce vials automatically during the loading / unloading process into pharmaceutical freeze-dryers**



# A B S T R A C T

How new technology in the field of loading & unloading systems for pharmaceutical freeze-drying processes allows inline vial management to reject, retrieve for sampling, or reintroduce vials automatically during the loading / unloading process into pharmaceutical freeze-dryers. The system has been designed for automatic detection & treatment of vials in an automatic line. Designed for detection and the subsequent management of a particular vial in the process line, the module is able to identify and separate a specific vial according to different parameters: stopper position, missing stopper, wrong stopper position, color variation, etc. After identification, it is capable of performing several tasks: rejection of the vial to a rejection container, separation of vial for sampling, separation of one vial for a specific function, introduction of a pre-prepared vial or re-introduction of a vial subsequent to removal. This case study shows how the implementation of this new system effectively responds to high demanding specific challenges.

## Customer

European CMO

## Challenge

This Contract Manufacturer had the need to work with several different products, vials formats and recipes. The necessity to produce high value products for one of his customers requires the use of product temperature sensors measurement during the process, to monitor the loaded vials and avoid loading defect vials and take samples to analyse the process after the lyophilization cycle

## Solution

Telstar in its commitment to solve the customer's challenges offered a loading and unloading module system able to fulfil the URS:

- Introduce and retrieve wireless temperature sensors without decreasing the high nominal loading speed.
- To monitor the loaded vials and avoid loading defect vials.
- To take samples in order to analyse the process after the lyophilization cycle.

## Results

- Fully automatic inspection module able to reject, retrieve for sampling or reintroduce vials.
- Detection when vial has no stopper.
- Detection of wrong stopper position.
- Detection of different colours of stopper.
- Total flexibility to handle different formats of containers from 2 ml up to 50ml with minimum and quick change parts in de loading/unloading module.

- Very compact lay-out.
- Easy integration with RABS and isolator.
- Full speed: 600VPM 2R vials / 400VPM 10R vials.

## URS challenges

Telstar received the URS from the customer with the important requirements that are treated in this article.

## Placement and retrieve wireless sensors

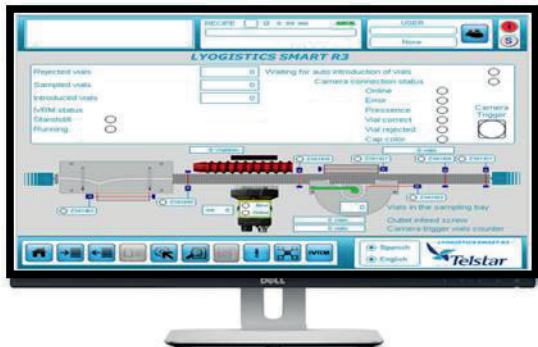
It is a common way to control the batch uniformity, controlling the product temperature. Even though, handling wired temperature sensors in automatic loading and unloading systems is an impossible task. The solution is to use wireless temperature sensors which can be managed by the loading system without any difficulty.

The customer requested to place the sensors in certain positions in certain shelves in order to monitor the temperature. These points were considered to be strategic points during the process.

Product Sensors	Integrated wireless sensors are required. 2 sensors per shelf.
Product Sensors	Wireless sensors must be able to be placed in the strategic position chosen by the user.
Product Sensors	The position of wireless sensors must be able to be selected by the user.
Product Sensors	Wireless sensors must be recovered after unloading process before sending vials to capping station.

Smart R3 provides the user with the option to place a pack of vials with wireless sensors integrated or in the case of thermolabile products, at the beginning of the loading process. This allows for the opportunity to take vials filed at a certain moment, replace the stopper and change it for a stopper with the sensor integrated.

Smart R3 is operated by Lyosuite SCADA which easily provides the user with information about rejected vials, number of loaded... Smart R3 analyse 100% of vials and by the use of editable recipes, the user could select the specific moment or position when he wants to introduce the vial with the sensor.



After the lyophilization cycle, all the vials are unloaded and they pass through the detector system that detects the wireless sensor and recover the vials which contain it.

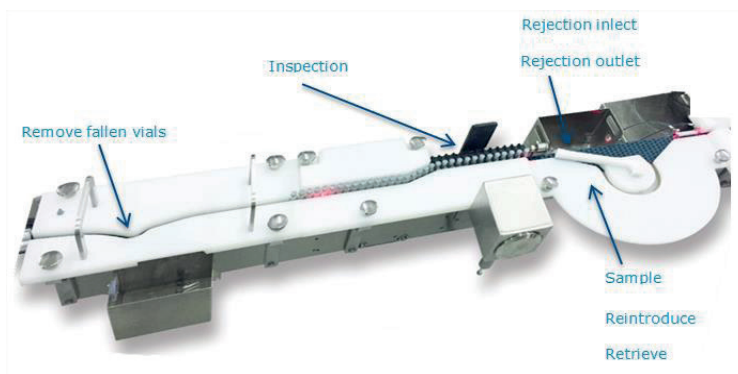
During technical discussions in the pre-sales phase, the customer revealed that they currently have issues such as loss of projects due to the demands of their customers who have asked for the monitoring of product temperature. They have been limited to what they can offer as they are unable to integrate wireless sensor in their current freeze dryers.

The system integrates several mechanisms ensuring appropriate processing of lyophilized products as well as reducing the risk of batch contamination, spoilage and the time of operator intervention. Vials are transported by conveyors and screws without pushers, neither bellows nor mechanisms in contact with product, which allows the module to work in an open system without concealed parts guaranteeing cleanliness and greater performance.

## Monitoring of processed vials after the lyophilization cycle

The CMO needs to deliver a report to one of his customers that certifies that the residual moisture is in between a certain acceptance criteria and this customer requires that this humidity is measured by the Karl Fischer method.

With the objective to monitor the batch uniformity in terms of residual moisture after the lyophilization process, the customer wanted to select certain vials and place it into a known position in a certain row. This means, the customer knows where the loaded vial is and after recovering the freeze dried vial, he can elaborate a matrix and analyse the batch uniformity.



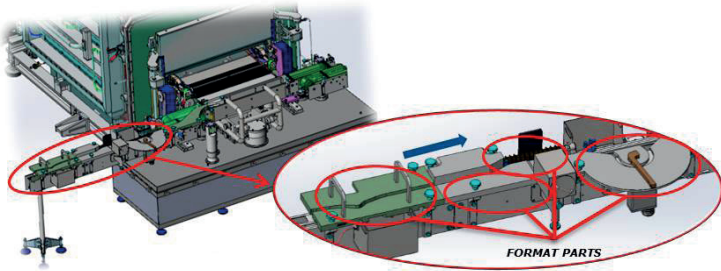
The compact module is featured by a diaphanous nature, unobstructed and clear. No racks, belts, or linkages occupy the work area and all mechanisms are under the base plate or closed. The compact and versatile solution, which has been conceived for management at high process speeds of up to 600 vials per minute, is compatible with cold sterilization methods as Hydrogen Peroxide and offers easy integration with RABS and isolators.

## Flexibility to handle different formats of containers

The customer works as a CMO and has the need to manage different formats of vials. This requires them to process their freeze-dried products in a versatile loading and unloading system adaptable to different format of containers.

Code	Name	Description	GMP CRITICAL
E.1	Formats	<p>The machine must be capable to receive and work with vials with all combinations of the following materials:</p> <ul style="list-style-type: none"> <li>Vials from 14 mm to 54 mm in diameter</li> <li>Vials from 35 mm to 100 mm in height</li> <li>Stoppers from 13 mm to 28 mm in diameter</li> </ul> <p>A useful height of 114 mm is required for each shelf.</p>	NO

Telstar offered a versatile solution which was able to work with the numerous containers required by the customer. By using a screw system, it makes it easier to work using the same installed unit (with minor format changes/adaptations) to handle different product formats, providing a large array of configurations which offers the management of several formats of production. For that reason the loading/unloading inspection module driven by conveyors and screws was the technical solution applied.



The versatile module has been configured to be integrated to industrial-scale single-side or pass-through freeze-dryers and the vial detection/sampling system will work according to the freeze-dryers features, only inlet side, inlet and outlet side (same side) and inlet and outlet side (opposite side).

### Customer feedback

The customer was extremely pleased with the performance and the results.

### Plant Manager

“The project has been a huge success for us. With the implementation of this module, the lyophilization line has increased its performance allowing us to manage projects that until this moment were unthinkable for us due to the limitation of our previous line”.

### Production Supervisor

“With this module we have simplified the loading of wireless sensors. Now it is easy to program a recipe and they are loaded automatically, where we decide. The format change between loading and unloading is simple, just three or four pieces that easily perform cleaning and sterilization inside the isolator with hydrogen peroxide.”

### Conclusion

The inspection module system has proven to be a reliable and efficient solution, addressing the mentioned customer’s challenges. The system allows inline vial management to reject, retrieve for sampling, or reintroduce vials automatically during the loading / unloading process into the freeze-dryer. The module is able to identify and separate a specific vial according to different parameters such as stopper position, colour variation, wireless sensor inside, etc. After identification, it is capable of performing several tasks: rejection of the vial to a rejection container, separation of vial for sampling, separation of one vial for a specific function, introduction of a pre-prepared vial or re-introduction of a vial subsequent to removal.

## Telstar’s Lyophilization Technology Specialist



Ángel Díez, Lyophilization Technology Specialist at Telstar, holds an MEng in Industrial Chemical Engineering from the “Universidad de Valladolid (UVA)” Spain. In his senior year, he was collaborating as an intern at the Laboratory Sciences and Equipment Department at Azbil Telstar Technologies. After graduating, he became a full-time member of the department working in freeze drying process development as well as the R&D Department as a Process Engineer. Since 2015, Ángel has been a Lyophilization Technology Specialist, participating in a wide variety of projects, leading technical improvements and standardization of the freeze drying products range related to the Life Science industry. Currently Ángel is focused on offering technical support to the Sales Team and Product Managers at Telstar.

Need more information? Please, contact us: [pr@telstar.com](mailto:pr@telstar.com)

From Telstar we express our gratitude for your interest and your feedback

## Telstar Lyogistics Smart R3

Telstar Lyogistics Smart R3 is a new automated inline vial management device able to reject, reintroduce and retrieve vials during loading / unloading of pharmaceutical freeze-dryers. Developed by Telstar, the new system has been designed for automatic detection & treatment of vials in an automatic line without stopping or reducing the line speed. It is a must for applications like wireless temperature probes management in automated lines under isolators or close RABS.

Operated by a screw mechanism, without elements over the vials, the compact versatile system ensures the cleanliness and asepsis in the work zone. The module has been configured to be integrated to industrial-scale single-side or pass-through freeze-dryers and the vial detection/sampling system will work according to the freeze-dryers features, only inlet side, inlet and outlet side (same side) and inlet and outlet side (opposite side).

### About Telstar

Telstar, part of the azbil Group, is a company specialized in the development of engineering & construction projects, integrated process equipment and GMP consultancy solutions, including turnkey projects and critical installations, for companies associated with Life & Health Sciences (pharmaceutical & biotechnology, healthcare, cosmetic, veterinary and food & beverage industries, hospitals, laboratories & research centers). Acknowledged as one of the 10 major suppliers for the pharmaceutical industry, Telstar is one of the few international manufacturers able to offer integrated process solutions for the biopharmaceutical industry with in-house sterilization, freeze drying, containment, process water & waste treatment, clean air and cold storage technologies.

