

**WHITEPAPER**

**DEVELOPING INDUSTRY 4.0  
SOLUTIONS FOR  
PRE-FILLED SYRINGES  
MANUFACTURING OPERATIONS**

May, 2020

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## Introduction

*Pre-filled syringes are regarded as one of the most effective medical devices of administering medications to patients. The rapidly increasing demand for pre-filled syringes places enormous challenges on the pharmaceutical industry.*

The related technology developments keep pace with the growth of the global market for injectable medications. However, as far as manufacturing operations in pharmaceutical facilities are concerned, there is a key area with a big room for improvement yet to be developed. This is the logistic operations involving handling, transfer, and transport of pre-filled syringes towards the different production process stages. Such improvement area, involving a greater

quality, traceability, and productivity, necessarily requires the replacement of manual operations by fully automated systems.

Today, all this has turned even more relevant due to the pandemic of Covid19, which has brought out the urgent need for essential sectors such as pharma and medical to invest in Industry 4.0 technologies in order to become less and less dependent on manpower in manufacturing operations.

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### **„What are the major issues in the logistics of manufacturing drugs in pre-filled syringes?“**

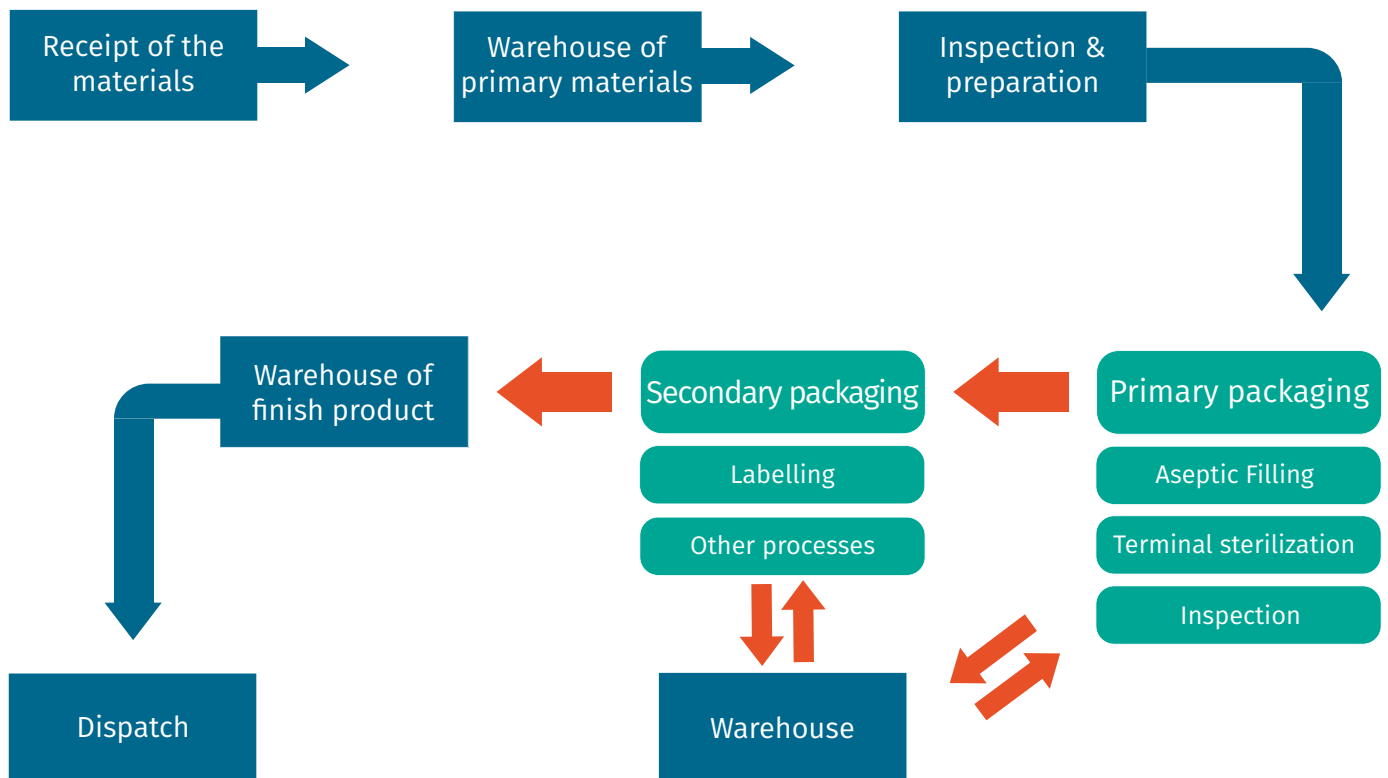
When manufacturing drugs packaged in pre-filled syringes (PFS), pharmaceutical companies focus their engineering efforts and financial investments on the filling process mainly. However, once the product is filled, there are several remaining process steps to be completed, which also pose a big challenge from the GMP perspective. As a matter of example, these operations are transfer to terminal sterilization (if applicable),

transfer to inspection and labelling machines, internal transport for temporary storage, etc. These operations, typically carried out manually, are a bottleneck in the production area and require a lot of human intervention, making them susceptible to the potential associated risks. Moreover, being an intensive manpower job, there is more need for space due to the “physical” work involved.

Pre-filled syringes are supplied by medical device manufacturers in a ready to use (RTU) package. The package is basically formed by two components; a nest, where a set of empty syringes are placed and a tub, which supports the nest and protects the syringe set. These components allow preserving the integrity and quality of the syringe, so they are key elements that should be ideally used during processing.

On the other hand, since the different operations

such as filling, sterilization, inspection, labelling, etc. are often not synchronized, or they are performed in different areas, **it is quite often required to transport large quantities from one place to another and keep them on hold or keep some temporary storage.** Moreover, these areas can be separated by long paths and in some cases, involve different buildings or even different sites. In these cases, the only way to overcome these issues are carrying out **palletization and de-palletization procedures.**





For the manpower, this means loading/unloading tubs in pallets and manage transport and storage. This job makes the worker dependent of machinery rhythm along his or her work shift. It is a tedious and quite boring job.

However, these workers must observe operational procedures and take care in the handling to guarantee the traceability and cosmetic appearance.

**The dependence on manual operations involve, especially in long term, higher risks of having quality issues and productivity losses in the logistics of pre-filled syringes manufacturing.**

This makes this job not so easy to replace by other personnel who has not been properly trained. Another issue that can appear is the sudden need of increase the rates of production.

A machine may have room for increase its speed, but to cope with that, at the beginning or the end of line, it will be necessary to increase of the number of operators for product transferring, feeding in machines, removing from them, etc. and from one point to another. This might lead to messy production areas. And the problem is that the space available is maybe the same.

So, the production areas become crowded of people which turns into a difficult situation to manage by operations.



In order to overcome these pitfalls, one can think that the best solution is to replace completely the personnel by a fully automated synchronized packaging line that connects all the different steps of the production.

This might be an attractive idea, but the main problem is the total loss of flexibility. So, that could be only feasible in few cases.

***Basically, when the factory produces one single product and at high production rates. As soon as you need to produce different products,***

***different sizes or different quantities, a lean manufacturing is only possible with flexibility.***

Just imagine what would be connecting different machines with tub conveyors.

There are many issues to overcome: to the complexity of synchronization between machinery, add the distances between them, maybe even in separate rooms. And what if any machine has a stoppage? Then, all the line must stop. At the end, we will always need to buffer intermediate product.

## „How to achieve a lean manufacturing in all process steps?“

*In summary, the main challenges that currently have factories processing pre-filled syringes are related with the logistics and specially, with the need to fill the gap between different machinery with flexible and efficient operations.*

**The answer to these challenges is the use of robotics.**

Robotics are particularly suitable for companies which need efficiency and flexibility, reducing the number of personnel needed for a series of mechanical operations.

Robotics are providing a shift in paradigm because rather than choosing among available standard options to try to fit the process to the machine, it is possible to configure a solution making the technology and the machine to fit the process.

Nowadays, robotics is playing a key role in the future of the pharmaceutical industry, as it continues to define new models for manufacturing.

**„STERISYS started the idea of bringing robotics in the logistics of pre-filled syringe manufacturing.“**

We analyzed the ideal properties that should have a new automated system to replace manual operations, and we determined the following ones:

- **The solution should take advantage of the existing package elements, nests and tubs, for safe handling.**
- **The solution should have a small footprint to be able to be implemented in existing operative conditions.**
- **The solution must guarantee the quality and traceability along all the process. The solution should work without requiring any human intervention: Zero Human Touch philosophy.**
- **The solution should work in reverse flow: From syringe to pallet and from pallet to syringe. In this way, it can be used for both: feed and collect tubs and syringes, depending on the application.**
- **The solution must be easily adaptable to different applications and scalable to higher production capacities.**



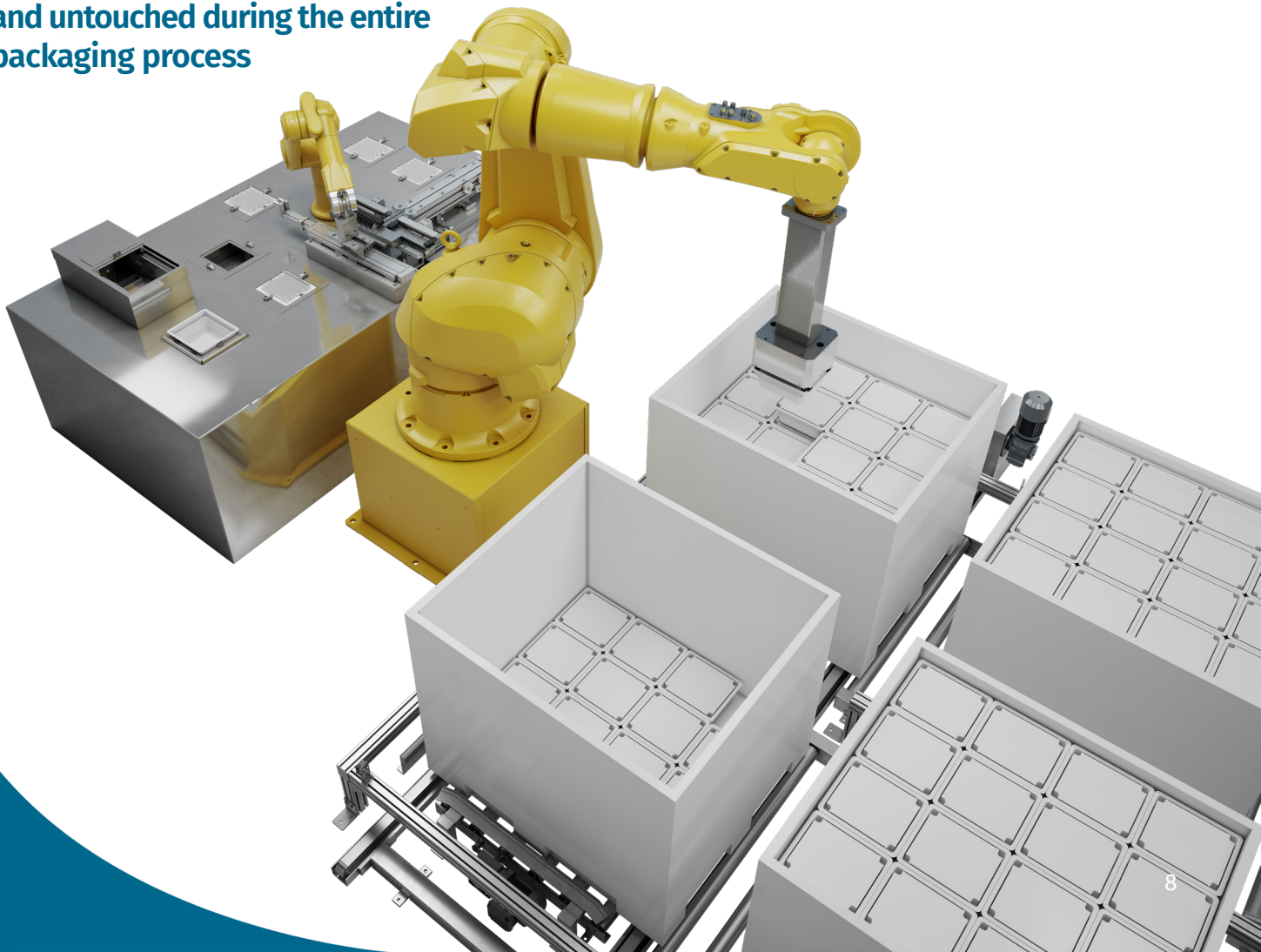
*Today, STERISYS can offer an end-to-end solution that can easily be integrated into existing production processes and guarantee reliable, safe, and rapid feed processes, bringing lean manufacturing to pre-filled syringes.*

This innovative solution uses the original standard support elements such as nests and tubs, which are handled by anthropomorphic robots. If required, STERISYS can offer customized and fully automated systems for sorting and feeding syringes – e.g. mixed in blisters or in any other formats – reintroducing them in nests and tubs for taking advantage of the solution.

No operator has to manually handle, at any moment - neither nests nor tubs, which significantly simplifies and enhances the yield of the logistic chain.

Operators are just there to manage pallets and supervise machinery operations. Operations carried out with our solutions benefit from the fact that they are customizable to any requirements, as independent units or as part of an existing production line.

**The benefit of the STERISYS robotized handling solutions is that the product and the syringe itself remain protected and untouched during the entire packaging process**



## „How is the solution working?“

The solution requires the implementation of two additional components and can be easily coupled with the existing nests and tubs:

### TUB PROTECTIVE COVER

The Tub Protection Covers (TPCs) are rigid plastic covers designed for optimal tub stacking and protect syringes during transportation. The protective cover therefore has four main functions:



- The stack support elements are assembled to position tubs on top of each other. Stacks of 8-9 units can be formed in a straight orientation.
- Mechanical influences on syringes are avoided when stacking max. 7-8 units - syringes are secure and dust-free.
- The special design of the protective cover allows the gripper to move the protective cover and the nest together, in one single work step.
- Our robot grippers are designed to match individual customer requirements. This makes it easier to continue using already existing materials and avoids additional costs.

## INTERMEDIATE TUB CONTAINER (ITC)

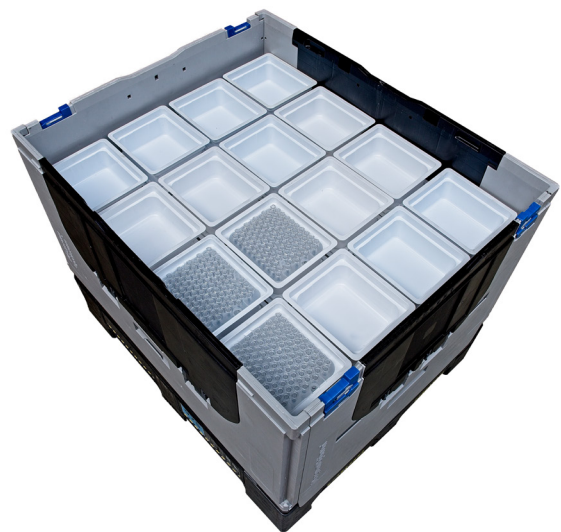
The second component is a container specifically designed to store tubs, which can be either with or without nested syringes inside.

These containers can be used at different packaging process stages, so we have called them Intermediate Tub Container (ITC).

Indeed, they are based on standard EU or AM pallets but with walls and a support pattern on the bottom part to address the tubs.

Thanks to the rigid design of the TPCs, it is also possible to stack empty tubs into our ITC. This is an important feature because it allows storing tubs while the syringes are being processed and right after, being reintroduced in the tub for next operation.

Thanks to the implementation of these two components: TPCs and ITCs, it will be possible to have a logistics and handling system entirely managed with anthropomorphic robots while having the product protected along the process.



## Overall view of the concept

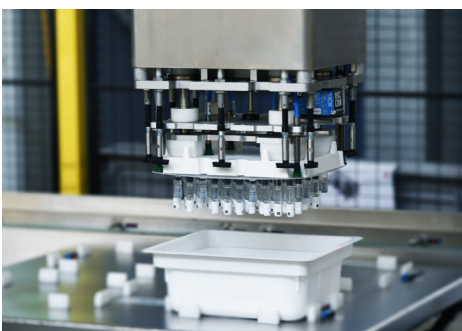
Once these components are included in the supply chain, everything becomes smooth and easy.

The robots have grippers specifically designed to handle the intermediate product in its different configurations: syringes, nested-syringes,

empty nests, covers, empty tubs, covered tubs, filled tubs or covered filled tubs.

Thanks to this ability, these robots can do any function of collecting and dispensing to or from the corresponding processing machines, which are basically:

- **Denesting robot for safe, automatic removal of syringes from nests**
- **Renesting robot for syringe placement into nests using highly precise nest positioning, fully automated with no risk of damage. This operation can be reversed to denesting.**
- **Palletizing robot for picking up tubs with TPC covers from a conveyor or ITC pallet to put them into another ITC pallet.**
- **Depalletizing robot for removing tubs with TPC covers from an ITC pallet and dispensing onto a conveyor or packaging machine. This operation can also be reversed to palletizing.**
- **In addition, TPC cover dispensing/storing systems are needed along the process in order to facilitate palletizing/depalletizing operations.**



Once you have all these elements in place, it is relatively easy to implement the philosophy Zero Human Touch in the logistics chain. It is just a matter of using the ITC pallet as the main logistic unit in the factory.

ITC pallets are used to collect the intermediate product from a machine and either store it or feed another machine with nobody handling manually neither tubs nor syringes.

## „Introducing ZHT logistics in the are of pre-filled syringes manufacturing“

The solution turns the pallet as the major logistic unit in the factory, being used as carrier to transfer, dispense and store nested syringes in tubs, so then, no operator will ever be needing to touch the product.



A solution based in anthropomorphic robots to handle syringes

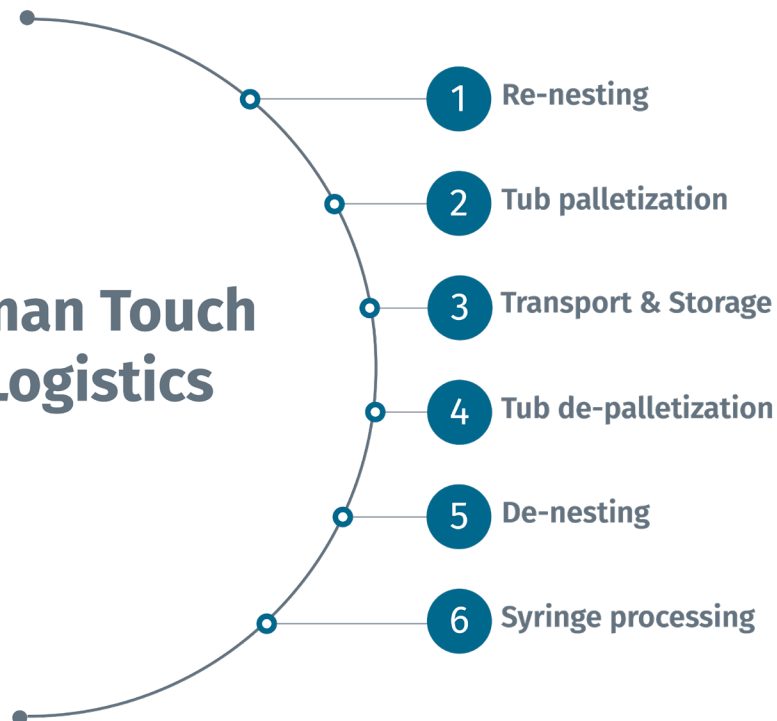


A solution to collect and feed processing machines with pre-filled syringes, automatically



Benefits: *Save space, save costs, safe workers, increase productivity, increase quality, avoid cosmetic defects*

### Zero Human Touch „ZHT“ Logistics



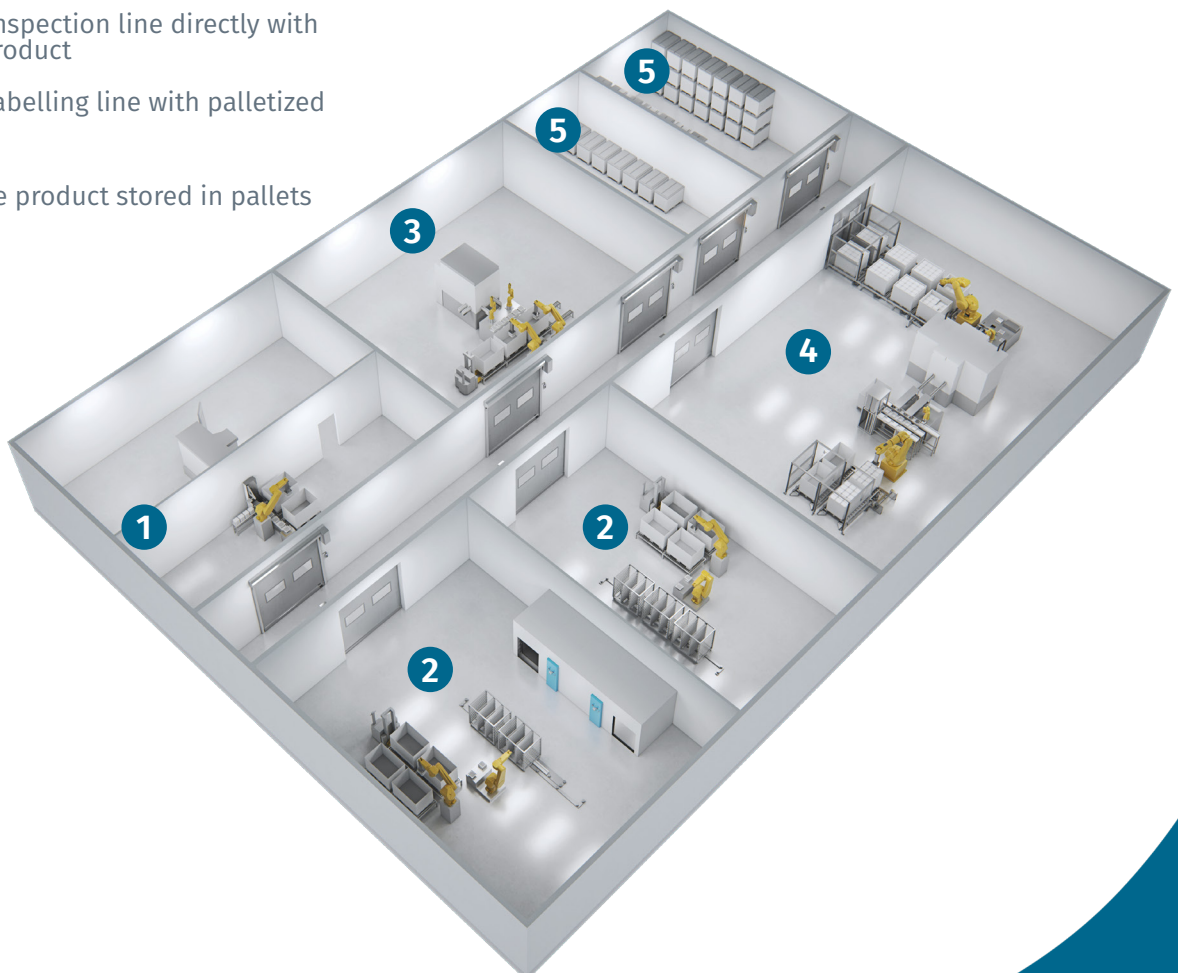
## „How does a „ZHT“ factory look like?“

The implementation of these components in the logistics and our robotized solutions will allow carrying out all the steps of the pre-filled syringes manufacturing, from filling machine exit to the last end-of-line machine with no human touch of the product.

The different automatic processes: filling, inspection, terminal sterilization (if apply) up to labelling, including buffering or storing areas, can be easily managed and connected just transporting pallets, making it the perfect environment for a lean production.

**A ZHT factory is a well-organized and highly productive factory with no crowded areas. The intermediate product is always protected and never touched by operators. Traceability is easy to implement and there's total flexibility in production thanks to the buffering or storing areas in the logistic chain.**

- 1 Tub palletization at filling line exit
- 2 Nested syringes transfer and tray loading/unloading
- 3 Feeding of inspection line directly with palletized product
- 4 Feeding of labelling line with palletized product
- 5 Intermediate product stored in pallets



## Conclusion

*Nowadays, with the growing demand for pre-filled syringes, manufacturers are facing big challenges in order to safely transfer, transport or store nested syringes.*

Who has ever tried to manage large quantities of nested syringes can understand how challenging can be the transferring of product along the different processing stages in a safe and efficient way; e.g. filling, sterilization, inspection, labelling, etc.

Pre-fillable syringes are hard to handle and not ergonomic for the hand. Manual tub loading/unloading, tray loading/unloading, etc. are boring tasks and consume time.

Pharmaceutical regulations also recommend avoiding manual handling as much as possible to ensure traceability and diminish risks for the product.

***Human centered production becomes inefficient and problematic and its replacement by traditional automation requires adapting processes to a completely new architecture without providing any flexibility. The use of anthropomorphic robots, with precise tools and components, solve both problems in one shoot.***

These robots can be easily implemented in the existing facility keeping flexibility while increasing productivity and enhancing quality assurance. The return on investment is fully guaranteed because they are a fully proven technology. Robots are reliable and do not need to rest. They are a key player in the Industry 4.0 revolution.

**Feel free to contact us!**

**Our experts will gladly advise you on how to implement industry 4.0 solutions into your production processes!**



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