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INJECTA
THE QUEEN OF QUALITY

The pharmaceutical industry has been increasingly embracing injectables as a consistently profitable business sector.

For decades, injection has been largely limited to in-patient use, with health professionals actively involved in administering doses intravenously, intramuscularly and subcutaneously. The introduction of **prefilled syringes and injection devices** has reduced the fear factor associated with outpatient injections. In short, injection has evolved from a being a last choice dosing option for patients.

These syringe and cartridge based packages also reduce the possibility of errors in preparing and administering a subcutaneous injection.
However, it may not be surprising to find that all of the top 10 pharmaceuticals by sales in 2018 were injectable, most of which are biologics and biosimilar: **the future expansion of injectables is directly linked to the future of biologics**.

The industry shift to biologics has established a growing market for injectables and supporting technologies. The pharmaceutical industry is adopting more and more emerging technologies to improve product quality and manufacturing efficiency.

Considering the steady growth of these next-generation therapies, Pharma companies' main concern focuses on **product quality rather than production performance**. We can therefore claim that flexibility in manufacturing is fundamental to production success. Flexible facilities allow production of different product volumes that can quickly respond to changes in expected market demand and enable rapid switching between different products and product packaging (i.e. vials, cartridges or syringes for parenteral).

Pharmaceutical companies that move products to market faster will beat their competitors in an era that demands greater agility.

Within this scenario, we have come up with **INJECTA**, a new concept of aseptic filling machine for injectable pharmaceuticals. Our aim was to adopt an **innovative approach to handling nested syringes, vials and pre-capped cartridges**. We were motivated by the notion that conventional, fill-finish lines are not flexible in terms of primary packaging materials (such as vials, syringes and cartridges) as expected by the latest market requirements. They fail to meet the current need to produce a varied product portfolio. When therapies require smaller volumes and there is a higher number of different products to manufacture in medium to low production batches, **flexible methods of production** are essential.

INJECTA responds to this demand for high flexibility and to the challenges of the ever-increasing complexity of new drug substances. The use of **advanced robotic driven manipulations** versus conventional handling systems actually improves product quality and manufacturing efficiency.
INJECTA can handle pre-sterilised Ready-To-Use containers (syringes, vials or pre-capped cartridges), pre-oriented vials in trays as well as sterilised vials from depyrogenation tunnel, permitting high process flexibility and adaptability.

Specialised robots perform all handling activities with no glass-to-glass contact and in the absence of operator intervention. The result is "less time" spent validating aseptic conditions, and superior agility for multi-product manufacturing.

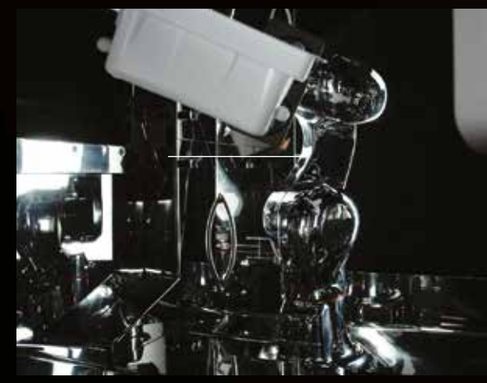
A very high level of modularity means INJECTA can be set for 1 or 2 filling groups for clinical trials of small production badges and for 5 or 10 filling groups for high production demand. It can be equipped with peristaltic or volumetric dosing pumps which are driven by the same system.

Winning features:
- Revolutionary in-line **100% process control, with single component reject from the nest**.
- Robot asynchronous movements, allowing single operation completion.
- Empty tub/tray transfer performed at robot base level without the use of conveyors.
- Use of a **linear stopper feeding system**, avoiding particle generation from vibratory bowls.
- De-nesting operation available for high-level quality control, with robot individual component handling.

The ultimate INJECTA "ISLE" project improvement, ready by the end of the current year, provides further benefits:
- All the operating units (filling, IPC & stoppering) are located in a **remote location** from the product path.
- Further risk deduction is achieved by integrating the fill-finish process within **gloveless** barrier isolation systems.
- **Easier access** to filling and stoppering areas from both sides of the machine.
- **Improved protection** of the fill-finish process by an uninterrupted unidirectional airflow.
- **Advanced ergonomics** with air recirculation duct redesign.
- Reduced isolator shell width with positive impacts on space ergonomics.

By embracing and adopting **new robotic technologies** throughout all production operations, from outer/inner bag opening to the stoppering station, INJECTA allows for a very smooth production process, drastically reducing human interventions and therefore cross-contamination risks.
INJECTA can be further integrated with an **in-line lyophilisation process**, where an automated Loading/Unloading system handles products into and out of the Freeze Dryer. At the end of the lyophilisation process, the pressure applied by the Freeze Dryer shelves closes the vials. Then, stoppered vials move to capping operations, relying on conventional standard primary packing components (alu caps).

INJECTA's fully automated technologies fulfil Authority guidelines for data integrity and keep up with new industrial principles.
In line with Industry 4.0 requirements for **interconnected production data**,



INJECTA's integrated automation platform allows for complete data accessibility and circulation, efficiency and ability to exchange big volumes of data.

In short, considering that pharmaceutical companies need technology support for automated and interconnected manufacturing, we can say that INJECTA, by providing **improved quality and flexibility in the production process**, can fully achieve this reality.
When effectively implemented, automation can increase efficiency, productivity and quality while reducing costs and time-to-market.