

dara-pharma.com

# PHARMA FILLING LINES

High-tech pharmaceutical  
packaging systems





Focused on quality,  
innovation, and technological  
excellence

Dara Pharma provides the pharmaceutical, biotech and cosmetic industries with the most advanced technological equipment in the market, contributing to the improvement of the well-being and quality of life of people.



#### CORE BUSINESS

Pharmaceutical packaging  
machinery design, development,  
and manufacturing

Dara Pharma designs, develops, and manufactures washing, sterilizing, filling, freeze-drying, and closing machines for vials, bottles, syringes, cartridges, and IV Bags to process liquid, semi-solid products, and powders in sterile conditions. The machines run either individually or can be integrated into a complete production line.



#### AFTER-SALES SERVICE

Supporting locally,  
acting globally

We have created a cross-functional team of more than 15 nationalities to give excellent after-sales service. Represented in more than 80 countries with continuous support from local offices and sales representatives.



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1996  
company  
founded

+400  
employees  
worldwide

+60  
machines completed  
per year

+1200  
machines installed  
worldwide

+80  
countries with  
business activity

97%  
exported

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Dara Tech Center  
and After Market

Excellence and safety for the demanding standards of the pharmaceutical and biotech industry

Dara Pharma, UNE-EN-ISO9001:2015 certified, maintains a rigorous quality management system that integrates continual improvement processes to achieve the highest quality and safety standards, aimed mainly at the pharmaceutical sector. Our equipment is designed in compliance with FDA, GMP and GAMP5, and can be operated in the pharmaceutical industry worldwide.



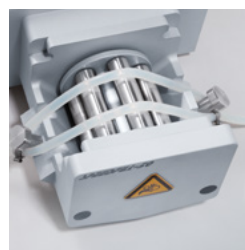


Tabletop filling equipment

## SX-50 SpeedFill

Tabletop peristaltic pump

No cross contamination / Filling from 0.1 ÷ 1,050 ml / Flow up to 6.4 l/min / Dosing accuracy  $\pm 0.5\%$   
Product changeover in 1 minute / Drip-free function / Automatic recalibration / Audit trail



### Optional equipment

- Dosing nozzles, nozzle support and peristaltic tubes.
- Additional peristaltic head, up to 3 heads in series.
- Peristaltic head completely made of AISI-316L stainless steel.
- IQ / OQ Validation package.
- Dosing tubes: thickness 2.4 mm, internal  $\varnothing$  0.5 / 0.8 / 1.6 / 3.2 / 4.8 / 6.4 / 8 / 9.6 mm.

## SX-50 Volumetric

Tabletop volumetric pump

Filling from 0.1 ÷ 250 ml / Dosing accuracy  $\pm 0.2\%$  / Drip-free function  
Automatic recalibration / Easy and quick maintenance / Output up to 6,000 uph



Valveless rotary piston pumps, in AISI-316L stainless steel or ceramic



Model	SX-50-V/S	SX-50-V/D
Output max.	6,000 uph	
Dosing range	0.1 ÷ 150 ml	0.1 ÷ 250 ml



Tabletop filling equipment

## SX-50 MicroFill

Powder micro dosing equipment

Cost-effective / Filling from 0.002 ÷ 25 g / Dosing accuracy  $\pm 0.5 \div 2\%$   
Output up to 1,000 uph



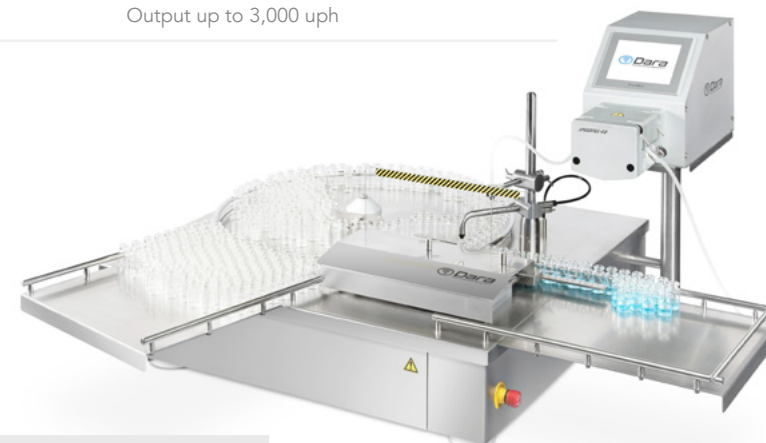
Model	SX-50/MF
Output max.	1,000 uph
Dosing range	0.002 ÷ 25 g



## SX-100

Tabletop machines for automatic feeding and filling of vials and bottles

Cost-effective / Filling from 0.1 ÷ 250 ml / Format changeover in 5 minutes  
Output up to 3,000 uph



Model	SX-100
Output max.	3,000 uph
Containers sizes	$\varnothing$ 65 - h 210 mm max.





Tabletop closing equipment

## SX-10 Syringe

Manual plunger  
insertion device

Cost-effective / Plunger insertion by compression  
Format changeover in 2 minutes

## SX-60 Syringe

Tabletop machines for  
automatic closing of syringes

Compact machine / Plunger insertion by compression  
or vacuum / Format changeover in 5 minutes



Model	SX-10-S	SX-60-S
Output max.	400 uph	1,000 uph
Containers sizes	-	Ø 36 mm max.



## SX-140

Tabletop machines for automatic closing  
of vials and bottles

Compact machine / Cost-effective / Output up to 1,500 uph



Model	SX-140-C	SX-140-R
Output max.	1,500 uph	
Containers sizes	Ø 60 - h 210 mm max.	



Vials

## SX-220-PP

Rotary machines for automatic feeding,  
filling, and closing of vials

Liquid filling from 0.1 ÷ 250 ml / Powder filling from 0.002 ÷ 2.4 g  
Format changeover in 5 minutes / Output up to 6,000 uph



Liquid filling



Powder filling



### Optional equipment

- Washing unit and sterilization tunnel for vials supplied in bulk.
- Checkweighing of the dose.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Vacuum-assisted insertion of stoppers to reduce the presence of oxygen in headspace.
- Automatic rejection of defective vials.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Laminar flow / RABs.
- IQ / OQ validation package.

Model	SX-220-PP/S	SX-220-PP/MF/S	SX-220-PP/D	SX-220-PP/MF/D
Output max.	3,600 uph		6,000 uph	
Containers sizes	Ø 65 - h 210 mm max.		Ø 25 - h 60 mm max.	



Vials

## SX-310-PP

Linear machines for automatic feeding,  
filling, and closing of vials

Filling from 0.1 ÷ 250 ml / 100% IPC / Output up to 7,200 uph



### Optional equipment

- Washing unit and sterilization tunnel for vials supplied in bulk.
- 100% checkweighing.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Vacuum-assisted insertion of stoppers to reduce the presence of oxygen in headspace.
- Automatic rejection of defective vials.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Laminar flow / RABs / Isolator.
- IQ / OQ validation package.

Model	SX-310-PP/S	SX-310-PP/MF/S	SX-310-PP/D	SX-310-PP/MF/D
Output max.	3,600 uph		7,200 uph	
Containers sizes	Ø 52 - h 110 mm max.		Ø 36 - h 75 mm max.	

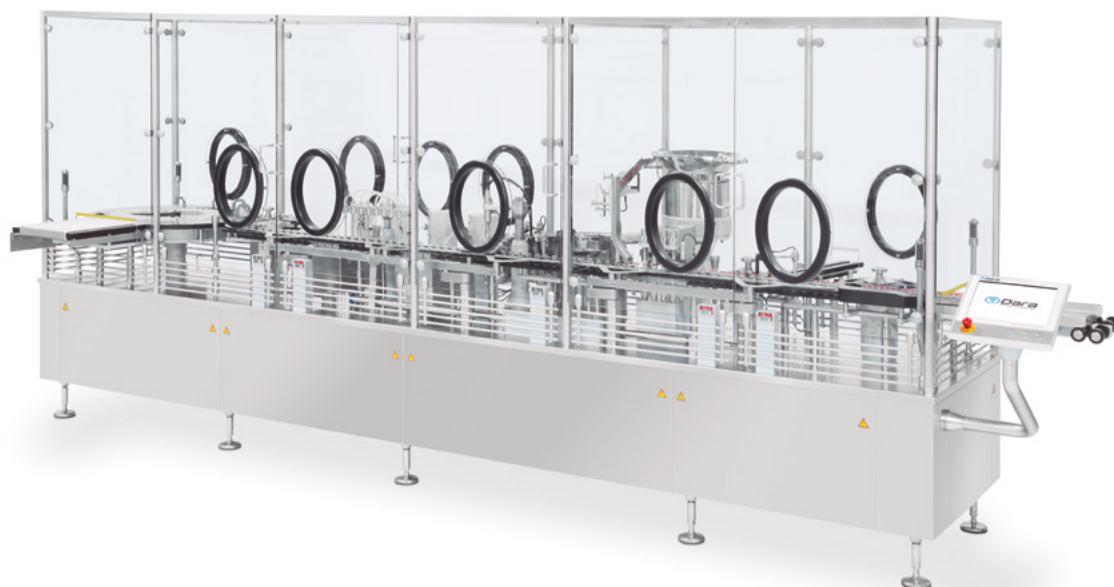


Vials

## HSL-PP

High-speed filling and closing  
machines for vials

Filling from 0.1 ÷ 540 ml / 100% IPC / Output up to 36,000 uph



### Optional equipment

- Washing unit and sterilization tunnel for vials supplied in bulk.
- 100% checkweighing.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Vacuum-assisted insertion of stoppers to reduce the presence of oxygen in headspace.
- Automatic rejection of defective vials.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Laminar flow / RABs / Isolator.
- IQ / OQ validation package.

Model	HSL-PP/4	HSL-PP/6	HSL-PP/8	HSL-PP/12
Output max.	12,000 uph	18,000 uph	24,000 uph	36,000 uph
Containers sizes	Ø 52 - h 110 mm max.			





Cartridges

## SYX / HSL Cartridge

Filling and closing machines for cartridges

Filling from 0.1 ÷ 50 ml / Output up to 24,000 uph



### Optional equipment

- Washing unit and sterilization tunnel for cartridges supplied in bulk.
- 100% checkweighing.
- Gas flushing before or during the filling process.
- Dosing system for CIP / SIP conditions.
- Level filling controlled by laser sensor, no overfilling.
- Automatic rejection of defective cartridges.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Laminar flow / RABs / Isolator.
- IQ / OQ validation package.

Model	SYX-C/S	SYX-C/D	HSL-C/4	HSL-C/6	HSL-C/10
Output max.	4,500 uph	8,500 uph	12,000 uph	18,000 uph	24,000 uph
Containers sizes	Ø 25 - h 95 mm max.		Ø 12 - h 75 mm max.		

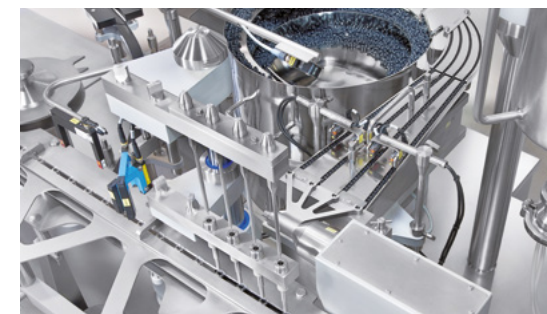
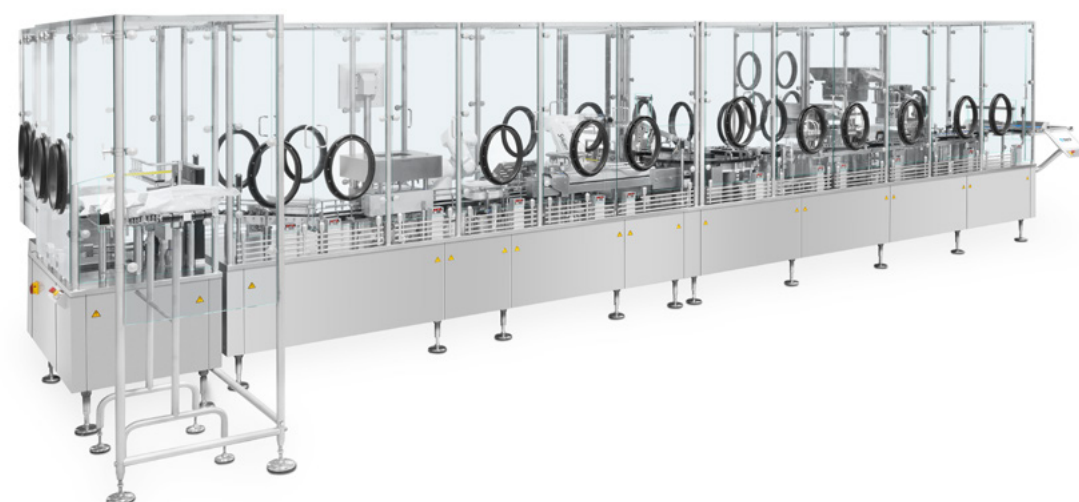


Vials / Syringes / Cartridges

## VSC

Multiformat filling and closing machines

Filling from 0.1 ÷ 100 ml / 100% IPC / Output up to 24,000 uph



### Optional equipment

- Washing unit and sterilization tunnel for vials and cartridges supplied in bulk.
- Denesting unit for RTU (Ready-to-use) formats.
- 100% checkweighing.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Automatic rejection of defective containers.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Laminar flow / RABs / Isolator.
- IQ / OQ validation package.

Model	VSC/1	VSC/2	VSC/4	VSC/6	VSC/8
Output max.	3,600 uph	7,200 uph	12,000 uph	18,000 uph	24,000 uph
Containers sizes	Ø 40 - h 140 mm max.				



Washing

## WM / RWM

Automatic washing units for vials, syringes, and cartridges

Multiformat machines / Quick format changeover / Output up to 36,000 uph



Linear washing unit WM



Rotary washing unit RWM



### Optional equipment

- Pre-washing cycle with ultrasound bath.
- Steam sterilization of pipes.
- Drying-in-place of pipes.
- Siliconizing cycle.

- Automatic rejection of defective containers and extraction for sampling.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- IQ / OQ validation package.

Model	WM-10	WM-20	WM-30	WM-40	WM-60
Output max.	7,200 uph	12,000 uph	18,000 uph	24,000 uph	36,000 uph
Containers sizes	Ø 78 mm	Ø 52 mm	Ø 42 mm	Ø 26 mm	Ø 26 mm

Model	RWM-10	RWM-20	RWM-30	RWM-40
Output max.	7,200 uph	12,000 uph	18,000 uph	24,000 uph
Containers sizes	Ø 78 mm			



Sterilization

## DT

Sterilization and depyrogenation tunnels for glass containers

Continuous processing / Automatic format control and adjustment / Output up to 610 kg/h



### Optional equipment

- Differential pressure control.
- Clean room sealed door.
- Automatic tunnel discharge.
- Cooling chamber sterilization.
- Automatic adjustment of chambers doors opening.

- Air speed monitoring.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- IQ / OQ validation package.

Model		DT-9	DT-20	DT-26	DT-40	DT-50
Output max.	2R	12,000 uph	29,000 uph	36,000 uph	> 36,000 uph	> 36,000 uph
	10R	6,350 uph	13,100 uph	18,850 uph	26,000 uph	32,000 uph
	30R	4,000 uph	8,400 uph	11,875 uph	16,500 uph	22,500 uph
	100H	690 uph	1,650 uph	2,055 uph	3,050 uph	3,600 uph





Debagging

**DB**

Automatic debagging for RTU vials,  
syringes, and cartridges

Automatic opening of the bag / Automatic transfer of the tub towards a downstream machine  
through an automatic sliding door / Output up to 225 Tubs/h



#### Optional equipment

- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- GAMP complying software.
- Laminar flow / RABs.
- IQ / OQ validation package.

Model	DB/A	DB/A+
Output max.	115 Tubs/h	225 Tubs/h

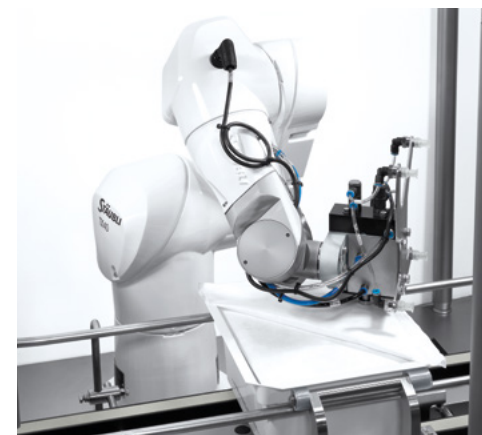
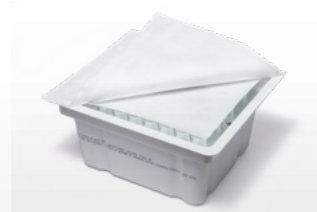


Delidding

**DL**

Automatic delidding for RTU vials,  
syringes, and cartridges

Tub pre-heating to avoid particle generation during the Tyvek lid removal  
Inner liner removal through vacuum / Output up to 225 Tubs/h



#### Optional equipment

- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- GAMP complying software.
- Laminar flow / RABs / Isolator.
- IQ / OQ validation package.

Model	DL/A	DL/A+
Output max.	115 Tubs/h	225 Tubs/h



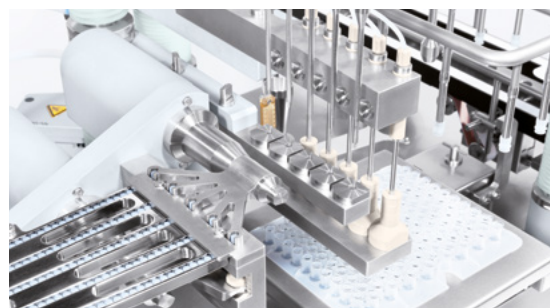


Filling / Closing

## NFL

Filling and closing machines for vials, syringes, and cartridges in nest

Filling from 0.1 ÷ 100 ml / Output up to 22,600 uph



### Optional equipment

- Automatic loading / unloading of the nest.
- Vacuum-assisted filling to prevent air trapped in the luer channel.
- Vacuum-assisted plunger insertion for rigid or Teflon coated plungers.
- Checkweighing of the dose.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Laminar flow / RABs / Isolator.
- IQ / OQ validation package.

Model	NFL/1	NFL/2	NFL/5	NFL/10
Output max. syringe 0.5-1 ml Long	2,300 uph	5,200 uph	11,400 uph	22,600 uph
Output max. vial 2R	2,100 uph	5,000 uph	10,200 uph	20,400 uph
Output max. cartridge 3 ml	1,200 uph	2,700 uph	5,300 uph	11,200 uph



Denester / Renester

## DN / RN

Loading and unloading machines for vials, syringes, and cartridges in nest

Compact machine / Quick format changeover / Output up to 24,000 uph



### Optional equipment

- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- "No glass-to-glass contact" denester.
- Monitoring and particle counting.
- Laminar flow / RABs / Isolator.
- IQ / OQ validation package.

Model	DN/N	DN/E	DN/E+
Output max.	9,000 uph	12,000 uph	24,000 uph



Eye drops / Nasal sprays

SX-180-OR / SYX-OR

Rotary filling and closing machines for eye drops and nasal sprays

Filling from 0.1 ÷ 250 ml / Output up to 8,500 uph



Optional equipment

- Checkweighing of the dose.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Torque monitoring and adjustment of 100% processed bottles.
- Automatic rejection of defective bottles.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 1.
- Monitoring and particle counting.
- Laminar flow / RABs / Isolator.
- IQ / OQ validation package.

Model	SX-180-OR	SYX-OR/S	SYX-OR/D	SYX-OR/D+
Output max.	3,600 uph	4,500 uph	6,000 uph	8,500 uph
Containers sizes	Ø 65 - h 210 mm max.		Ø 26 - h 60 mm max.	

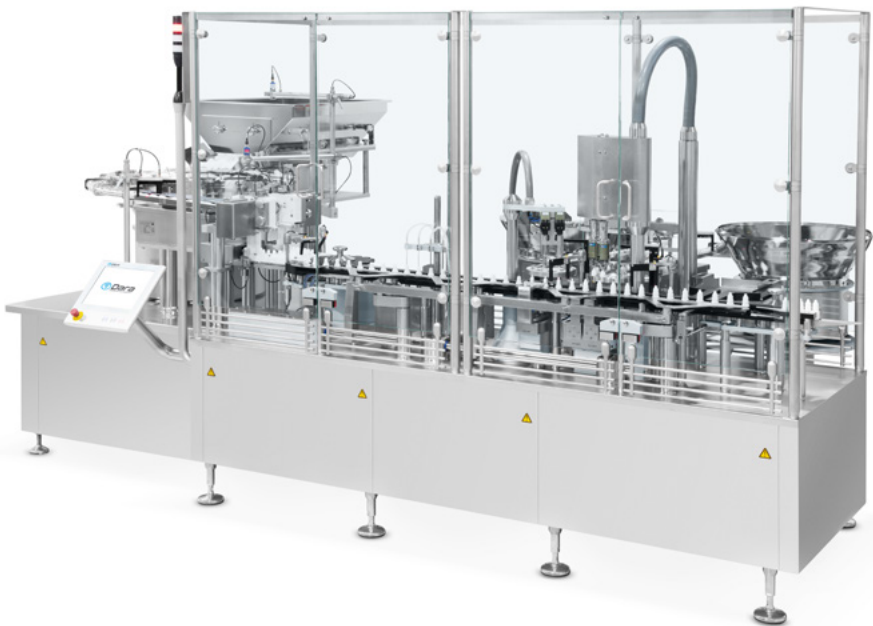


Eye drops / Nasal sprays

SX-310-OR / HSL-OR

Linear filling and closing machines for eye drops and nasal sprays

Filling from 0.1 ÷ 250 ml / 100% IPC / Output up to 24,000 uph



Optional equipment

- 100% checkweighing.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Torque monitoring and adjustment of 100% processed bottles.
- Automatic rejection of defective bottles.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Laminar flow / RABs / Isolator.

Model	SX-310-OR/S	SX-310-OR/D	HSL-OR/4	HSL-OR/6	HSL-OR/8
Output max.	3,600 uph	7,200 uph	12,000 uph	18,000 uph	24,000 uph
Containers sizes	Ø 65 - h 210 mm max.		Ø 52 - h 110 mm max.		





UDS / BDS

## UDS / BDS

Filling and assembling machines for UDS / BDS devices

Compact machine / Filling from 100 ÷ 250 µl ±0.5% / Output up to 24,000 uph



Aptar  
pharma

UDS



BDS



### Optional equipment

- Checkweighing of the dose.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.

- Vision control of the assembling process.
- Automatic rejection of defective devices.
- Monitoring and particle counting.
- Laminar flow / RABs.
- IQ / OQ validation package.

Model	UDS/S	UDS/D	UDS/4	UDS/6	UDS/8
Output max.	3,600 uph	6,000 uph	12,000 uph	18,000 uph	24,000 uph
Dosing range	100 ÷ 250 µl				



Microtubes

## SX / SYX / HSL Microtube

Filling, closing, and labeling machines for microtubes

Compact machine / Filling from 0.001 ÷ 100 ml / Output up to 12,000 uph



### Optional equipment

- Checkweighing of the dose.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Torque monitoring and adjustment of 100% processed microtubes.

- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Automatic rejection of defective microtubes.
- Monitoring and particle counting.
- Laminar flow / RABs.
- IQ / OQ validation package.

Model	SX-180-MT	SYX-MT/S	SYX-MT/D	SYX-MT/D+	HSL-MT/4
Output max.	3,600 uph	4,500 uph	6,000 uph	8,500 uph	12,000 uph
Dosing range	0.001 ÷ 100 ml				





IV Bags

## SX-170 IV Bag

Compact machines for automatic filling and closing of IV Bags

Compact machine / Filling from 50 ÷ 10,000 ml / Output up to 3,200 uph



Flexible preformed bags with single or multiple chambers, made of EVA, PVC, PE or PP.



### Optional equipment

- Injection ports or connectors insertion.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Closing by port / connector insertion or by thermal / high-frequency welding.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Laminar flow / RABs / Isolator.
- IQ / OQ validation package.

Model	SX-170/S	SX-170/D
Output max. for 500 ml bag	400 uph	800 uph
Dosing range	50 ÷ 20,000 ml	



Plastic syringes

## SFL-Luer / Vet

Rotary machines for processing of plastic syringes

## HSL-Luer / Vet

Linear machines for processing of plastic syringes

Compact machine / Filling from 0.1 ÷ 120 ml / Output up to 24,000 uph



### Optional equipment

- Filling from the tip of preassembled syringes.
- Vacuum-assisted plunger insertion.
- Checkweighing of the dose.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Automatic rejection of defective syringes.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Laminar flow / RABs.
- IQ / OQ validation package.

Model	SFL-Luer/S	SFL-Luer/D	HSL-Luer/4	HSL-Luer/6	HSL-Luer/8
Output max.	3,600 uph	6,000 uph	12,000 uph	18,000 uph	24,000 uph
Containers sizes	Ø 6.85 ÷ 36 mm				



Syrups

## HSL-B Syrups

Linear filling and closing machines  
for syrups and suspensions

Filling from 1 ÷ 1,050 ml / 100% IPC / Output up to 24,000 uph



### Optional equipment

- Automatic feeders for glass or plastic bottles.
- Air rinse with vacuum station for bottles.
- 100% checkweighing.
- Gas flushing before, during or after the filling process.
- Torque monitoring and adjustment of 100% processed bottles.
- Dosing system for CIP / SIP conditions.

- Automatic rejection of defective bottles.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- Laminar flow / RABs / Isolator.
- Ex-proof available: ATEX / NFPA-497 / NEC-500.
- IQ / OQ validation package.

Model	HSL-B/2	HSL-B/4	HSL-B/6	HSL-B/8
Output max.	6,000 uph	12,000 uph	18,000 uph	24,000 uph
Containers sizes	Ø 60 - h 190 mm max.			

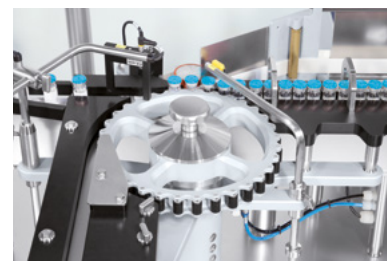


Vials / Syringes / Cartridges

## SYX-Lab

Labeling machines for vials,  
syringes, and cartridges

Compact machine / Reliable, fast, and robust labeling / Output up to 36,000 uph



### Optional equipment

- Backstop or finger grip assembling.
- Safety device assembling.
- Torque monitoring and adjustment during plunger rod insertion.
- Thermal transfer, laser, or inkjet printer.
- Label presence detection on the container.

- Barcode reader.
- Label OCV / OCR vision control system.
- Rejection of labels with printing defects.
- Rejection of containers with process defects.
- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- IQ / OQ validation package.

Model	SYX-Lab/12	SYX-Lab/18	SYX-Lab/24	SYX-Lab/36
Output max.	12,000 uph	18,000 uph	24,000 uph	36,000 uph
Containers sizes	Ø 86 - h 240 mm max.		Ø 60 - h 200 mm max.	

Model	ASL-Lab/S	ASL-Lab/D	ASL-Lab/4	ASL-Lab/6	ASL-Lab/8
Output max.	4,500 uph	8,500 uph	12,000 uph	18,000 uph	24,000 uph
Containers sizes	Ø 28 mm max.				



## Containment systems

### LAF / RABS / Isolator

#### Protection and containment equipment

Specific solution for any need

Due to the growing concern for product and operator protection and the complex regulatory framework of the pharmaceutical industry, it became essential to design the processing equipment together with the containment system.

Aseptic pharmaceutical manufacturing requires the production area to be free from microbiological and particle contamination. The environmental conditions for sterile processing are designed to maintain product sterility and are ISO 5 or Grade A classified, considering the following parameters:

- Particle level ( $> 0.5 \mu\text{m}$ ) less than 3,520 particles/m<sup>3</sup>.
- Vertical air flow laminarity.
- Humidity control.
- Temperature control.
- Air recirculation.
- Cleaning and decontamination procedures.

In accordance with these standards, Dara Pharma has developed a wide range of products for different environmental conditions and levels of protection:



#### LAF - Laminar Air Flow

It is a dynamic barrier of HEPA-filtered unidirectional air flow to move particles away from the filling/closing area. The line must operate in a clean room grade B or higher.



#### oRABS - Open Restricted Access Barrier System

A physical barrier between the operator and the product in addition to the dynamic barrier of HEPA-filtered airflow (LAF), composed of a glass cabinet, gloves, transfer ports, etc. The air is taken from and expelled directly into the room where the equipment operates. The line must operate in a clean room grade B or higher.



#### cRABS - Closed Restricted Access Barrier System

A physical and hermetic barrier between the operator and the product. The air is recirculated through dedicated return air ductwork in a sealed chamber. The system allows working at pressure differentials (upper / lower) to the surrounding environment, and monitors and controls the processing parameters (V, P, T, Hr, etc.). The line must operate in a clean room grade B or higher.



#### ISOLATOR / MODULINE™

It is the highest available level of containment for both sterile and toxic products, equipped with a hermetic chamber, rapid transfer ports (RTP) and predefined action protocols. The system features a dedicated decontamination system (VHP), sterility control, particle sampling and operating parameters that allow operating in an ISO 8 or class D classified room.



## Complete production lines

### Turn-Key Solutions

#### Complete tailor-made solutions

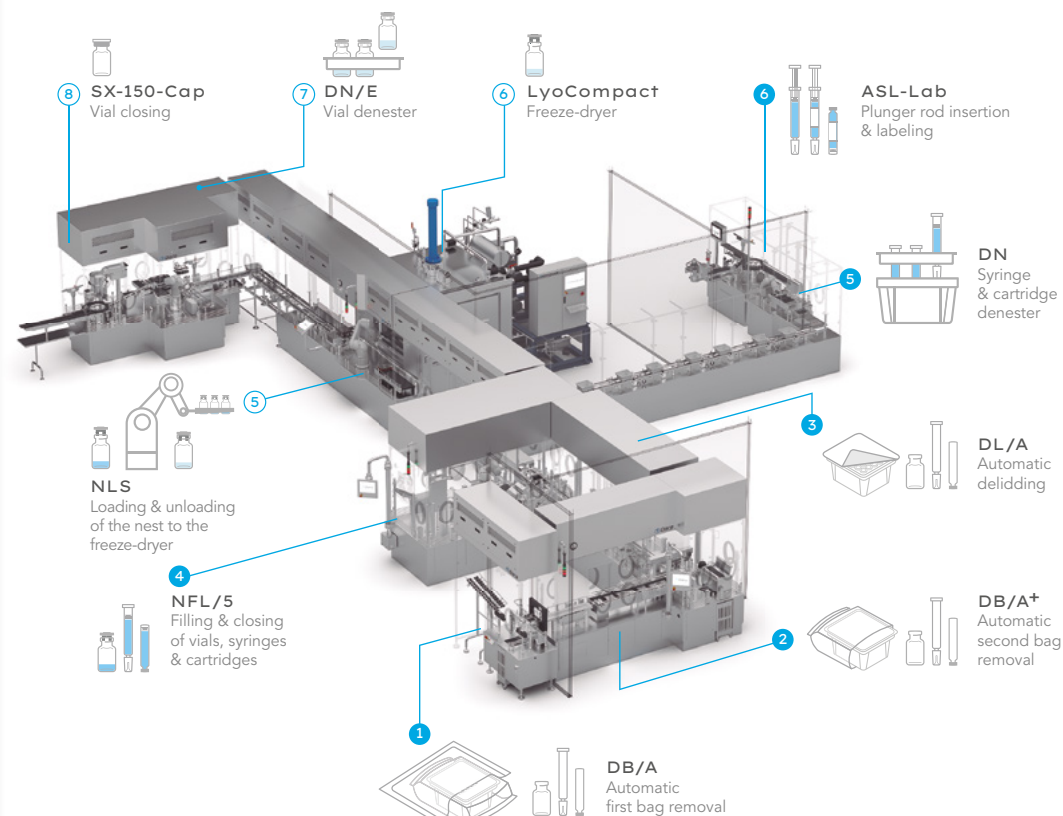
Adapted to client's layout / Multiformat lines / Full line integration

The continuous evolution and development of drugs and their routes of administration forced the pharmaceutical industry to invest in complex and reliable production lines that can be adapted to the specific needs of each client.

That is the reason why Dara Pharma has created the most complete and advanced range of multiformat equipment in the market, by evolving from manufacturing stand-alone machines to integrating complete lines that can process not only the formats in Nest or those supplied individually in Bulk, but also offer mixed solutions where customers can combine both options depending on the processed format.

Beyond customized products, Dara Pharma provides:

- Consulting during the conceptual phase of a project.
- Dedicated project manager throughout the manufacturing phase.
- Specific technical support for each unit that composes the line.
- Integration of ancillary or third-party equipment.
- Validation and guarantee of the complete line.
- Local and global technical assistance and support.







## Documentation and qualification

### Documentation and qualification

In pharmaceutical production, Good Manufacturing Practices (GMP) are essential to guarantee that the manufacturing process is constantly controlled according to the quality standards, and the drugs can be used safely.

Therefore, there must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process, ensuring clarity and traceability of the product quality data acquisition.

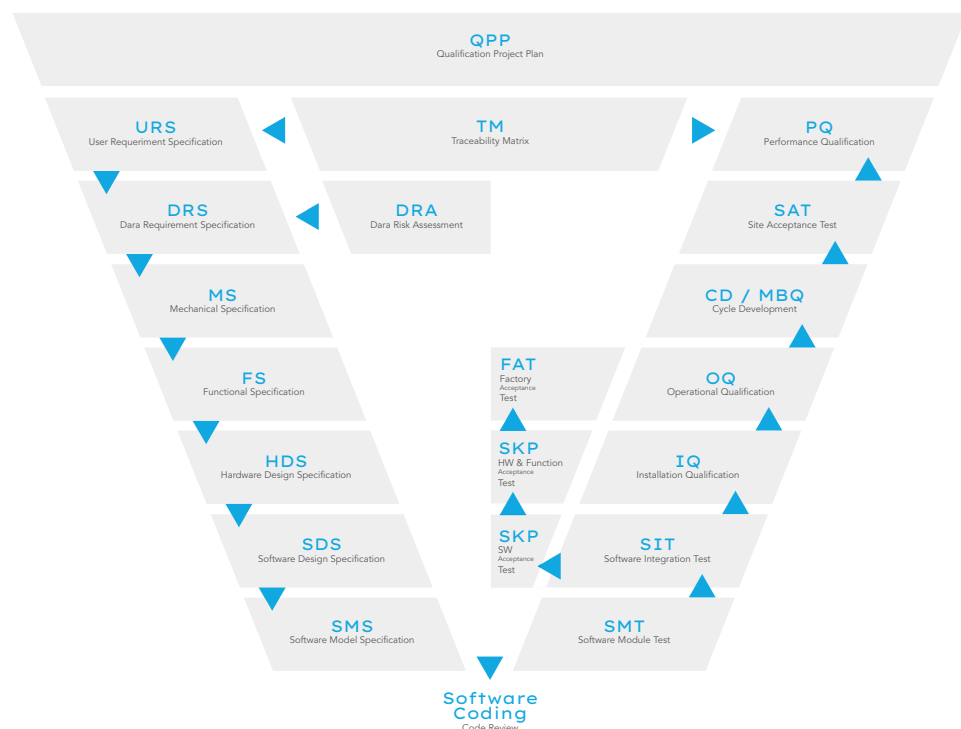
At Dara Pharma, we defined specific actions to ensure

that our document management, which we call GDP (Good Documentation Practices), fulfills this objective.

The document management starts with the client's specifications (URS) which help us understand the customer's needs and define the machine's configuration accordingly. The required machine's functionality will be tested later during the qualification tests.

The whole process is described in the picture below, showing the comprehensive Qualification Project Plan (QPP) that covers from mechanical assembly to software and control configuration:

### GMP & GAMP "V" PROCESS



## Documentation and qualification

The qualification documentation can be adapted to the specific needs of the client offering an individual approach.

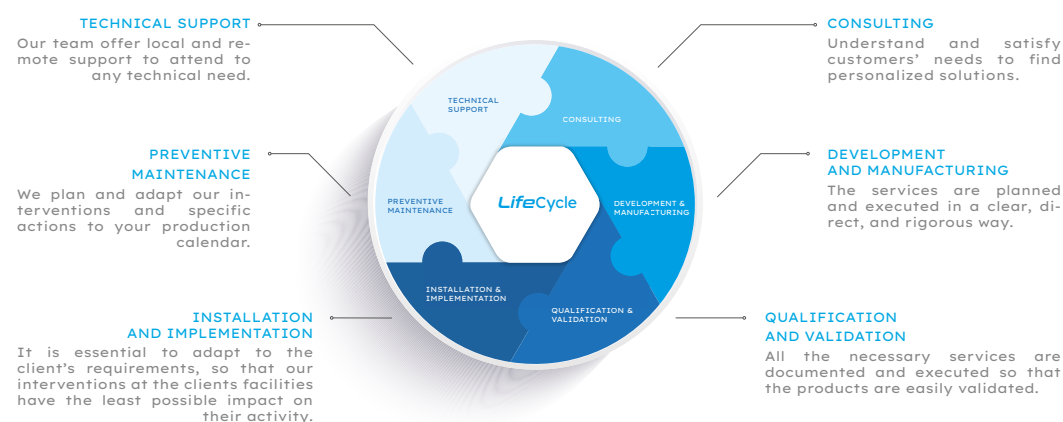
### DESIGN PROTOCOLS

- Qualification Project Plan (QPP)
- Functional and Design Specifications. (FDS)
- Hardware Design Specifications (HDS)
- Software Design Specifications (SDS)
- Risk Assessment (RA)

### TEST PROTOCOLS

- Design Qualification (DQ)
- Computer System Validation (CSV)
- Factory Acceptance Test (FAT)
- Site Acceptance Test (SAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Installation and Commissioning (IAC)
- Record of qualification deviations
- Record of qualification change controls

Dara Pharma's experts can take care of preparing and executing all necessary protocols.



Personalized protocols.



Documentation package for GMP equipment.



Dara Tech Center

## Dara Tech Center

Learn and develop together

Dara Pharma's long history in machinery manufacturing for the pharmaceutical industry, has allowed us to create a team of cross-functional specialized experts and put their knowledge and experience at the disposal of our clients.

The services offered by the Dara Tech Center are the following:

### R&D

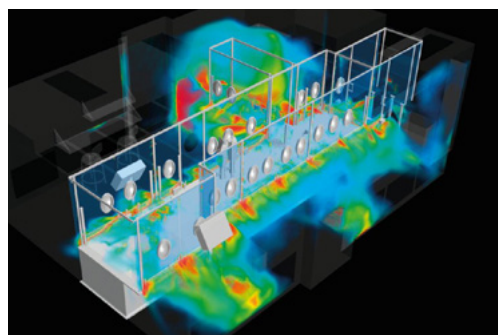
- Development of new mechanisms (machines, modules, stations ...)
- Design and construction of prototypes.
- Development of software and new electronic cams.
- Fatigue tests of new mechanical elements.
- Testing, identification, and definition of the functional limits of each equipment or technology.
- Verification of the laminarity of the air flow on new equipment.

### LABORATORY

- Definition of dosing mechanical and electronic configurations.
- Dosing accuracy and speed tests for both liquid and powder products.
- Screw cap verification tests: application and removal torque monitoring, quality, etc.
- Closing tests: tightness, crimp quality.
- Performance tests for new formats.
- Vials performance analysis during transport with pressure changes, LAF, considering different materials, etc.
- Liquid performance analysis during transport.
- Customer training.



Design and construction of prototypes.



Vaccine processing line CFD simulation.



After Market

## After Market

Always connected, always available

Dara Pharma is a synonym for trust and reliability. Our pursuit of excellence and customer-oriented service complement our high-quality equipment and high level of commitment.

Dara Pharma offers, from the very beginning, a wide and flexible range of products and services designed to provide you with optimal support and ensure the machine's performance at its full capacity.

Dara Pharma's range of service 4.0, following the "Flexibility in motion" concept, takes advantage of cutting-edge technological advances, such as augmented reality or predictive maintenance, to provide the best technical support in terms of quality, efficiency, effectiveness, and response time.

Our technicians are available 24/7 to assist and solve any technical problems remotely worldwide.

Dara Pharma's service excellence is achieved thanks to a cross-functional team of more than 15 nationalities and personalized customer attention managers.

Represented in more than 80 countries with continuous support from local offices and sales representatives.

## TECHNICAL SUPPORT



### Proactive services

Advanced training  
Certification  
Maintenance  
Inspections

### Reactive services

Dara Customer Service portal access  
Remote technical support 24/7  
Mechatronic staff availability in 24/48h  
Augmented reality  
Predictive maintenance – IoT

### Life Cycle services

Spare parts  
Customized spare parts  
New formats  
Retrofits  
Upgrades



Worldwide assistance, present in more than 80 countries.



Express technical assistance in 24/48h.



CLEANING  
STERILIZING  
FILLING  
FREEZE DRYING  
CLOSING  
ASSEMBLING  
LABELING

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*Flexibility in motion*