

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.









Double







Syringes

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.

Our team is represented in more than 80 countries with continuous support from local offices and sales representatives.



EUROPE +34 93 737 67 15 · USA +1 (872) 204 1449





service@dara-pharma.com















SHZBHZOU

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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** 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.















SX-50 SpeedFill

Tabletop peristaltic pump

No cross contamination / Filling from $0.1 \div 1,050 \, \text{ml}$ / Flow up to $6.4 \, \text{l/min}$ / 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 Ø:
 0.5 / 0.8 / 1.6 / 3.2 / 4.8 / 6.4 / 8 / 9.6 mm.

SX-50 Volumetric

Tabletop volumetric pump

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



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





SX-50 MicroFill

Powder micro dosing equipment

Cost-effective / Filling from 0.002 \div 25 g / Dosing accuracy ± 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





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. |





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



| Model | SX-140-C SX-140-R | |
|------------------|-------------------|------------|
| Output max. | 1,500 | 0 uph |
| Containers sizes | Ø 60 - h 21 | 10 mm max. |



SX-220-PP

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

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









- 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.
- Particle monitoring and 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 65 - h 210 mm max. Ø 25 - h 60 mm max. | | 0 mm max. |



SX-310-PP

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

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









- 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.
- Particle monitoring and 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 7 | 5 mm max. | |



HSL-PP

High-speed filling and closing machines for vials

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









- 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.
- Particle monitoring and 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. | | | | |



SYX / HSL Cartridge

Filling and closing machines for cartridges

Filling from $0.1 \div 50 \text{ ml}$ / Output up to 24,000 uph







- 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.
- Particle monitoring and counting.
- Laminar flow / RABS / Isolator.
- IQ / OQ validation package.

| Model | SYX-C/S | SYX-C/D | HSL-C/5 | HSL-C/10 |
|------------------|-------------|-----------|-------------|------------|
| Output max. | 4,500 uph | 8,500 uph | 12,000 uph | 24,000 uph |
| Containers sizes | Ø 25 - h 95 | mm max. | Ø 12 - h 75 | mm max. |



VSC

Multiformat filling and closing machines

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







- 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.
- Particle monitoring and 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. | | | | |



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



- 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 | | | | |



DT

Sterilization and depyrogenation tunnels for glass containers

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





- 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 |
|-------------|------|------------|------------|------------|--------------|--------------|
| | 2R | 12,000 uph | 29,000 uph | 36,000 uph | > 36,000 uph | > 36,000 uph |
| 0 | 10R | 6,350 uph | 13,100 uph | 18,850 uph | 26,000 uph | 32,000 uph |
| Output max. | 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 |





Automatic debagging for RTU vials, syringes, and cartridges

 $\label{prop:equation:constraint} \mbox{Automatic transfer of the tub towards a downstream machine} \\$ through an automatic sliding door / Output up to 225 Tubs/h



| Optional equipment — SCADA software to proces with FDA 21CFR Part 11. | ss data acquisition in accordance | |
|--|-----------------------------------|-------|
| GAMP complying software Laminar flow / RABS. | э. | Mas . |
| — IQ / OQ validation packag | ge. | |
| Model | DB/A | DB/A+ |

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



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





- 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 |



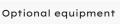
NFL

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

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







- 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.
- Particle monitoring and 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 |



DN / RN

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

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





- SCADA software to process data acquisition in accordance with FDA 21CFR Part 11.
- "No glass-to-glass contact" denester.
- Particle monitoring and 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 $0.1 \div 250 \text{ ml}$ / Output up to 8,500 uph









- 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.
- $\ensuremath{\boldsymbol{--}}$ Particle monitoring and counting.
- Laminar flow / RABS.
- 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 \div 250 ml / 100% IPC / Output up to 24,000 uph









- 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.
- Particle monitoring and 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 m | ax. |



UDS / BDS

Filling and assembling machines for UDS / BDS devices

Compact machine / Filling from 100 \div 250 μI ±0.5% / Output up to 24,000 uph







- 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.
- Particle monitoring and counting.
- Laminar flow / RABS / Isolator.
- 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 | | |



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



- 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.
- Particle monitoring and 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 | | |



SX-170 IV Bag

Compact machines for automatic filling and closing of IV Bags

Compact machine / Filling from $50 \div 20,000 \text{ ml}$ / Output up to 3,200 uph





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





- 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.
- Particle monitoring and 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 |



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



- 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.
- Particle monitoring and 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 | | |



HSL-B Syrups

Linear filling and closing machines for syrups and suspensions

Filling from $1 \div 1,050 \text{ ml} / 100\% \text{ IPC} / \text{Output up to } 24,000 \text{ uph}$





- 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.
- 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. | | | | |



SYX-Lab

Labeling machines for vials, syringes, and cartridges

ASL-Lab

Assembling and labeling machines for syringes

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









- 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. | | | | | |



LAF / RABS / Isolator

Protection and containment equipment

Specific solution for any need

Due to growing concern for product and operator protection and the complex regulatory framework of the pharmaceutical industry, it has become 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 μm) less than 3,520 particles/m³.
- 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

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™

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 operation in an ISO 8 or class D classified room.





Turn-Key Solutions

Complete tailor-made solutions

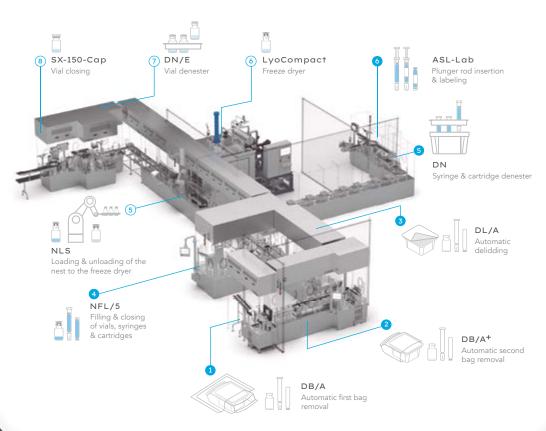
Adapted to client's layout / Multiformat lines / Full line integration

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 formats in-nest or in bulk. Our systems also offer mixed solutions where customers can combine both options depending on the processing 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

In pharmaceutical production, Good Manufacturing Practices (GMP) are essential to guarantee that the manufacturing process is constantly controlled according to 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.

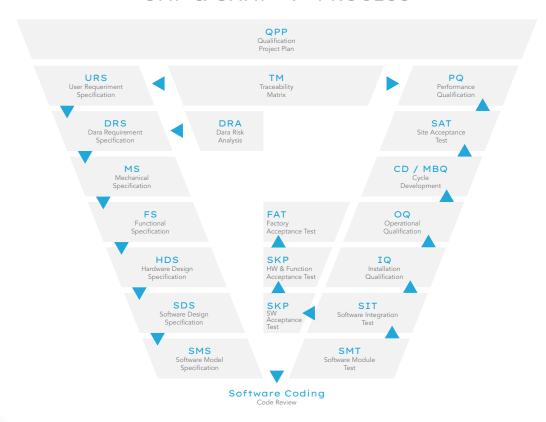
At **Dara Pharma**, we defined specific actions to ensure that our document management, which we

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 equipment's configuration accordingly. The equipment'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





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 Analysis (RA)

TEST PROTOCOLS

- Design Qualification (DQ)
- Computer System Validation (CSV)
- Factory Acceptance Test (FAT)
- Installation and Commissioning (IAC)
- Site Acceptance Test (SAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- 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

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

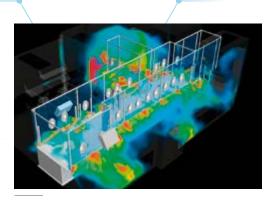
- Development of new mechanisms (machines, modules, stations...)
- Design and construction of prototypes.
- Development of software and new electronic cams
- Fatigue tests of new mechanical elements.
- Testing, identification, and definition of the functional limits of each equipment or technology.
-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

Always connected, always available

Dara Pharma is a synonym for trust and reliability. Our pursuit of excellence and customer-oriented service complements our high-quality equipment and our 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 to ensure optimal machine performance.

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.

Our support team is 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

Pol. Ind. Coll de la Manya Galileo Galilei, 5-19 · 08403 Granollers Barcelona · SPAIN t: +34 938 718 784

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dara-pharma.com

Flexibility in motion