

## COMPANY PROFILE



# SGD PHARMA

## delivering to the demanding pharma glass market

Experience, commitment and development are key to any company's growth – but even more so in the difficult market of pharmaceutical glass. In this market, in fact, we need to consider technology, but also regulation and standards compliance and – even more important – patient safety and well-being. And this is where the company in this article – SGD Pharma – has a strong position.

### **A GLOBAL AND PATIENT-ORIENTED PLAYER IN PHARMACEUTICAL PRIMARY PACKAGING**

With a historical know-how of more than 100 years inherited from Saint-Gobain, SGD Pharma is renowned worldwide as a technical reference in glass packaging.

Delivering the demanding pharmaceutical market, SGD Pharma combines its control of the glass process with the implementation of GMPs for pharmaceutical primary packaging in all its manufacturing facilities. The company commits to supply con-

tainers offering good adherence with drugs and patients.

This combined expertise is the basis of SGD's performance, confirmed with its leading position on the market. To achieve operational excellence in its five facilities, SGD Pharma exchanges best practices and aligns its manufacturing and quality process.

### **TUBULAR CONVERSION**

In 2013, SGD Pharma started tubular conversion. The company is using its long expertise in glass process and its commitment to the pharmaceutical market. The facility is equipped with state-of-the-

art converting machines and has acquired the knowledge to reach international standards and world class tubular glass containers.



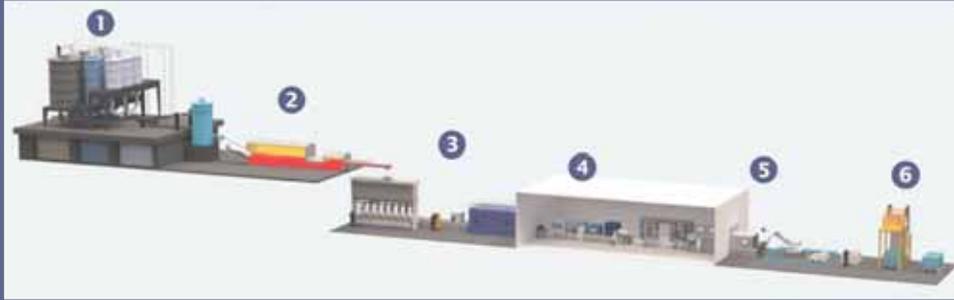
To succeed in its ambition, SGD Pharma relies on fundamental values shared with its employees.



### A STRONG AND GROWING POSITION ON THE PARENTERAL MARKET

The parenteral market is growing due to worldwide rise in general healthcare consumption and increasing development for complex diseases areas.

## PRODUCTION PROCESS FOR MOULDED VIALS



### 1 Step 1: Batching

After incoming control, raw materials are stored separately in silos. The glass composition is weighed, blended and put into the furnace.

SGD Pharma produces three types of glass described in the pharmacopeia:

1. Type 1: borosilicate glass, neutral in mass
2. Type 2: soda-lime glass with high hydrolytic surface resistance
3. Type 3: soda-lime glass with low hydrolytic resistance

These three types of glass can be flint or amber.

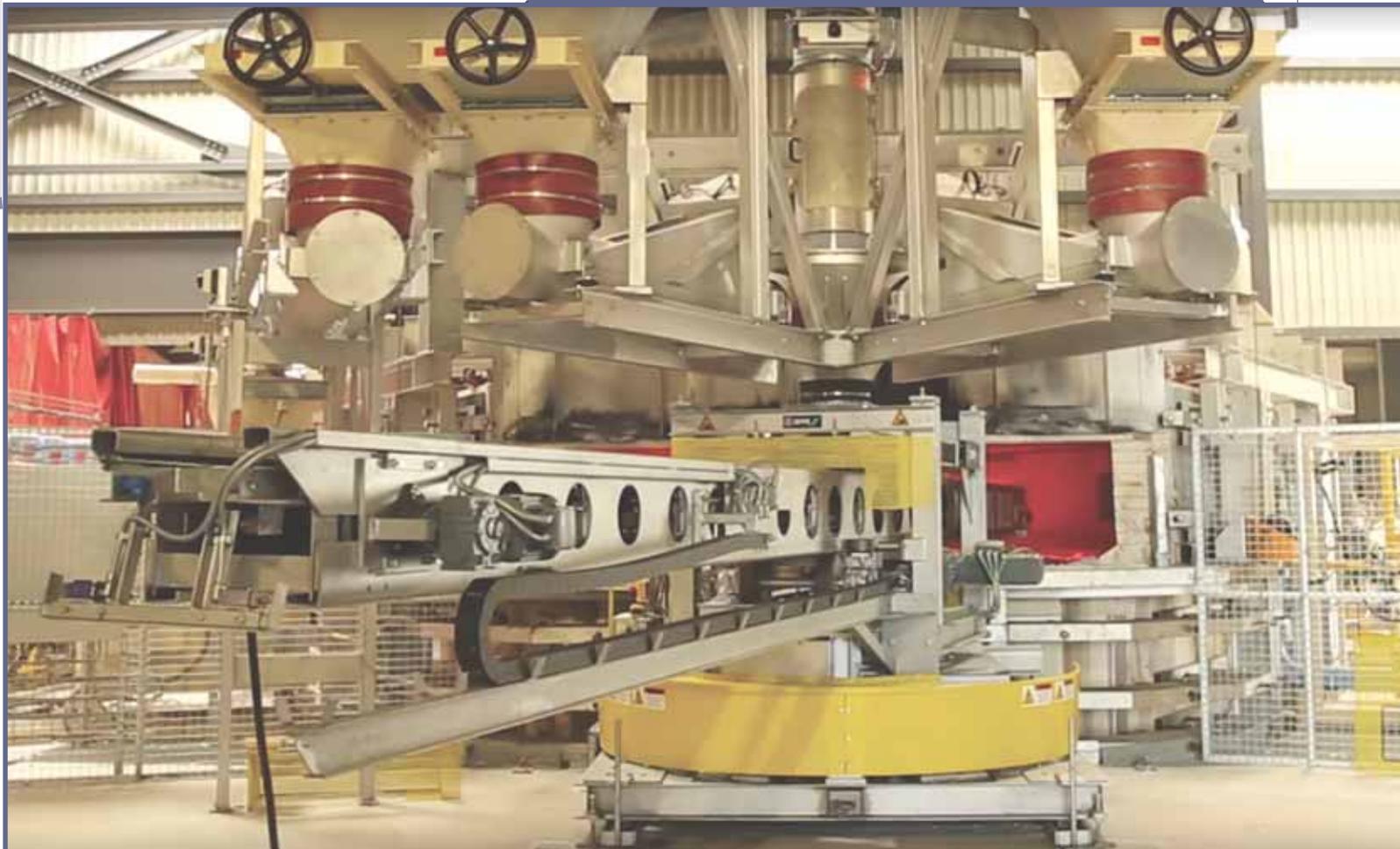


### 2 Step 2: Melting

Specially designed furnaces can reach temperatures of up to 1,600°C (2,900°F).

Raw materials are converted to molten glass in the furnace over a 24-hour period.

Gravity and convection currents facilitate the optimum blending of the materials.



## COMPANY PROFILE

SGD Pharma focuses its investment to support this dynamic market on mature and emerging zones.

- To widen its product offer, SGD Pharma enters into the tubular glass market through external growth.
- SGD Pharma strengthens its capabilities in pharmaceutical glass containers for injectable and infusion markets.
- The R&D department imagines solutions easy-to-use in the new pharmaceutical facility format: Smaller-scale, flexible and multiproduct, these facilities use single-use technologies, continuous processing and modular design.

With a global footprint and a strong sales force, SGD Pharma is recognised worldwide as a key player that customers can rely on to support new product development, day-to-day delivery, quality or regulatory support.

SGD Pharma benefits from a long know-how and a best-in-class manufacturing footprint. The company has a long-term investment plan to regularly leverage its manufacturing facilities and develop people competencies to be at the cutting edge of the technology. SGD Pharma commits to have the same standard in all its facilities. In 2016, all plants are certified according to ISO 15378 standard, pharma GMP's compliant and equipped with ISO 8 clean rooms.

Commitment is a key value for SGD Pharma and includes responsibility towards customers and patients; employees; society.

**Innovation:** SGD Pharma is recognised as an innovative leader in glass for pharmaceutical primary packaging. The company dedicates important resources to be one-step ahead, respond to customers' expectations and commit with patient safety.

**Safety** is a major priority for SGD Pharma. Best practices,

### 3 Step 3: Forming

Gobs are formed, cut and delivered into the blank moulds.

The vial is formed using the Press&Blow or Blow&Blow process. In both these cases, the vials are formed in two steps:

1. A preform or blank and the neck are formed
  2. The blank is transferred to the finished mould to form the finished vial
- The fully-automated IS machines are equipped with multiple stations to form 4-48 vials per cycle.

After forming, all vials are controlled and pass through the annealing lehr to release glass mechanical stress.





#### 4 Step 4: Inspection in the clean room

Once formed and cooled, 100 per cent of the vials and bottles are inspected in a clean room environment to control:

- Dimensions – including wall thickness and diameters
- Glass integrity
- Seal and bottle integrity
- Neck and bottom
- Defects such as chipped glass, blisters, distortions, finish distortions affecting tightness



preventive and corrective actions, are implemented daily to continuously protect employees' health.

SGD Pharma commits to constantly train its employees and offer them career opportunities within the company.

#### INNOVATION COMMITMENT

As a leading company in primary packaging for the pharmaceutical market, SGD Pharma makes the difference by innovation:

- Be one step ahead
- Highlight technology breakthrough
- Ensure regulation and standards compliance
- Support customers in their specific development

In 2015, the company set up a new R&D organisation to enhance patients' safety. Composed of various talented experts, its worldwide R&D networking team work to continuously develop new solutions.

To offer future and sustainable development to both SGD Pharma and its customers, the pharma and biotech companies, the team is working over the whole product life cycle:

- Raw material
- Product Design

## COMPANY PROFILE

- Process
- Quality Control
- Use of products by customers
- Drug delivery
- Raw material: glass composition for better drug compatibility and less extractables
- Product design: lighter container, good mechanical resistance, easier to control, better for handling and supply
- Process: improve productivity, reduce rejection rate to deliver products with steady quality
- Quality control: reduce critical defects and particles to protect drug integrity
- Use of products by customers: optimise filling and supply chain to reduce rejections and drug shortages
- Drug delivery

The R&D department implements this 360° approach for drug manufacturers to better process and handle containers, to improve drug compatibility, to reduce critical defects and recall risks. SGD Pharma inspires confidence for patient safety.

### SGD PHARMA, SUCCESSFUL IN INNOVATION

SGD Pharma has continuously dedicated significant resources to Research and Development. These continual R&D efforts have allowed the company to become:

- A pioneer in the implementation of clean rooms for inspection and packing in all its factories.
- The first pharmaceutical packaging company to be certified ISO 15378 (ISO 9001 in addition to the GMPs – Good Manufacturing Practices).

SGD Pharma also has proven track records of product range extension:

- U-save® vial, a unique design
  - U-shaped bottle for a complete liquid delivery.
  - Provides 100% of product recovery for high value nasal

### 5 Step 5: Packing

Before packing, all vials and bottles are transferred to the clean room where they are turned upside down and blown to minimize the risk of the presence of loose particles.

Shrink-wrap packs are formed inside the clean room to ensure the maximum cleanliness.

Automated palletization offers consistency and avoid human manipulation of the vials.



### 6 Step 6: Release

Each label contains critical data for complete traceability.

Batch release is based on manufacturing track record and QC results.

SGD Pharma systematically issues compliance certificates with each delivery.



- spray drugs.
- U-save® is used worldwide and approved for several nasal sprays (calcitonine...)
- EasyLyso®, simply stronger vial
  - Specially designed injectable

- vials to comply with the specific requirements of the lyophilization process.
- Reduce risk of breakage thanks to the optimized design.

## PRODUCTION PROCESS FOR TUBULAR GLASS

- A full range of products available from 5 ml to 100 ml successfully embraced by biotech and pharma labs.
- Asolvex:
  - Unique Type I glass with a low aluminium level
  - On the market since 2000 after 10 years of development by SGD Pharma R&D team.
  - New packaging possibilities for use with sensitive products : Blood derived products including albumen, Nutritional products (injectable), Biological products, Medication from genetic engineering...
  - Approved by 100% of customers, SGD Pharma delivers today 1 million vials made of Alsovex glass per day.

Social and environmental stakes leads SGD Pharma to build and set up its strategy taking into account sustainable development.

SGD Pharma commits to reduce its impact on the society and on the planet. Th company can rely on a corporate identity, strong values and employees'



### 1 Step 1: Tube feeding

The raw materials are glass tubes supplied by globally renown manufacturers such as Schott and NEG. Clear or amber, the tubes are made of neutral borosilicate glass (5.0 expansion range) with a high degree of hydraulic resistance. The tubes are loaded by robot onto a rotative machine.



### 2 Step 2: Forming

The tubes are heated, shaped and cut to give the dimensional parameters in three main steps:

1. Shoulders and neck forming (including 100% on-line dimensional inspection)
2. Tube parting – heating and cutting to set vial height
3. Bottom glazing – heating, glazing and cooling



## COMPANY PROFILE

involvement. Daily actions, innovation, continuous improvement and strong collaboration between departments and countries support SGD Pharma to produce better glass vials and to ensure patient safety.

SGD Pharma men and women are daily involved to contribute to satisfy customers as well as to support sustainable development with focus on three main axes:

### 1. ENVIRONMENTAL COMMITMENT

SGD Pharma business uses a lot of energies. The management of natural resources and energy is a key indicator as regards to environmental as well as global performance. This indicator helps to build a profitable growth on a long term basis, including planet stakes and benefiting our customers, our stakeholders, our teams and our partners.

The quality and performance of its manufacturing facilities are worldwide renowned amongst the glass industry. It is the result of the involvement of the company's teams and regular investments to optimise resources (energy, raw materials...) and protect the environment.

SGD Pharma implements its environmental process using four pillars:

### 2. SOCIAL COMMITMENT

SGD Pharma has 2,750 employees split on three continents: they are men and women producing and selling primary packaging for drugs, a committed job to care of health and patient safety.

SGD Pharma is willing to be a responsible and attractive company.

Manufacturing pharmaceutical glass is a business so specific that competencies and know-how are an invaluable capital. Thanks to highly involved employees, SGD Pharma maintains years after

### 3 Step 3: Forming

The vials are cooled and blown with filtered air.

Total (100%) inspection of:

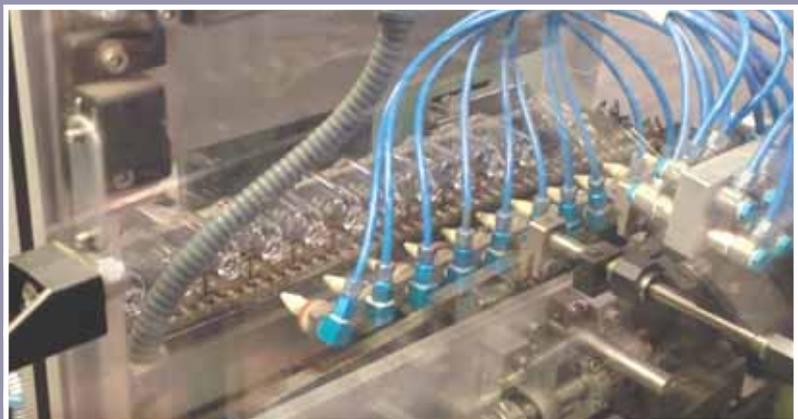
- Total length and bottom concavity by electromechanical gauge
- Internal neck diameter by camera



### 4 Step 4: Annealing

The vials are individually picked up and place on the conveyor belt of the annealing Lehr without any glass contact.

Perfect annealing is carried out to release residual stress using a monitored thermal cycle.





## 5 Step 5: Final inspection and packing

Final inspection is carried out under clean room conditions. Optional cosmetic inspection is performed by off-line camera. The vials are packed in shrink-wrapped PP trays or in cleanpacks, and then palletized.



years its technical knowledge and continue to develop its glass expertise.

Training employees is a critical goal:

- SGD Pharma has several training centres to maintain and develop its know-how and its employees competencies
- SGD Pharma develops relationships with schools and universities to attract talents and ensure permanent renewing of its experts.
- Safety is a major priority for our company. Daily and preventive actions are implemented to strengthen the safety of all employees all over the world. The goal is to apply EHS best practices thanks to shared experiences between the manufacturing facilities.

During the World Safety Day in 2016, employees attended workshops to make them aware of different situations and ensure

that they know the emergency procedures. In China, employees have been trained to evacuation and to carry out first aid. In France, employees participate in workshops regarding hand hygiene and fire prevention.

### 3. LOCAL COMMITMENT

SGD Pharma wants to highlight the positive impact of its presence on the local community to its involved partners, local authorities, neighbours, employees, customers, NGO, and surrounding companies.

In India, SGD Pharma supports the development of the Vemula village where the facility is. The company has participated in:

- The improvement of the school facilities as well as supply of school material
- Easier access to drinkable water with two bore wells and a water tank

- Support of the local police department to organize new recruits training

In Kipfenberg, Germany, the access to the facility was shared with neighbours: children had to cross when trucks had to deliver raw materials. This cohabitation was very dangerous for both. In 2015, SGD Pharma and the town of Kipfenberg redesigned this access. A road was built to give a safer access to the neighbours and allow SGD Pharma closed its borders for trucks to make their deliveries in safe and dedicated environment. ■



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