How to inspect glass containers before filling

Alessandro Pettenuzzo, Account Manager, Stevanato Group - Engineering Systems Division
Global vaccine market

Vaccine market share (2016)
Market scale: $26,000 million

By Company
- GSK: 23%
- MSD: 23%
- Pfizer: 23%
- Sanofi: 19%
- MTPC: 1.3%
- Others: 10%

By Disease
- Streptococcus pneumoniae / meningitis: 23%
- HPV: 10%
- Influenza: 13%
- DTP combined (3, 4, or 5 diseases): 16%
- Others: 9%
- MR combined (including mumps): 5%
- Rotavirus: 5%

Source: Prepared from Evaluate pharma

Four large companies (GSK, MSD, Pfizer, Sanofi) have the majority of the market (88%)

No. 1: Streptococcus pneumoniae;
No. 2: pediatric combined,
No. 3: influenza
Vaccine market by region

Market share by country (2016)

U.S. 54%
Europe 11%
Japan 8%
Others 26%

Market forecasts (2011-2022)

(Millions of U.S. dollars)

Source: Prepared from Evaluate pharma
Injectables units by segment

IMS-reported container Units split by Drug Market Segment

- Vaccines
- Chronic Conditions
- Acute Care
- Other

Legend:
- Bags & Bottles
- Ampoules
- Vials
- PFS-based
- Cartridge-based
Glass containers for pharmaceutical use

**Market Trends**

<table>
<thead>
<tr>
<th>2013-2018</th>
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<tbody>
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<td>+</td>
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</tbody>
</table>

- **Anti-Diabetics**
- **High Value Drugs in Valuable Markets**
- **Rare Diseases**
- **Vaccines in Emerging Markets**

- **Anti-coagulants**
- **Vaccines**
- **Anti-infectives**
- **Anti-inflammatory agents**
- **Haematological agents**

- **MS treatments**
- **Human growth hormones**
- **Obstetric agents**
- **Cancer therapies**
- **Pain relievers**

- **Anti-Diabetics**
- **Self-Injections**
- **MS treatments**

- **Human growth hormones**
- **Haematologica**

- **1° Healthcare**

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Glass converting line: typical configuration

Suitable for Ampoules, Vials, Cartridges and Syringes
Neck/cone forming

Forming tools to give the right shape to the neck / cone
Glass converting process: mouth forming
Glass converting process: bottom forming
How to inspect glass containers before filling
Dimensional inspection: introduction

- 100% inspection of all dimensions
- Automatic rejection of defective pcs
- Customizable quality level
- Automatic calibration system
- Performance per chuck
- Measurements and statistics in real time

General production data
Details for each single parameter
Dimensional inspection: vials

- 1-2 cameras for the **neck profile area** (installed on the forming machine)
- 1-2 cameras for the **internal diameter of the bottom area** (installed on the afterforming line)
Inspection Controls on the Neck Profile (1 of 2)

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Inspection Controls on the Neck Profile (2 of 2)

Shoulder Angle

Neck Axiality

Angle below Collar

Mouth Planarity

Angle upon Collar

Neck Ovalization

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Internal controls

A dedicated camera measures the internal diameter of the neck, while an electro-mechanical gauge measures the total length and the bottom concavity.
Syringes: cone inspection (1 of 3)

Cone/Body Diameters

Cone Planarity/Perpendicolarity
Syringes: cone inspection (2 of 3)

Cone/Shoulder Angles

Cone Heights
Measurements – Cone Inner Diameter
Flange and dimensional inspection

Measurements

- Flange Profile
- Flange Thickness
- Flange Planarity

Total Length

Electro mechanical gauges

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Inspection technology

Inspection Technology

Dimensional Inspection

Cosmetic Inspection
Cosmetic inspection: in-line and off-line solutions

1-8 cameras for the inspection of:

- Body and collar area
- Neck area
- Bottom area
- Shoulder area

There are two possible alternatives: in-line or off-the-line inspection systems.
In-line cosmetic inspection

The cameras for the cosmetic inspection are installed on a line between the oven and the packing machine. The **packing machine** and the **cosmetic inspection system** are usually installed inside a **clean room**.
Examples of defects detectable by the system
In-line cosmetic inspection

The in-line system permits to detect black spots with sizes starting from 0.3x0.3mm

Surfaces that have been formed or with irregular thickness introduce a level of noise that is seen by the system as the presence of defects. This phenomenon is known as false rejection and it is the reason why the camera cannot be set with the minimum detectable limits for all the areas.

Improvements of the lighting conditions and increase of camera resolution contrast the false rejection allowing the progressive reduction of the rejection limits.
High resolution

Use of high resolution cameras in order to detect critical defects shapes
Cosmetic inspection

1-8 cameras for the inspection of:

- Sealing surface area
- Collar area
- Lower Collar area
- Neck area
- Shoulder area
- Body area
- Bottom area

Areas of cosmetic inspection
Sealing surface

This camera is able to find defects on the surface of the collar:
- black dots
- scratches
- bubbles

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>FEATURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camera</td>
<td>Matrix</td>
</tr>
<tr>
<td>Position</td>
<td>In axis with vial</td>
</tr>
<tr>
<td>Resolution</td>
<td>0.020 mm</td>
</tr>
<tr>
<td>Minimum defect</td>
<td>0.200 mm</td>
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</tbody>
</table>
Collar - neck

This camera is able to find defects on the collar and neck:
• black dots
• folds
• scratches
• bubbles

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<tr>
<td>Camera</td>
<td>Linear</td>
</tr>
<tr>
<td>Position</td>
<td>Perpendicular to the vial</td>
</tr>
<tr>
<td>Resolution</td>
<td>0.030 mm</td>
</tr>
<tr>
<td>Minimum defect</td>
<td>0.200 mm</td>
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Lower collar area

This camera is able to find defects on the **surface of the collar**:
- black dots
- bubbles

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<td>Camera</td>
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</tr>
<tr>
<td>Position</td>
<td>Tilted about 12°</td>
</tr>
<tr>
<td>Resolution</td>
<td>0.030 mm</td>
</tr>
<tr>
<td>Minimum defect</td>
<td>0.100 mm</td>
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Shoulder

This camera is able to find defects on the surface of the shoulder:

- black dots
- folds
- scratches
- bubbles

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</tr>
<tr>
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<tr>
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<td>0.030 mm</td>
</tr>
<tr>
<td>Minimum defect</td>
<td>0.300 mm</td>
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</table>
This camera is able to find defects on the surface of the **body**:
- black dots
- scratches
- folds
- airlines
- bubbles

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<tr>
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<tr>
<td>Minimum defect</td>
<td>0.300 mm</td>
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Bottom rotation

This camera is able to find defect on the surface of the bottom and in the area close to the body and bottom radius:
- black dots
- scratches
- bubbles

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<td>Minimum defect</td>
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Bottom static

This camera is able to find defects on the surface of the **bottom**:  
• black dots  
• scratches  
• bubbles

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Syringes cosmetic inspection

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cone cosmetic inspection</td>
</tr>
<tr>
<td>2</td>
<td>Shoulder cosmetic inspection</td>
</tr>
<tr>
<td>3</td>
<td>Body cosmetic inspection</td>
</tr>
<tr>
<td>4</td>
<td>Flange cosmetic inspection</td>
</tr>
<tr>
<td></td>
<td><strong>Radius body/flange inspection</strong></td>
</tr>
<tr>
<td>5</td>
<td>Internal Cone Inspection</td>
</tr>
<tr>
<td>6</td>
<td>Flange shape Inspection</td>
</tr>
<tr>
<td>7</td>
<td>Flange surface Inspection</td>
</tr>
</tbody>
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Syringes cosmetic inspection

The system detects any type of cosmetic defects, such as:

- Cracks
- Scratches
- Inclusions
- Air lines
- Dirty points
- Knots
- Chips
- Etc.
NAM HS – Needle assembling machine: configuration

1. Inlet clip belt\dual belt
2. Needle assembling and pre-curing device
3. Curing area
4. Inspection area
5. Reject station
6. Selected reject station
7. Outlet clip belt\dual belt

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NAM HS – Needle assembling machine: inspection list

**Total length**
1. Chipping needle test
2. Straightness
3. Precision glue dispensing
4. Cupola glue geometry
5. Cosmetic body test
6. Deep glue test
7. Glue dispenser monitoring by inspection

**All rotation test**
- Different rotation speed on demand
- 80% of the syringes free for analysis
- No metal contact on gripper
- Two reject station; one for generic reject and one for request reject
- Flow test
NAM HS - Needle assembling machine  straightness and precision glue dispensing

Example
Off-line cosmetic inspection

Three inspection areas:
1. Star wheel 1
2. Main turret
3. Start wheel 2
Off-line cosmetic inspection

Station 1:
- BOTTOM inspection

Station 2:
- COLLAR inspection
- SHOULDER inspection
- BODY inspection

Station 3:
- RIM inspection

NOTE: In addition it is possible to equip the machine with the Printing inspection camera
Converting technology: tailor made solutions

A successful case history

In 2005 a Japanese pharmaceutical company decided to produce internally prefilled syringes

The scope of the project was the construction of a machine to be put in line with a Gröninger washing/siliconization line, so compatible with the pharmaceutical Environment
Converting technology: tailor made solutions

- The task consisted in the introduction in the machine of many GMP concepts and customer’s specific requirements in connection with the Japanese mentality.
- A specific requirement was moreover the strong elevation of the automation rate, since the company had no experience on glass working.
Converting technology: tailor made solutions

- Motorized protection cage
- Infra-red temperature control
- Special burners controls
- New tube loader
- Upgraded software
- Complete traceability

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Converting technology: tailor made solutions

Thanks to the equipment supplied by *Spami*, in 2007 the company received the prestigious award of “*Best Facility of the Year*” (ISPE, Interphex) being the “pharmaceutical manufacturing facilities in the world that demonstrate global leadership by introducing cutting edge, innovative technology”.

![2007 Facility of the Year Award](image)
Converting technology: tailor made solutions

Spami has prepared a tailor made solution, which represents nowadays the most advanced production line for vials worldwide.

Several innovations introduced in this development, have been applied to other machines, contributing in this way to the general improvement of our technology.

Besides the many improvements on the forming and annealing process, the major innovations consist of:

- a glass tubing double washing machine
- an advanced cosmetic inspection system
Converting technology: tailor made solutions

Advanced cosmetic inspection

Originally the final customer’s specification foresaw a very accurate manual cosmetic inspection with specifically trained operators: 30” of control on each single vial.

SPAMI has developed a specific machine able to achieve the same accuracy of inspection, without the generation of high false rejection.
Thank You

For further information please visit engineering.stevanatogroup.com