



Ompi Day Monterrey

Maintaining Quality While Expanding Globally

The Stevanato Group and Ompi of America Open Mexican Plant

Glass containers for parenteral drugs continue to show strong growth due to several factors including new drugs from the biotechnology industry coupled with expanding usage of insulin and vaccines in the developing world.

With the exception of x-ray contrast media and some oncology drugs, the injection volume of parenteral drugs is usually below 20 mL with subcutaneous or intramuscular injections being less than 1 mL. The glass containers for these small volume parenteral drugs include ampoules, insulin and dental cartridges, pre-fillable syringes and vials all made from

tubing glass although vials can also be made by molding glass. In terms of tubing glass containers for pharmaceuticals, ampoules still lead the market with a 40% global market share but overall growth is flat while vials (27%), cartridges (20%) and pre-fillable syringes (13%) are all growing in sales¹. The issue faced by manufacturers

is not only to increase their production capacity to support the growing need of a particular market but to insure that the product quality is maintained at the highest standard achieved by the current manufacturing plants. This

is the challenge taken up by the **Stevanato Group** in order to directly supply the local markets from the American continent itself. The Glass Division of the **Stevanato Group**, consisting of Nuova Ompi (Padova, Italy), Alfamatic (Latina, Italy) and Medical Glass (Bratislava, Slovakia) manufactured over 1.9 billion containers in 2008 making the company one of the top three producers of tubing glass containers for medical use in the world. In addition

to traditional pharmaceutical glass containers, **Nuova Ompi** is the global leader for pen-cartridges for diabetes care and recently introduced **EZ-fill™** pre-fillable syringes². In order to keep pace with increasing global demand, the **Stevanato Group** has

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Global production of pharmaceutical containers from tubing glass



Vials and Cartridges produced in Mexico



Pre-fillable Syringes

¹ Guadagnino E. and Nicoletti F. Transparent thinking. Pharmaceutical Manufacturing and Packaging Sources, August 2008, 44-48.

² Eakins M. N. EZ-fill™ – Offering a new choice in glass pre-fillable syringes. Pre-filled Syringes; the Container of Choice for Today's Injectables. OnDrugDelivery April (2008), 8-11.



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built a green-field production facility near Monterrey in the northern Mexican state of Nuevo Leon to specifically serve the North and South American markets, with emphasis on the United States marketplace. The location was chosen with care and took account of the local tradition of glass working, the high concentration of excellent technical universities and the transportation network in that the plant is situated on the “NAFTA” Highway, less than 2 hours from the US border at Laredo, Texas. The official opening ceremony for the production plant took place in October 2008.



Key Cav. Sergio Stevanato, Stevanato Group CEO at inauguration of Monterrey Plant

However, expanding capacity by building new plants globally can be challenging for all companies including manufacturers of glass containers. Customers will expect the high standards of component quality be exactly the same from a new plant that is located remotely from the headquarters as from a plant built next door. Accordingly the plan to build the new plant had two parts – the design and physical construction of the building and of equal importance, the qualification of the converting machinery, training of the technical staff and implementation of quality management systems.

The manufacturing plant is being built in two stages with an area of 7,000 m² (75,300 ft²) being completed first followed by an additional 5,000 m² (53,800 ft²).



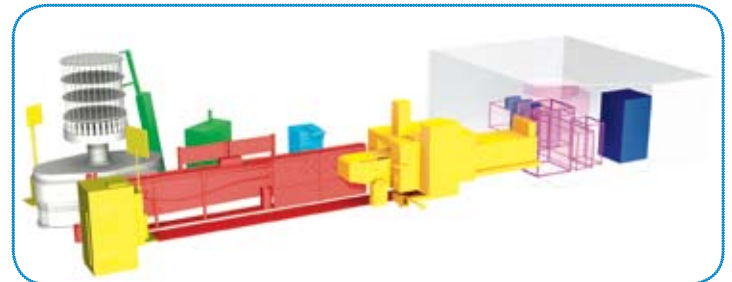
Key Inauguration of Monterrey Plant

Four production lines will be installed by the end of 2008 year to produce both insulin pen-cartridges and vials with further production lines being installed in 2009 through to 2010 to bring the first phase to its full capacity of 10 cartridge lines and 6 vial lines providing an overall capacity of around 260 million containers when fully operational. The second stage scheduled to begin in 2011, will have enough space to add an additional 16 production lines when fully operational.



Key Monterrey Plant in Mexico

The building and installation of the converting and inspection equipment was the responsibility of the Engineering Division of the **Stevanato Group** consisting of two companies, **SPAMI** and **Optrel**.



Key Schematic of production line of pharmaceutical containers from tubing glass

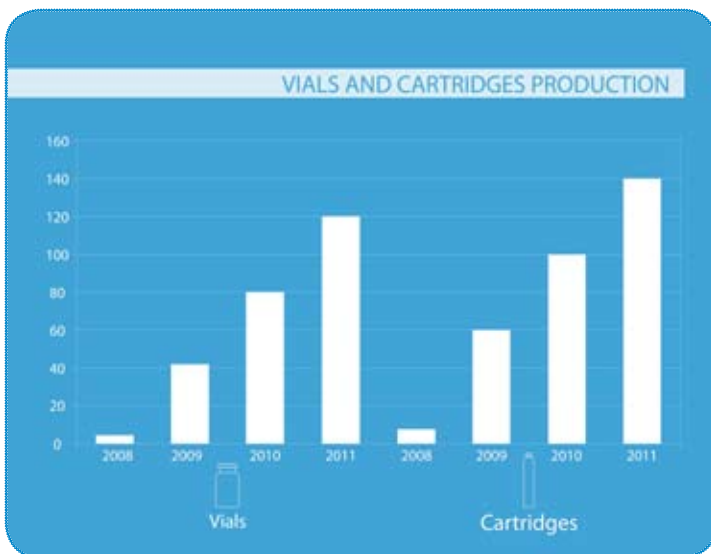
SPAMI has over 30 years of experience in designing and building glass converting equipment and besides being used by the Glass Division, the machines and integrated forming lines equipped with **Optrel**'s automated



Key Spami high technology converting tubing glass machine

visual inspection systems are sold around the world to other major glass converters. The most advanced series of these high-technology fully automated integrated lines have been installed in Mexico.

The formation of glass containers from tubing glass is achieved in a series of complex steps each one requiring careful quality control to achieve a high quality final product. Tubing glass canes are fed into the forming machines designed to form either cartridges or vials. The glass is heated by gas jets to enable the formation of the required shapes with the actual temperature of formation measured by pyrometers that automatically control the gas jets. This is important since overheating has a deleterious effect on glass.

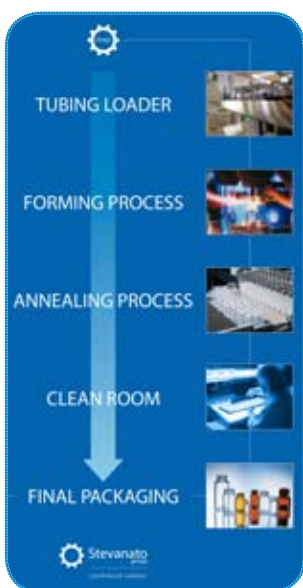


Increasing plant production

Immediately after formation, the containers then undergo the first of a series of 100% visual inspections by camera systems. Here a NOVIS system measures critical dimensions of the container as the container is being rotated and any container failing this inspection is rejected. After passing through an annealing tunnel designed by **SPAMI**, the containers then pass into a clean room environment

undergo another 100% inspection by the CLEANER camera system designed to identify critical surface defects such as airlines, chips and scratches. Acceptance criteria can be tailored to individual pharmaceutical company requirements. Finally the containers move to automatic packing machines.

Having the latest equipment with the capability to manufacture top quality glass containers does not automatically guarantee the ability to reproducibly achieve this end result. This is where training and operational experience comes into play and was critical in the planning of the Monterrey site. A team of eight technicians spent 12 months in an intense training course on all aspects



Material Flow

of glass container production. Since the machinery is manufactured in-house in Italy, the training program used the same machines that were to be used in Mexico. The mechanical and electrical engineers were tutored on the job in the production facilities in Italy and some of the technical trainers have been temporarily transferred to Mexico to assist in the start up of the facility. A similar training process will take place for the staff to support the installation of the 2nd and 3rd series of machines as was instituted for the first phase. The quality management systems for Mexico are based on those in place in Europe so that the quality standards will be same for components from Europe and from Mexico. This has been achieved by not only by a detailed general transfer protocol put in place by **Nuova Ompi** but also being cognizant of any additional requirements of individual clients.

In summary, the **Stevanato Group** has opened a new production facility in Northern Mexico to support primarily support the market for insulin pen-cartridges and vials in the United States. The key issue from the pharmaceutical companies' point of view is that the quality of the components had to match the high quality delivered from the Group's current manufacturing plants in Europe. In order to achieve this goal, technical teams were formed in Italy and a program of intense training over a 12-month period was carried out before the technical teams were transferred to Mexico thus ensuring maintenance of component quality while expanding globally.



Quality assurance as satisfaction of customer expectations



"60th Anniversary"

Stevanato Group: 60 years of excellence

Founded in 1949 by Cav. Giovanni Stevanato the company is now a multisite group with more than 1.000 employees all around the world. The Stevanato Group would like to thank all our partners, customers and suppliers for helping its strong growth.



EZ-fill™ Vials and Cartridges

Integrated solution for clean and sterile pharmaceutical glass containers ready to be filled

EZ-fill™ Vials and Cartridges: presented during the last Pharmapack in Paris 21-22 January 2009. Mr. Paolo Golfetto, Stevanato Group R&D Manager gave a speech focused on the new integrated solution to meet the market requirements focusing on a new process and packaging concept that enlarge the range of glass containers ready to be used.



Pharmapack Symposium

Argentina, Japan, India and China Symposiums

4-Days "Reliability of Drug Delivery Systems for Injectables" held by Ompi in cooperation with PDA and other pharmaceutical partners in Buenos Aires (24th June), Tokyo, Mumbai and Beijing (11th, 14th, 17th November 2008). More than 500 members attended the events. More details at www.pharmapack-symposium.org



New Corporate WebSite

Visit our new web site

Stevanato Group has developed its new website in response to the strong growth requirements of the pharmaceutical industry and is consistent with our mission to exceed customer expectations today, while investing in the future in order to support a constantly evolving and complex global market. Please visit www.stevanatogroup.com



www.ez-fill.com

READY TO FILL - THE EZ WAY



Launched on the market for the very first time, the concrete fruit of investments in research and development, estimated at 18 million euros this year, the EZ-fill™ vials and cartridges are an extension of the EZ-fill™ range and will provide pharmaceutical companies with a clean, sterile, non-pyrogenic glass container, ready to be filled.

"It is a remarkable added value for the pharmaceutical companies" states Sergio Stevanato, CEO of Stevanato Group. They can outsource the first part of the manufacturing process, thereby reducing their costs and concentrating their resources on research, which is their core business. In addition, one of the upsides of EZ-fill™ for vials and cartridges is that it can be easily integrated into the existing pharmaceutical manufacturing plants, both automatically and semi-automatically.

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5 - 6 March 2009

PharmaEd Resources' Pre-Filled Syringes Forum 2009
Radisson-Plaza Warwick, Philadelphia, PA USA

17 - 19 March 2009

Interphex

New York, NY, USA, Booth n. 962

20 - 24 April 2009

PDA 2008 Annual Meeting

Las Vegas, NV, USA, Booth n.916-1015

11 - 15 May 2009

Proceasep

La Habana, Cuba

9 - 11 June 2009

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Rimini, Italy, Booth n. 32