

Stevanato Group: 2012 will witness the doubling of the Mexican plant and the expansion of the EZ-fill™ vial and cartridge department in Italy

In keeping with its business plan, Stevanato Group has officially announced the doubling of the plant in Monterrey (Mexico) by the end of 2012, as well as the expansion of the EZ-fill™ sterile vial and cartridge department at the company's original production facility in Piombino Dese (Padua), which will begin within the next few months, a full year ahead of schedule.

The timely continuation of this expansion and internationalization strategy is the result of the excellent economic performance reported by the Group (+ 12%) and the Glass Division (+ 16%) in 2010, within a pharmaceutical industry that is currently recording an average annual increase of just 5%.



Stevanato Group locations.

Doubling the size of the plant in Mexico

“Organic growth,” said Company President Cav. Sergio Stevanato, “is the basis of every solid industrial company. That’s why, in keeping with our business plan, we have decided to begin doubling the plant in Mexico. The investment plan will initially open with the amount of 4.5 million Euros, which is expected to double early in 2012, and will reach 30 million by the time the plant has been completed.”

The Monterrey plant, inaugurated just 3 years ago in northern Mexico, is located in a strategic position to supply the North American market and is equipped with the industry’s most advanced process technologies. Stevanato Group has managed its design, building and development directly through its Engineering Division, Spami.

The facility is situated on an 40,000 m² lot, 20,000 m² of which will be covered upon completion of the project. It will employ 250 people and will be capable

of supplying enough glass containers, ampoules, vials and cartridges for pharmaceutical use to satisfy the demand

of not only the North American market but also the South and Central American markets as well.



*The doubling of the Mexican plant (in green).
The products manufactured are ampoules, cartridges and vials.*

The expansion of the EZ-fill™ vial and cartridge department in Nuova Ompi plant (Piombino Dese).



It has been decided to provide a 4 million Euro investment a full year in advance with respect to the industrial plan, in order to initiate the second phase of the project which is dedicated to

the production of sterile vials and cartridges. EZ-fill™ is the brand name under which Stevanato Group produces pre-sterilized ready-to-fill glass containers for pharmaceutical companies. Initially dedicated to the production of sterile syringes, today the

EZ-fill™ brand includes vials and cartridges. Presently the total "Ready-to-fill" syringe market has reached the value of nearly 1 billion Euros, with a total 2.8 billion pieces.

"Ready-to-fill" solution has thus provided for the development of a subsequent phase, or rather the expansion of the production processes to include other types of glass containers for pharmaceutical use, such as vials and cartridges. Once again, the results have exceeded the expectations, thus demonstrating the real need for solutions that are capable of vertically integrating a complete knowledge of the pharmaceutical processes.

In order to satisfy the increased demand, Stevanato Group has decided to anticipate by a full year the transition from the pilot phase - already in full swing - to the process

of industrialization sterile cartridges and vials. This investment will allow the company to obtain production volumes of up to 40 million containers per year.



www.ez-fill.com

News regarding glass delamination

Glass delamination is a known phenomenon that can cause glass particles to appear in a vial. As the intravenous administration of such particles could seriously affect patients' health this problem has forced a number of drug product recalls in recent years. Stevanato Group has approached with high priority this issue even if no customers' complaints have yet been received.

On this subject, several questions have been raised by the market and by the Pharma Industry, such as for example: "How can delamination be predicted? What parameters can be used to investigate delamination propensity? Are European Pharmacopoeia (EP) titration values a reliable indicator of delamination resistance? Which glass type is more suitable to which preparation?"

The **Stevanato Group laboratories**, in collaboration with external institutional

laboratories have successfully carried out studies to answer these questions. Some results were presented during the Rx-360 "Symposium on Glass Delamination" that was held in Arlington, VA on May 26 2011. A summary was published in the July-August **PDA Letter Issue** in an article titled "Delamination Propensity of Pharmaceutical Glass Containers by Accelerated Testing with Different Extraction Media" by Emanuel Guadagnino, Scientific Advisor of Stevanato Group and Daniele Zuccato, R&D Glass Division Project Manager. The conclusions developed by this study can help provide pharmaceutical manufacturers with information needed to help prevent glass delamination in their processes. In synthesis it turned out that delamination propensity of treated/untreated glass vials can even be predicted, but interaction drug/glass surface must be studied on a case by case basis. Close

collaboration with Pharma industries has now been established in order to evaluate together the suitability of specific glass vials to get into contact with pharmaceutical preparations and to finalize the most appropriate solution.



Surface alteration after ageing test of a not controlled thermal forming process

NEWS in brief

Paolo Golfetto, R&D manager of Nuova Ompi, presented the paper titled "Glass Processing and Impact on Mechanical and Chemical Properties" at the 2011 PDA Europe The Universe of Pre-filled Syringes and Injection Devices (Basel, 7-11 November 2011).

The paper, focused on the advantages of "Zero Defect" containers, especially with biotech drugs, is available at the PDA website www.pda.org or by e-mail marketing@stevanatogroup.com

Upcoming Events

February 2012:

PDA Clinical trials - Basel (7-8)
Pharmapack - Paris (15-16)

March 2012:

PDA Parenteral Packaging - Berlin (13-14)
DCAT - New York (12-15)
EAHP - Milan (21-23)

April 2012:

Pharma Congress - Duesseldorf (24-25)
PDA Annual Meeting - Phoenix (16-20)

May 2012:

Interphex - New York (1-3)
Japan Workshop - Tokyo (22)
Korea Pack - Seoul (22-25)
FCE - Sao Paulo (29-31)
AFI - Rimini (30May-1June)

June 2012

PDA Glass Conference - Bethesda (4-5)
Bio forum - Boston (18-21)
Achema - Frankfurt (18-22)