FLEXmag

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Focus

Technoflex: PP, tripled production capacity here we come!

India: manufacturing hub for Global Pharma.

TTS 101, one transfer set, two applications

TECHNOFLEX

Editorial

Welcome to the second issue of our Flexmag magazine. For this second edition, we wanted to put the spotlight on Polypropylene; material of the future for our industry and around which Technoflex was among the first to develop a specific offer with Inerta®. It is a major focus area for our R&D investments, enabling us to offer our partners tailor-made technological solutions, and is also key in terms of production capacities since we intend to triple our potential in the short term to serve our customers.

Our customer base is becoming increasingly international, highlighted in this issue by the example of India. The sectors in which we are involved are also more and more diversified, like the bags designed for preserving transplantation organs.

Finally, this work of adapting to each customer's specific needs naturally takes place upstream with the preparation of the arrival of our new machines. Each time, it is a true partnership which is built up for each project, as Dirk Beckschewe, Plümat Project Manager, points out in the interview he gave to Flexmag.

A final word to the numerous readers who sent us their comments on the first issue: they have helped us to improve this edition. Thanks to them and happy reading to all.

Olivier Chesnoy
Chief Executive Officer

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Issue 02 – March 2012

Quick facts

Technoflex in Mumbai (India)

With an estimated increase of 15% annually between 2010 and 2014, the Indian pharmaceutical industry offers new development opportunities for Technoflex. Directors, R&D managers and project managers were able to meet the Technoflex team which exhibited for the first time at the CPhI Trade Fair in Mumbai last December. A successful first!

First FDA-approved product from umbilical cord cells

The FDA has just given its first green light to a therapy which uses human blood stem cells from the placenta and the umbilical cord. This new therapy aims to treat people with disorders affecting the hematopoietic (blood forming) system, hematologic malignant tumors, genetic primary immunodeficiency diseases or even bone marrow deficiency, etc.

These types of blood cells, called progenitor cells, are infused into the patient and migrate to the bone marrow where they divide and mature. Moving around in the blood system, they help to construct new cells and restore the immune functions of the existing cells.

AFSSAPS is no more

AFSSAPS (French Health Products Safety Agency) becomes ANSM (National Agency for the Safety of Drugs and Health Products)

The bill relating to the reinforcement of the safety of drugs and health products was finally passed by the French Parliament in December 2011. It overhauls the health and safety system for health products to reconcile patient safety and access to therapeutic advances. In addition to this name change, ANSM's board will no longer include representatives from the pharmaceutical industry and must improve the evaluation of drugs, including those already on the market. Concerning pharmacovigilance, ANSM must scientifically evaluate the information gathered throughout a product's lifetime. It will also have access to the list of all clinical trials carried out by the laboratory before the marketing authorization and may order new studies.

Schedule

February 15-16 2012

Pharmapack EUROPE

Pharmapack Europe

Paris, Grande Halle de la Villette

- Pharmapack is the first platform for exchanges dedicated to packaging and drug delivery systems innovations for the pharmaceutical industry.

Conference by Jean Yves Bauer, Project Manager "*IV drugs: Development of a polypropylene closer system that guarantees inertness and integrity of the flexible bag*".

May 01st to 03rd 2012

Interphex

New York, Javits Center

- The meeting place to create innovative solutions that improve manufacturing and supply chain performance for pharmaceutical, biologic, generic and service provider professionals.

May 22-23 2012

Pharmapack NORTH AMERICA

Pharmapack North America

Philadelphie, Convention Center

- The new drug delivery systems and packaging technology conference and exhibition. Philadelphia is home to one of the strongest pharmaceutical and biotech clusters in the U.S., with four times the national concentration of pharmaceutical manufacturing facilities.

Conference by Christian Frayret, Sales Manager "*IV drugs: Development of a polypropylene closer system that guarantees inertness and integrity of the flexible bag*". Date and schedule will be announced on www.technoflex.net.

Technoflex :

PP, tripled production capacity here we come!

Christophe Idiartegaray, *Technical Manager*

Today, Technoflex is accelerating the growth of its activity by significantly increasing its capacities both in terms of industrial equipment and in terms of ISO 7 clean rooms. Three new machines have been undergoing validation since November 2011. This new equipment which is produced in partnership with the main German manufacturers allows Technoflex both to increase its production capacities of PP bags, and to offer the market new products.

The first new product introduced, the bags manufactured on the Plümat 2, will be adapted to the needs of filler-customers who require a container suitable for aseptic filling. This machine automatically integrates the fitting of a twist-off, then welds it onto a tube to seal the assembly perfectly. The filling tube is closed by an ultrasonic weld. This solution enables Technoflex to offer a closed container which is radiation-sterilizable, and adapted to aseptic filling. The critical operations are carried out under laminar air flows to limit the initial bioburden of the products.

This machine also introduces the new Technoflex "boat port". Like the tube-design bags, the boat port bags will be available with one or two ports, and the aseptic finish will also be available for this new connector.

This major investment will bring the PP bag production capacity to 35 million for 2012, compared to 15 million in 2011. It is planned to triple this last figure to 45 million units in 2013 after a production ramp-up of all the machines

Since 1999 Technoflex has been the precursor in the development of polypropylene bags.

The experience gained on this more technical material has allowed the company to standardize and optimize the production of its bags on its Inerta® range of films.

Interview with Dirk Beckschewe

Project Manager at Plümat in charge of the Plümat2

Sylvie Ponlot : *The Plümat 2 is a crucial acquisition for Technoflex's development. What is your feedback from Plümat?*

Dirk Beckschewe :
We began this project confidently because you are experienced people and this is not the first program we've worked on with Technoflex! From examining the specifications, to signing the contract and up to delivery last December took one year. Right from the outset, regular meetings were held at Technoflex. They enabled us to better understand your requirements, compare ideas and determine what was possible and what was not. The machine's design was a very important step. In fact, when you visited our workshops in Germany to see how the work was progressing and validate the design, there were no surprises. Many departments were involved in this project, designers, assemblers, electronics engineers, programmers, etc.

SP : *You highlighted the challenges related to its design. Can you tell us more?*

DB : This machine has the same features as the first Plümat delivered in 2006. But although the method of manufacturing the bag remains unchanged, many options have been added which give greater flexibility in the choice of the process. These different modules such as the automatic assembly of the twist-offs, ultrasonic welding and the CCIT welding, had never been integrated on the same tool before, this was our main challenge. It is also the key point of this new line because it meets a very specific offer from the pharmaceutical industry. It is ideal for the aseptic market!

We also changed the machine's control screens and above all the machine's software application. This application is now much more efficient and much faster, offers more functions and greater flexibility. Adapting it, creating it and testing it on the new system was another challenge.

PLÜMAT
Solutions are our business

Plümat, leader in technology for processing pharmaceutical solutions in flexible plastic packages made of polyolefins is a family company created in 1975 in Espelkamp (Germany) with an activity on the international scene.

TTS 101: one transfer set, two applications

Sylvie Ponlot

In 2007, two factors coming directly from the users of perfusion products led Technoflex to develop a new generation of needle-free transfer sets to render drug reconstitution safe, the TTS 101:

- An FDA (US) publication concerning injuries caused to clinical staff by syringe needles.
- An alert by the National Health Service (UK) showing that 62 % of accidents are linked to errors by staff concerning the drug to be reconstituted, or errors of choice or dosage during reconstitution.

Because the vial is directly connected to the bag by the transfer set, it is easy to check the product added and the reconstituted dose. This procedure guarantees better traceability which represents a significant advantage for the quality of the patient's therapeutical follow-up.

The TTS 101 is now also used as a connector when taking samples from polymer vials containing dimethyl sulfoxide (DMSO), an intracellular cryoprotectant helping to conserve frozen transplantable human tissues. This new application requested by a biomedical company led to a specific modification of the set by Technoflex's R&D team to eliminate the vial-syringe-needle combination. When combined with a single-use syringe with luer lock the flask is emptied in total safety and the product can therefore be transferred into the cryopreservation bags.

Medical issue

Transplantation organ preservation: a major challenge

The removal of an organ interrupts the vascularization (all the blood vessels irrigating an organism, organs, etc.) which causes cell death. To prevent this, the transplantation organ is perfused with a chilled solution because hypothermia slows down cell metabolism. This perfusion cools the organ, removes the donor's blood and provides the necessary components which maintain "basic" cell metabolism.

The organ is preserved in two ways:

- Using a perfusion machine (common in the USA but very rarely used in Europe)
- Static preservation: the principle is to place the transplantation organ in a sterile container after hypothermal perfusion, and to add the preservation solution until it completely covers the organ.

The shortage of organs for transplantation means that teams have to remove organs at locations which are increasingly distant from the recipients, which explains the increase in the cold ischemia time (when blood circulation stops). This has resulted in the development of more and more efficient packaging for transplantation organ preservation solutions.

Rajiv Kakodkar

India: manufacturing hub for Global Pharma

After significant inroads in the Drug Substance manufacturing space, India is well on its way to becoming a major player in the manufacturing and supply of Drug Products. With a turnover of US $ 21 billion, the Indian pharmaceutical industry constitutes 8 % of the world's pharmaceutical production and is expected to join the Top 10 global pharmaceuticals markets in terms of sales by 2020.

With over 160 factories approved by the US Food and Drug Administration and over 1000 WHO GMP, this industry employs over 4.2 million people, both in manufacturing and ancillary sectors.

Opportunity for India

The industry is expected to significantly boost its share of the generics market on the back of its expertise in process engineering and its low cost advantage. There is a global shift towards use of generics as governments worldwide are under tremendous pressure to curtail steeply escalating healthcare budgets. The US market has a share of over 28% of the world's generics market and is still by far the largest generics market. In Europe, Germany and UK have the highest generics penetration rate.

Competence in delivering solid dosage forms from world-class facilities is now being extended to sophisticated parenteral and ophthalmic preparations. Investment in dedicated facilities for cytotoxic preparations, hormones, and biologics are also on the increase.

The comfort level with the patent regime, is also attracting global innovator companies to India - both as a market with high growth potential as well as a global base for outsourcing of process and formulation R&D, Clinical research as well as manufacturing of drug substances and now drug products.

Quality:

a Master Plan for contamination prevention

Dominique Saint Ellier,
Director of Quality Assurance / Regulatory Affairs

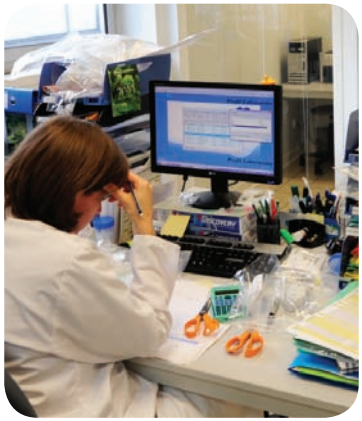
The increase in the production of polypropylene products, the extension of ISO 7 class production zones and the development of bags for aseptic filling has led Technoflex to a more comprehensive approach to contamination prevention.

How do we consider all the aspects of the contamination issue? Have they been correctly integrated in the Quality Management System? Are all the reference documents known and applied? How can we internally and externally communicate and promote the combat against contamination?

To answer these questions Technoflex has devised and put in place a Master Plan for contamination prevention. It integrates sharing of responsibilities and describes all the measures chosen and their implementation. No doubt a subject for subsequent Flexmags!

Sandwich courses, the circulation of knowledge

Sandwich courses are based on periods of acquisition of know-how within a company and training in theory at schools, universities, etc. The company retains contact with the university world and the student brings a fresh and instructive approach. Trainees gain in-depth knowledge of the profession. At the end of their apprenticeship they arrive on the job market with comprehensive training under their belt and professional experience which is greatly valued by companies and recruiters.



Interview with Nathalie Belot,

Human Resources Director

Sylvie Ponlot : *Technoflex recently organized round tables bringing together several heads of educational establishments and teaching managers. What happens at these round tables and what issues are involved?*

Nathalie Belot : To optimize the cooperation between schools and Technoflex, the educational establishment heads describe their constraints. We present our activity and our products. Technoflex employees provide information on our departments and our professional disciplines. The educational managers are therefore informed of the recruiting process and the jobs where there are insufficient candidates and can better understand our expectations. The dynamics are great and there is a real desire to bring together the industrial world and young people. It is very encouraging!

SP : *Which departments and jobs are concerned by these sandwich courses?*

NB : All Technoflex's departments have had at least one student under an apprenticeship contract or a professionalization contract. Over the last 5 years we have integrated 30 young people under such programs and 55 trainees aged from 15 years to university and engineering school level.

SP : *What are Technoflex's commitments with respect to the apprentices and trainees?*

NB : Training and accompanying the students in obtaining their diplomas is our primary commitment. The second is to be able to offer them a long-term contract if a job becomes available at the end of the apprenticeship period, and if the student has successfully integrated the company during his block-release training.

SP : *How are they integrated into their departments?*

NB : The students follow the same onboarding path as all newly recruited employees. It enables them to discover our activity, our procedures (quality, respecting Good Manufacturing Practices), our environment (clean rooms) and all the associated requirements.

SP : *Are you looking for people with specific profiles? What advice would you give to a candidate on a sandwich course program?*

NB : We regularly look for plastics process technicians and engineers, and maintenance or IT technicians, but also for the future engineering project managers who will develop tomorrow's products. My advice? You have to show that you are keen to work in an innovative company and successfully integrate. And above all, you have to like team work!

From apprentice to apprenticeship supervisor

Following my apprenticeship at Technoflex, I went on as a development engineer at Bioluz Laboratories (a Technoflex subsidiary). I have now reintegrated the parent company and, in turn, I have been asked to become a tutor for an apprentice. My experience will help me to pass on a great deal of knowledge and practical advice.

Here, apprentices are immediately confronted with real problems. They have to learn to develop responsibility for their work, because they tackle with sensitive projects.

During the first year they must learn how our R&D department operates and acquire the basic techniques essential for understanding our profession. It is a discoveries year that must not be neglected if they want to become independent as quickly as possible. During the second or third year, being able to entrust them with a project aimed at validating their diploma and gaining a better understanding of their future job is a critical issue.

The apprenticeship supervisor's role is not to be overprotective of students, but to set gradual objectives, adapted to their pace, so that they can reach the required level and be fully efficient at the end of their training. It is a fulfilling experience both for the student and for the apprenticeship supervisor.