

FLEX mag

June 2012 **#03** The news magazine of the Technoflex Group

Brazilian regulations modelled on the FDA

Ramping up efforts for disabled workers!

Focus

Controlling particle contamination

TECHNOFLEX

Flexmag is already on its third issue! This time, the focus is on the highly-specific pharmaceutical environment required for our activities, i.e. the importance of avoiding any particle contamination of products for use by patients in injection contexts. For Technoflex, this vital priority applies in everyday production, of course, under the supervision of the Quality team. But as our installation team explains, the process begins even before a new machine is installed in our clean rooms. Also in this issue, our international scope zooms in on Brazil, where for the past few years, the market has been booming. Brazil's fast-growing pharmaceutical industry (both international and local) offers a wealth of opportunity, if we can use innovation to stay a step ahead of the pack...

Finally, we wanted to shed special light on the integration of different profiles within our teams. As you will see from Véronique Négrini's experience, when there is a supportive team spirit, a handicap is no obstacle to seamless integration. And this is a strong value at Technoflex!

Enjoy this issue!



Olivier Chesnoy
Chief Executive Officer

Note: Please let us know what you think of Flexmag; we are always interested in your input. Comments can be sent by email to: flexmag@technoflex.net.

FLEXmag, a world of connections:

- 2 - Editorial
- 3 - Quick facts - Schedule
- 4 - Focus:
Controlling particle contamination
- 5 - Interview:
Bruno Discazeaux, Bag Department Maintenance Manager
- 6 - Business:
The Inerta® "Papillon" bag dislikes folds!
- 7 - Perspectives:
Brazil's pharmaceutical industry unscathed by economic crisis
Brazilian regulations modelled on the FDA
- 8 - Profiles:
Ramping up efforts for disabled workers!
Jean François Soulé-Susbielle, Technoflex's new Industrial Director



FLEXmag

The news magazine of the Technoflex Group
Zone Artisanale de Bassilour
64210 BIDART - France

Website: www.technoflex.net
E-mail: flexmag@technoflex.net

Publishing Director: Olivier Chesnoy

Chief Editor: Sylvie Ponlot

Contributors: Dominique Saint Ellier,
Nathalie Belot, Julia Beauquis, Nicolas Chato,

Rewriting: Sylvie Ponlot

Printing: Varela +34 943 45 89 25

Photo credit: Sylvie Ponlot, Franck Laharrague

Design and production:

+33 (0)1 47 51 80 07

Translation: Raptrad imagine

Issue #03 - June 2012

Quick facts

Setting our sights on the West!

In May, Technoflex took part in the Interphex trade show in New York, as well as the 1st Pharmapack North America conference in Philadelphia. The latter event, modelled after Pharmapack Europe, focuses on innovation in primary packaging and drug delivery technology. Philadelphia boasts the largest concentration of pharmaceutical companies in the United States, making this event an excellent opportunity for Technoflex to initiate new projects.

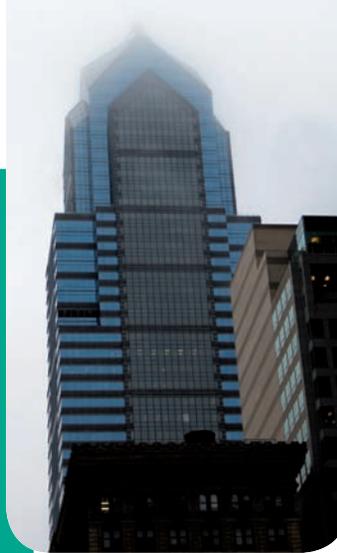
Technoflex opens its doors for Industry Week

“(.. .) You need to make your professions more attractive, and do away with stubborn preconceived notions about the industry. Even in the 21st century, the image of Zola’s miner villages is still very much alive,” said the Minister of Industry at the launch of Industry Week 2012. Created last year, this national event aims to improve the image of the industrial sector, and addresses the challenge of staff recruitment through a partnership with the national employment agency (Pôle Emploi). Technoflex took part in the event, hosting students from the Industrial Engineering and Maintenance Technological University Institute of Bayonne. They visited the production plant and learned about all of the company’s business lines.

Surfing the blue wave at technoflex.net

The Technoflex website has a whole new look! With a new graphic charter, reorganized headings, and a more user-friendly layout, we have covered all the bases to ensure visitors more fluid navigation and quicker access to information. A new Media section has also been added, to keep the specialized media up-to-date on the company’s latest press releases and provide them with access to downloadable photos and videos.

Surf’s up at www.technoflex.net!



Schedule

August 21 to 23 2012



ICSE South America

São Paulo - Trans America Expo Center

- For the second year running, Technoflex will take part in the International Contract Service Expo (stand C11) in São Paulo. ICSE is a major platform for making international contacts in the fast-growing pharmaceutical industry – see article page 7. With major support from the government, this sector in Brazil aims to become a leader in the world market, particularly in generics and biotechnologies.

August 04 to 26 2012

Technoflex closed in August for the summer holiday

- Technoflex will be closed for the summer holiday from 04 to 26 August 2012. During this period, a telephone answering service will be in place on +33 (0)5 59 54 66 66..



Controlling particle contamination: A regulatory and moral obligation

Sylvie Ponlot

Medically, cases of thrombosis, embolism, heart attack and stroke have been attributed to the presence of particles in injectable medicines. Technoflex products are used for pharmaceutical applications, which means that particle contamination must be controlled. From the receipt of raw materials to shipping our finished products, this ever-present challenge is one of Technoflex's priorities.

All Technoflex production is carried out in ISO Class 7 and ISO Class 8 clean rooms (as per ISO 14644-1). The air is changed 20 times per hour and filtered by multiple air treatment units with successive filtration systems (efficiency: gravimetric 85%, opacimetric 95%, and absolute 99.99%). The rooms are inspected according to a clearly-defined program, focused in particular on their rate of particle contamination. In addition to the regular measurements, an inspection under UV light is conducted each week, to validate the cleaning done over the weekend.

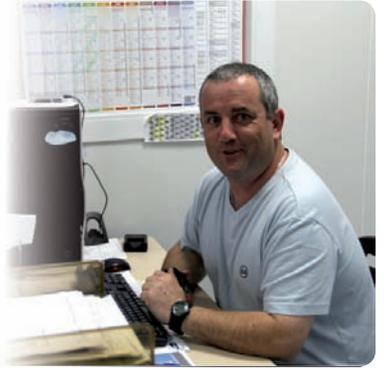
The process begins even before materials enter the clean room: received in double packaging, raw materials

undergo a series of compliance checks before being released. Any questionable products are immediately isolated until further inspection. An additional special procedure is done on reels of film – the raw material used for bags – before they are brought into the clean room. The first packaging is removed in an overpressurized airlock chamber, and the second packaging is removed when the reel is positioned on the production line.

All work tools are also inspected. Computer equipment is cleaned regularly and placed in protective cabinets to prevent any contamination. The same procedures are applied to production equipment. After production, as a precau-

tionary measure to protect them after they leave the clean room, finished products are double-packaged before being boxed and stocked in the shipping stores.

From measures ensuring the quality of the work environment, to raw material and product inspections, and internal audits... a variety of means are used to verify proper application of the prevention procedures. The quality department tracks and analyzes the results in a management chart, and this data is then used as input for Technoflex's improvement initiative. All of these measures contribute to one common goal: ensuring the integrity and purity of our medicines for patients' safety.



Interview with Bruno Discazeaux

Bag Department Maintenance Manager

Sylvie Ponlot: Technoflex has made it a priority to combat particle contamination. How is a clean room prepared before the arrival of a new production machine?

Bruno Discazeaux: It is an operation which demands good organization and rigour. We do not have the least margin for error! We start by isolating the room, temporarily blocking access to it and altering the flow of personnel. We isolate the other production lines with special tarps and delineate the spot to receive the new production line. To minimize the time the room is open, the partitions are removed at the last minute, and adhesive mats are placed along all routes of circulation.

SP: *Do the machines undergo a special cleaning process before going to their final location?*

BD: We first ask our suppliers to ensure that each machine undergoes a full cleaning operation before being sent to us. As soon as we receive it, we remove any protective packaging that is incompatible with the clean room, such as cardboard, wood or polystyrene. A preliminary cleaning operation is done outside, and a second one is carried out on entering the clean room. This is when the “major cleaning” is done. No part of the machine is overlooked. For this, we use wipes and products validated by the quality department. Once this step is complete, the production line can then be installed in its final location.

SP: *The room then needs to be decontaminated, doesn't it?*

BD: Yes, exactly. The protective covers are removed from the other production lines and control areas so that full cleaning and decontamination can begin. At this stage, a specialized sub-contractor takes over, eliminating any soiling on the floor and coarse particle contamination and small detritus by vacuuming the walls, trims and grids, as well as the airlock chamber. Then comes the decontamination operation: always carried out from the top down, the ceilings, walls, furniture and, finally, the floors are disinfected. From start to finish, the cleaning and decontamination procedure takes 18 hours and requires the intervention of 3 people.



The Inerta® “Papillon” bag limits folds!

Sylvie Ponlot

In administering a diluted drug from an IV bag, one of the primary goals is to give the patient the exact prescribed dose. With conventional bags, however, some high-viscosity solutions stay blocked in cavities created by folds. Folds form during the filling procedure, especially in the final sterilization stage. Because of these folds, a residual amount of the drug is not administered, with the risk that the patient does not receive the required dose.

In response to this problem, Technoflex's R&D department has developed and patented the “Papillon” IV bag. Its innovative design ensures patients better administration of the prescribed dose of a drug. The bag's lateral edges feature wider welds, which are face-to-face, and its narrower format prevents the formation of folds.

This major improvement in drug administration is also being used in other Technoflex applications. The “Papillon” bag design adapts to multi-compartment bags, and Technoflex is studying the design for specific requests.



Statutory

Technoflex renews its ISO 15378 certification

Technoflex has just had its ISO 15378 certification renewed. A version of ISO 9001:2000, this internationally recognized certification includes Good Manufacturing Practices (GMP) for the design, manufacture and supply of primary packaging for drugs. It meets the pharmaceutical industry's primary requirements in terms of packaging quality and safety – a major priority for Technoflex!

Brazil's pharmaceutical industry unscathed by economic crisis

Sylvie Ponlot

In the past two years, driven by the emergence of a large middle class and the ageing of the population, the Brazilian pharmaceutical sector has risen from 12th- to 9th-ranked worldwide. And according to IMS, it is poised to move into 7th place by 2016. This dynamic growth has prompted major laboratories around the world to step up their development, and is attracting new players in the industry. Last July, for example, the French laboratory LFB signed a technology transfer contract with the Brazilian State-owned company Hemobras, for the pharmaceutical outfitting and validation of a plasma-derived medicine plant. Another French player, Sanofi-Aventis, has opted to establish strong local presence. Since its acquisition of Medley, Brazil's third-largest pharmaceutical laboratory and the industry leader in generics, Sanofi-Aventis is now No. 1 in all product segments.

The generics windfall

As patents on many blockbuster drugs expire and governments keep up their efforts to contain healthcare costs, the global generics market is set for major growth. Since being introduced on the market in 2001, generics have changed the face of the Brazilian pharmaceutical industry. According to the Brazilian Ministry of Health, there are now more than 540 registered pharmaceutical companies in Brazil (36% of domestic origin). Almost 70% are concentrated in the state of São Paulo. Boosted by the booming generics market (representing 20.6% of sales), Brazilian laboratories are investing massively in R&D to develop higher-added-value products. Major pharmaceutical laboratories are also finding local partners to transform imported products.

Source IMS Health, UBIFRANCE.

Brazilian regulations modelled on the FDA

As in other countries, pharmaceuticals in Brazil have to meet strict regulatory requirements. ANVISA, Brazil's National Health Surveillance Agency, created in 1999, has modelled its operations on the FDA. It is tasked with reviewing drug marketing authorization applications and monitoring patent enforcement. Linked to the Ministry of Health, ANVISA is financially autonomous and managed by an independent Board of Directors. In addition to reviewing registration applications, the agency's duties include conducting health inspections on health care product manufacturing plants and processes, issuing or withdrawing Good Manufacturing Practices certificates, and setting up and coordinating toxicological & pharmaceutical surveillance systems, ... ANVISA is also responsible for monitoring, regulating and inspecting products which pose public health risks.

Ramping up efforts for disabled workers!

Integrating disabled people into working life is crucial in terms of social integration and financial autonomy. Technoflex has 15 disabled-status workers on its staff, and continues to work on this priority. Through a joint

effort with advisers, manufacturing managers and the occupational health service, Technoflex has provided permanent employment for disabled workers who previously only had interim work.

An integration success story

Nathalie Belot, Director of Human Resources

Véronique Négrini, Bag Area Operator, is hearing impaired. With Bernadette Arotcarena, Bag Department Manager, she looks back on her integration experience.

Nathalie Belot: *How was Véronique trained and integrated into our staff?*

Bernadette Arotcarena: We brought in an interpreter to facilitate our communication and her understanding of the instructions related to her position.

Véronique Négrini: I was paired with Bernadette for my training. She carefully explained the quality criteria for manufacturing bags to our customers' standards.

NB: *Did you encounter any difficulties?*

BA: It definitely wasn't easy at first. Technical data are part of our everyday work, and each new employee has to appropriate this information to be operational. For Véronique, this adaptation took a bit longer. We made up our own professional code of signs, to fit our needs. We understand each other perfectly, even if we don't use the same sign language!

NB: *Would you say that this integration was a success?*

BA: Yes, absolutely. We met this challenge with flying colours. The objectives were met, and Véronique has been successfully integrated. For me personally, it was a rewarding experience which I would willingly repeat.

VN: I now feel totally at ease and fully integrated, both in my work duties and during breaks with my colleagues!

Jean-François Soulé-Susbielle, Technoflex's new Industrial Director



In February, Jean François Soulé-Susbielle assumed his position as Technoflex's new Industrial Director. After earning an engineering degree from the Ecole Nationale Supérieure d'Arts et Métiers, he began his career with the Gascogne group, in the paper production department. In his last position at Gascogne, as Industrial Director of Packaging, he oversaw five plants in four different countries.

His experience in industrial management, particularly continuous improvement tools, is a major asset for the Technoflex group. Also a serious athlete, he has raced competitively and, now as an amateur, continues his triathlon, marathon and white water swimming activities.

His other outlet for the inherent stress of work is handiwork. "I'm not one for twiddling my thumbs," he explains. "I always need to be doing something, to keep myself busy. So when I am not racking my brain, I roll up my sleeves. I like to build things!"

