

VALOIS PHARMA, THE WORLD'S LEADING MANUFACTURER OF HYDROFLUOROALKANE (HFA) METERING VALVES FOR PRESSURIZED METERED DOSE INHALERS (PMDIS) USED IN THE TREATMENT OF ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), HAS CO-ORGANIZED THE FIRST CHINESE PMDI HFA TRAINING SESSION.

Valois Pharma, world leader in nasal and pulmonary drug delivery devices, has co-organized with the SFDA (Chinese State Food and Drug Administration) training centre, through Aptar Pharma Asia, the first Chinese training session on HFA pMDI development, held in Shanghai on October 27th and 28th 2009.

Transition from CFC to HFA propellant: a complex issue for the pMDI industry

Production of CFCs (chlorofluorocarbon), which deplete the ozone layer, was banned by the developed nations in 1996, in accordance with the 1987 Montreal Protocol. However an "essential use exemption" was granted to the pharmaceutical industry, notably for pMDI manufacture, to allow replacement products using HFA to be brought to market. As there are differences in physico-chemical properties between the two propellants, moving to HFA meant that both the drug formulation and the components of pressurized inhalers, and in particular metering valves and elastomer gaskets, had to be completely redesigned. China is currently organizing this transition from CFC to HFA pMDIs.

A head start for Valois Pharma

Valois Pharma was ahead of the game in gaining expertise in HFA formulations from the early 1990s, especially about the way that they interact with metering valve components. Combining in-house development and manufacturing of elastomer gaskets with the deployment of a dedicated HFA valve development team (internally managing component design, analytical tests, control of extractible materials and compatibility tests) has allowed the company to become world leader in this segment.

Sharing expertise for the first Chinese training on pMDI development

The two-day training session was co-organised with the SFDA training center. The SFDA is the State Chinese regulatory body in charge of supervising development, approval, manufacturing, sale and use of foodstuffs and drugs. The session was dedicated to pMDI HFA formulation development and pMDI quality controls during filling and production processes. About 60 delegates attended 13 presentations given by highly respected experts, who included:

- Mr. Wang Ping, **SFDA**: "2010 Chinese pharmacopie-inhaler standard update"
- Mr. Sunhuimin, **SFDA**: "pMDI HFA134a quality standard in China"
- Dr. Chenguilang, **SFDA**: "The quality control and measurement during pMDI production and finished product"
- Chris Baron, **Valois Pharma**, Associate Director Business Development Pulmonary: "pMDI HFA formulation patents / Importance of valves and their elastomer gaskets within pMDIs"
- Dr. Gerallt Williams, **Valois Pharma** Director Laboratory Services: "HFA pMDIs - some product development challenges/ pMDI in-vitro testing"
- Dr. Xianming Zeng, **TEVA** Global Respiratory R&D Director: "Next challenge in respiratory drugs development"
- Dr. Youyizhong, Professor and doctor at **Changzhou N°1 Hospital**: "The situation of pMDI in China and some good advice on pMDI development"

A significant investment by Valois Pharma / Aptar Pharma in China

The training session was a great success, as it built on the significant industrial investment made by Valois Pharma in China through Aptar Pharma Asia, which was established in Suzhou in 1996. Today there are more than 220 Aptar Pharma Asia employees at the 4,500 sqm² factory in China, manufacturing and selling, among others, Valois Pharma brand metering valves for pressurized inhalers. Valois Pharma is a recognized market leader in China and continues to expand its activity, leveraging an in-depth network of local partners to forge strong links with a wide range of local players in China, including those in research, industry, academia and regulating bodies.

Valois Pharma, a division of Valois S.A.S, specializes in nasal and pulmonary drug delivery technologies with a broad product range that also provides solutions for other drug delivery routes such as buccal/sub-lingual, throat and dermal/transdermal.

Valois S.A.S., founded in 1947, is a world leader in the design, development and manufacture of proprietary spray, aerosol and alternative dispensing systems for the Pharmaceutical, Perfumery and Cosmetics markets. Valois S.A.S. is a wholly owned subsidiary of AptarGroup, Inc., a publicly traded company listed on the New York Stock Exchange (NYSE: ATR).

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