

# Facing the Challenge of Broadening the Benefit Spectrum

**René Bommer**

Director Business Development, Ing. Erich Pfeiffer GmbH, Pharma Division, Oeschlestr. 54–56, D-78315 Radolfzell, Germany

For more information, please email mail: [rene.bommer@pfeiffer-group.com](mailto:rene.bommer@pfeiffer-group.com)

**Jochen Kern**

Sales Director, Ing. Erich Pfeiffer GmbH, Pharma Division, Oeschlestr. 54–56, D-78315 Radolfzell, Germany



**Dr Bommer** is Director of Business Development at Pfeiffer Pharma Division. He received his PhD in Chemistry (1990) from the University of Constance in Germany. The areas of research were carbohydrates and antigens. He was a research associate at the Scripps Clinic in LaJolla, focusing on monoclonal antibodies and at Byk-Gulden Pharmaceuticals in Germany. After a lectureship at the University of Buenos Aires in Argentina, he joined Pfeiffer, a developer and manufacturer of mechanical dispensing systems for pharmaceutical purposes.

**Jochen Kern** is Sales Director Europe and Associated Marketing Director at Pfeiffer Pharma Division. He got his Master of Business Administration from the University of applied Sciences of Constance in Germany. He joined Pfeiffer in 1996.

## Introduction

The positive market reception for the Advanced Preservative Free system provided the **Pfeiffer** development team with a new, highly complex challenge. In the market there was a clear demand for extending the benefits of the Advanced Preservative Free nasal pump to other applications. What would be the best response? In this article, René Bommer and Jochen Kern, from Ing. Erich Pfeiffer GmbH, trace the development from a mono-product line to the new Cartridge system, a modular product.

## The Advanced Preservative Free Heritage

Launched in 2003, the Pfeiffer Advanced Preservative Free system (*Figure 1*) is a multidose system for the application of preservative-free solutions via the nasal route. Patented filter technology prevents bacteriological contamination of the drug product on its metal-free path. This mechanical device is 100% sealed and has interchangeable secondary packaging. Since its launch, the Advanced Preservative Free system has offered producers of unpreserved nasal medication around the world an effective solution and won a number of prestigious design awards.

## Finding a Solution for Non-nasal and Preserved Applications

The development of a new system, integrating all of the benefits of its predecessor, had two specific goals. It needed to be suitable for applications other than nasal, and for solutions containing preservatives. These objectives marked the start of an intensive two-year development phase at Ing. Erich Pfeiffer GmbH in Radolfzell, Germany. The brief was to develop a modular system to accommodate these diverse application needs and, if possible, set new standards in flexibility and customisation. It was also necessary to maintain the established performance levels of the Advanced Preservative Free system including low actuation force, strong priming and re-priming action, plus the emission of a smooth spray.



Figure 1 – The Advanced Preservative Free system.



Figure 2 – Cartridge nasal spray system.

## Cartridge Family Ready for Sampling

Now, in the third quarter of 2006, the new, modular Pfeiffer Cartridge system is ready for sampling (Figure 2). This follows an extensive testing period, as well as independent verification of the system's microbiological properties by the Qualis laboratory in Constance, Germany. Designed as an open platform, the family comprises otic, topical/oral and nasal sprays, as well as a nasal drop dispenser. Preserved and non-preserved solutions can be accommodated and dispensed by this product family. There are options of crimp, screw or snap-on closures, plus a choice of colours, material and designs.

For all of the applications, the pump functionality is essentially the same, leading to a smooth spray and high performance reliability. In the topical version, the tip-seal is smaller in size but the mechanical properties remain constant. For nasal applications there is a choice of two devices with the spray and drop dispenser. The Cartridge pump can be integrated into existing processes and products, and the interchangeable design aims at giving customers branding opportunities to support their

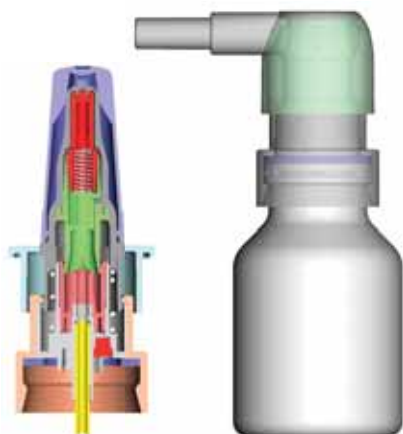


Figure 3 – Cartridge cross-section and 2D Cartridge.

product differentiation. Standardised filling procedures and assistance with regulatory affairs are key elements of the accompanying customer support package that has been created parallel to the development, ready for the market introduction (Figures 3).

The measurable results of this development process can be summarised in a verified two-digit list of unique benefits. Some are tip-seal driven, others related to microbiological integrity and several more are expressed in specific usage characteristics.

## Propriety Tip-seal Technology

The propriety and patented Pfeiffer tip-seal, and the special micro filter with its textile membrane, equip the Cartridge system to prevent microbes entering the system and to stop the clogging of the tip of the pump. This is key when dispensing crystalline solutions, such as throat medication containing sugar or steroidal medication. The sealed mechanism brings reliable protection against evaporation and particles or dust. Eliminating the risk of evaporation is crucial when dispensing a range of substances – for example those containing alcohol with its volatile behaviour.

The tip-seal is instrumental to the system's proven priming and re-priming action, leading to a significant reduction in drug wastage. This protection against a loss of prime means for example that even after a two-week period of inactivity in a bathroom cupboard, the Pfeiffer Cartridge spray will dispense the correct dosage, in the appropriate concentration.

## A Metal-free Route

The Pfeiffer Cartridge system facilitates a fully metal-free path for the pump's contents. This feature is expected to have a meaningful impact in the rapidly growing field of homeopathic medicine for instance. Being highly diluted, homeopathic medicines are extremely sensitive to contamination, even from the mild scent of everyday substances such as peppermint or coffee. Any contact with metal during dispensing would be detrimental to medicines of this type and potentially render them completely ineffective. From a regulation point of view, it is also a source of confidence and efficiency for pharmaceutical manufacturers to be able to completely eliminate the need for tests relating to metal content in dispensers, for example where active pharmaceutical ingredients such as proteins and peptides are concerned.

## The Customisation Challenge

In developing the new Cartridge system, Pfeiffer faced challenging demands for flexibility, without compromising any aspects of performance, dependability or user-friendliness. The resultant modular product family is geared to allow the relatively simple customisation of the dose volume. Regardless of changes in the outer dimensions of the package, for example, to accommodate products specifically for adults or children, the overall spray package

height remains constant, regardless of the dosage. Filling flexibility is also facilitated by the ability to integrate the production of two dose-volumes in the same line.

The concept behind the secondary packaging is two-fold. From a design and marketing perspective the aim is to offer clear product differentiation without complexity. From the development point of view, the constant design of the primary packaging aims to fulfill regulatory criteria at the start, independent of the parallel development of the secondary packaging (including inter-changeable finger flange). In other words, since the primary package is not adjusted, its registration remains valid, so there is absolutely no need for usability trials or other related, resource-consuming administrative activity.

## Conclusion

The Cartridge family has the clear objective of ensuring that scientifically proven characteristics translate directly into sales and marketing advantages for pharmaceutical manufacturers (*Figure 4*). The resultant modular system is unusual in its ability to provide the market with reliable performance excellence and a clear competitive business advantage, all under the umbrella of flexibility. Minimum investment is thus required to bring maximum success on the market, through using one dependable dispensing solution for many formulations and applications. In the Cartridge family, marketing and science meet in a win-win situation to satisfy the toughest efficiency, performance and design requirements of the increasingly competitive global pharmaceutical market.



*Figure 4 – The Cartridge Family.*

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