Prefilled syringes is a fast growing market and the pharmaceutical industry is rapidly expanding the use of PFS applications in the hospital and in the homecare setting, especially for newly released drugs and therapeutic areas such as infectiology (vaccines) and oncology. A 2010 visiongain study predicted a growth from two billion prefilled syringes sold in 2009, to 6.83 billion in 2025.1

With all that has been written and said about prefilled syringes over the last decade, new solutions brought by leading world-class component providers and contract manufacturers for the pharmaceutical industry, is there still anything truly important remaining to be said?

I would argue that yes, there definitely is! Specifically: large-scale industrially manufactured and quality controlled drugs presented in prefilled syringes are still almost non-existent in the critical care emergency therapeutic arsenal where, not surprisingly, they are mostly expected for patient safety.

We are talking about well-known drugs, commercialised for decades around the globe and sold in glass ampoules or vials in million of units monthly to hospital at a value perhaps reaching €1 per dose. Drugs used day in, day out, to a point that they become commonplace, and despite all the best efforts and awareness of medical staff, are not handled according to the hazardous underlying risk to the patient.

These are drugs that can save your life, or may kill you. They are still prepared, diluted and dosed in syringes by thousands of critical care nurses around the world, every day to treat patients – some of them, in case of need only – during planned/ routine and emergency anaesthesia and surgery.

These are drugs such as, to name but two, atropine and ephedrine.

But, as the title of a 1999 US Institute of Medicine report states: “To Err is Human”.2
Here are some key figures:

**6 500 000**
Number of operations each year in France.¹

**8 000 000**
Annual number of anaesthesia procedures in France.²

**180 000**
Estimated number of avoidable medical errors with severe adverse effects* during hospitalisation in France per year.³ (*Prolonged hospitalisation, disability, death.)*

**48 000 AND US$8.1 BILLION**
Number of deaths each year attributable to nosocomial infection in the US, and the additional costs related to prolonged hospitalisation due to nosocomial infections in the United States in 2006.⁴

**71.5%**
Of accidents reported in the hospital environment in France are needle stick injuries which induces for the medical staff a risk of exposure to blood.⁵

**5 000 000**
The number of atropine glass ampoules sold in France every year, which are manually prepared in syringes in hospitals with risk of glass cuts for the medical staff.⁶

**70%**
Of atropine syringes prepared by the hospital staff for use in case of emergency situation and ultimately wasted due to lack of necessity for the patient during the operating procedure and lack of proof of product stability and sterility for a later usage (unpublished market survey data from Laboratoire AGUETTANT, France, 2010).

In light of these numbers, it is not surprising that the European Board of Anaesthesiology (EBA) recommends: “Prefilled syringes should be used wherever possible”.⁷

Laboratoire AGUETTANT has taken up the challenge to develop and make available to hospitals what is now and should be in evidence: a STERILE POLYPROPYLENE NEEDLE-FREE PREFILLED SYRINGES (Figure 1) for the operating room and emergency room (OR/ER) with emergency drugs.

Laboratoire AGUETTANT succeeded in regulatory approval with up to 36 month proven stability (with no special temperature conditions) of two drugs, ephedrine and atropine, in ready-to-use sterile polypropylene prefilled syringes for in-patient use. The commercial launches are progressing rapidly in Europe (France, the UK, Belgium and, via commercial partnerships, in Sweden, Finland, Denmark and Norway), with launch in Canada expected shortly. An AGUETTANT syringe in a blister pack is shown in Figure 2.

Figure 1: A Selection of Sterile Polypropylene Needle-free AGUETTANT Prefilled Syringes.

Having successfully completed pilot research on injectable WFI (water for Injection), a NaCl 0.9% drug application, and with two other resuscitation drugs in the completion phase of development, the goal of Laboratoire AGUETTANT is dramatically to increase security and improve ergonomics in the critical care arena worldwide.

AGUETTANT’s aims are to:
- Contribute to Medical Errors eradication
- Eliminate the nosocomial infection risks
- Prevent the risk of exposure to blood and accident for the medical staff
- Reduce drugs and supplies waste and provide to the medical staff more valuable time; to attend to their patients’ needs while spending less time in drug preparation
- Secure and simplify drug reconstitution for the hospital and homecare market.

Figure 2: An AGUETTANT Prefilled Syringe Packaged in a Blister Pack.
AGUETTANT’s ready to use prefilled syringe quality design includes:

- Needle-Free system with a Luer Lock connection (ISO 594-2 compliant)
- Tamper evidence and guarantee against leakage
- Outer Sterility of the PFS in its sturdy blister pack (Terminal steam sterilisation)
- Clear identification of the drug with compliance to ISO Colour coded label (NF ISO 26825)
- Double sided graduation for improved ergonomics.

The main benefits linked with polypropylene are that it is lightweight and ergonomic; robust against shock and cracks; and is an affordable material, widely known by and familiar to medical staff.

AGUETTANT’s Sterile Polypropylene Prefilled Syringes are covered by two international patents (sterility of rubber stopper and opening system).39

AGUETTANT’s sterile polypropylene prefilled syringe is part of the AGUETTANT System® portfolio, which includes also the unique MULTI DOSE, MUTI USAGE after first use, disposable Self Injector Pen for subcutaneous application.

Come and visit us at Pharmapack Europe, Grande Halle de la Villette, Paris, February 13-14, 2013. We are at Booth #154.

REFERENCES

8. IMS data 2012.

“THESE ARE DRUGS THAT CAN SAVE YOUR LIFE, OR MAY KILL YOU. THEY ARE STILL PREPARED, DILUTED AND DOSED IN SYRINGES BY THOUSANDS OF CRITICAL CARE NURSES AROUND THE WORLD”
SOME SKILLS ARE ESSENTIAL
SOME PRODUCTS AS WELL

AGUETTANT has designed a unique polypropylene prefilled syringe to improve safety and quality of care whilst optimizing cost levels.

Ready to use
• Prefilled, preassembled and presented in a blister pack
• Sterility guaranteed inside & outside through terminal sterilization

Integrity
• Guaranteed by the frangible obturator

Tamper evident
• Patented opening system with pre-perforated label

Needle free
• Secure connection with its universal Luer Lock

FOR YOUR PREFILLED DEVELOPMENT