Why the Usage of Manufactured Ready-to-Administer (RTA) Injectable Products is **Safer, Reduces Waste, and Improves Accuracy?**

Healthcare professionals work in very challenging environments. These challenges impact hospitals, forcing them to reconsider their processes. One solution to reduce the burden on frontline workers is to use ready-to-administer (RTA) injectable products. The use of manufactured RTA injectable products can reduce errors and the potential for patient harm. Additionally, RTA injectable products provide benefits related to nursing workflow, pharmacy workflow, and cost-saving measures[1,2].

1. THE SAFEST INTRAVENOUS DRUG DELIVERY SYSTEM

Manufactured RTA injectable products are produced under strict Good Manufacturing Practices (GMP) conditions, ensuring they meet the required standards of identity, strength, quality, purity and potency. The GMP guidelines cover all aspects of the manufacturing process, from the selection of raw materials, equipment, and facilities, to the training of personnel, quality control, and documentation. This includes extractable and leachable studies conducted on drug solutions, manufacturing materials, containers, and packaging materials. These studies evaluate potential impurities that could be released into the medication and inadvertently expose the patient to undesired substances[3,4]. An expert panel from the Third Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems (2018), concluded **that manufactured RTA products remain the safest intravenous drug delivery system due to their many benefits and overall low risk profile[2].**

4X

ERROR RATE

4X HIGHER RISK OF MEDICAL ERRORS AND CONTAMINATION

ERROR RATES ASSOCIATED WITH THE PREPARATION AND THE ADMINISTRATION OF INTRAVENOUS PUSH MEDICATIONS (TRADITIONAL PRACTICE) ARE FOUND TO BE HIGHER (10.4%) COMPARED TO THE ADMINISTRATION OF RTA PRODUCTS (2.5%)

2. REDUCES THE RISK OF MEDICATION ERRORS AND CONTAMINATION

Error rates associated with the preparation and the administration of intravenous push medications (traditional practice) are found to be higher (10.4%) compared to the administration of RTA products (2.5%)[5]. According to a survey from the Institute for Safe Medication Practices (ISMP), **81% of the respondents, mainly nurses, reported preparing parenteral drugs in less-than-ideal conditions (e.g., at the bedside, on a counter or desk in the nursing station, or on a computer workstation).** Only 35% of survey respondents reported that their institution requires that another practitioner independently double checks certain sterile, injectable medications and/or infusions that have been prepared or admixed outside of the pharmacy[6]. Moreover, contamination rates are higher for the preparation of parenteral medication in the clinical environment compared to the pharmacy environment. The almost 100-fold higher chances of contamination when reconstitution is performed in the clinical environment should urge hospitals to review their reconstitution process and apply risk-reducing measures to improve patient safety[7]. To prevent medication errors in hospitals, it is recommended by the American Society of Health System Pharmacists (ASHP) that medications should be available in RTA packaging to avoid further manipulation by the person administering the medication[8,9].

3. WASTE REDUCTION

Medication waste has a significant negative impact on the healthcare budget and detrimental effects on the environment. **Since critical drugs are prepared in advance, 20-50% remain unused and are then discarded. The overall mean wastage rate is 38%**[10]. One source of waste is comprised of compounded medication, as leftovers are usually being discarded due to a short shelf-life after preparation[11]. Prevention of medication waste would positively impact healthcare budgets and reduce environmental impacts[10]. Manufactured RTA injectables reduce the amount of waste since they are produced under strict GMP guidelines and are stable at room temperature for two to three years.

4. IMPROVES DOSE ACCURACY

A study on the accuracy of syringe preparation by anesthesiologists has shown that **29% of the syringes were found to contain drug concentrations outside the designated range of acceptability**[12]. The manufacturing of RTA products under strict GMP guidelines ensures that patients receive consistent and predictable doses of medication.

Although manufactured RTA injectable products may have a higher unit cost than compounded preparations, they can save healthcare facilities substantial amounts of money in the long run by reducing the costs associated with drug preparation and wastage, including the appropriate destruction of expired sterile preparations (e.g., controlled substances).

Ultimately, there are also significant costs associated with the management of controlled substances, such as disposal, management, and regulatory compliance. In the context of the current opioid crisis, and given the high abuse potential of fentanyl, hydromorphone, and morphine it is imperative that (1) product waste is minimized; and (2) waste procedures are followed to ensure safe disposal[13]**.**

STERINOVA
READY-TO-ADMINISTER INJECTABLES

Medinfo : 1 844-329-2939
medinfo@sterinova.com

3005 José-Maria-Rosell Ave
Saint-Hyacinthe QC J2S 0J9 Canada
450 252-2520

REFERENCES

1. Adapa, R. M., Mani, V., Murray, L. J. et al. (2012). Errors during the preparation of drug infusions: a randomized controlled trial. *Br J Anaesth.*, 109(5), 729-734. doi: 10.1093/baj/aes257

2. Gabay, M., Hertig, J. B., Degnan, D. et al. (2020). Third Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems - 2018. *Am J Health-Syst Pharm.*, 77(3), 215-220. doi: 10.1093/ajhp/zxz277

3. Health Canada. (2018). *Guidance Document Quality (Chemistry and Manufacturing) Guidance: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs).* Health Canada Guidance Document.

4. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). (1999). *Guidance for Industry Container Closure Systems for Packaging Human Drugs and Biologics. Chemistry, Manufacturing, and Controls Documentation.*

5. Hertig, J. B., Degnan, D. D., Scott, C. R. et al. (2018). A Comparison of Error Rates Between Intravenous Push Methods: A Prospective, Multisite, Observational Study. *J Patient Saf, 14* (1), 60-65

6. Institute for Safe Medication Practices (ISMP). (2020). ISMP Survey Provides Insights into Preparation and Admixture Practices OUTSIDE the Pharmacy. November 4, 2020.

7. Larmené-Beld, K. H.M., Frijlink, H. W., and Taxis, K. (2019). A systematic review and meta-analysis of microbial contamination of parenteral medication prepared in a clinical versus pharmacy environment. *Eur J Clin Pharmacol, 75*, 609-617.

8. Arora, P., Muehrcke, M., and Hertig, J. (2022). A Cost-Effectiveness Study Comparing Ready-to-Administer and Traditional Vial-and-Syringe Method for Opioids. *Pain Ther, 11*, 937-950.

9. American Society of Health-System Pharmacists. ASHP guidelines on preventing medication errors in hospitals. *Am J Health-Syst Pharm. 2018;* 75, 1493-1517.

10. Barbariol, F., Deana, C., Lucchese, F. et al. (2021). Evaluation of Drug Wastage in the Operating Rooms and Intensive Care Units of a Regional Health Service. *Anesth Analg, 132*(5), 1450-1456. doi: 10.1213/ANE.0000000000005457

11. Smale, E. M., Egberts, T. C. G., Heerdink, E. R. et al. (2021). Waste-minimising measures to achieve sustainable supply and use of medication. *Sustainable Chemistry and Pharmacy, 20*(100400), 1-7.

12. Stucki, C., et al. (2010, March 24). Accuracy of Syringes Prepared in Anaesthesiology. Pharmacie des Hôpitaux Universitaires de Genève [Conference presentation abstract].

13. Hertig, J., Jarrell, K., Arora P. et al. (2020). A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste. *Hospital Pharmacy,* 56(5), 584-591. doi: 10.1177/0018578720931754