CONSIDERATIONS FOR MEDICAL DEVICE DELIVERY AND PRODUCT CLASSIFICATION

As technology evolves to meet the needs of patients, device options are expanded to cover multiple delivery profiles and drug types. In some cases, drugs may require reformulation in order to move a therapy that is traditionally provided via a large volume infusion to something that could be provided in a handheld device or an on-body delivery system (OBDS). This process can result in a range of delivery volumes, viscosities and dose delivery profiles (time and rate).

An On-Body Delivery System (OBDS) is affixed to the body of the user and actively delivers medicinal product for administration through a needle or soft cannula.[1] OBDSs can deliver a bolus of medication directly to the patient, via a subcutaneous delivery route. Because OBDSs can deliver larger volumes of medicinal product, the question remains on whether the dose delivery profile classifies the device as an injector or as a pump. Answering this question is key to applying the correct product classification and standards during development, and therefore, the determination of pump or injector should be decided as early as possible in the development process.

Using available information from the FDA[2] and ISO,[1,3] the key consideration to determine if the OBDS qualifies as an injector or a pump is whether the dose delivery profile is tied directly to the clinical efficacy of the product. If the drug sponsor confirms the delivery rate has significant impact on the clinical efficacy via its clinical study, the OBDS will be classified as infusion pump. Otherwise, it will be classified as an injector. Key differences between injector and pump are summarized in Table 1 below.

TABLE 1: COMPARISON: INJECTOR VS. PUMP

	INJECTOR	PUMP
FDA Product Code	FDA Product Code: QLF	FDA Product Code: FRN
Dose Delivery Profile	Delivery is comprised of administration of a fixed dose of drug product from a prefilled container in a predetermined time	Delivery is comprised of administration of a fixed dose of drug product from a prefilled container in a predetermined time
Determination of time and rate of delivery	Rate and time of delivery is based on patient tolerability and/or convenience	Rate and time of delivery is based on clinical relevance (e.g., medication efficacy)2
FDA Recognized Consensus Standards	ISO 11608-6:2022	ISO-26825, Second Edition 2020-10 ISO-7886-2, Second Edition 2020-04 AAMI TIR38:2019 ISO 9626, Second Edition 2016-08-01 ISO 23908, First Edition 2011-06-11
Applicable Regulations	21 CFR 880.5860 – Piston Syringe	21 CFR 880.5725 – Infusion Pump

Overall, the determination of the product classification should be a collaboration between the device manufacturer and drug manufacturer to ensure the impact on the dose delivery profile and clinical efficacy is considered. Determination of the product classification as early as possible in the development process will ensure the appropriate requirements are mapped correctly to the product to enable a successful FDA submission.

References:
1. ISO 11608-6:2022 Needle-based injection systems for medical use – Requirements and test methods – Part 6: On-body delivery systems
2. Xavier Health Combination Products Summit, Development and Regulatory Considerations for On-Body Injector Combination Products, September 23, 2021
3. ISO 11608-6:2022 Needle-based injection systems for medical use – Requirements and test methods – Part 1: Needle-based injection systems