The Role of a Public Drug Quality Standard

A public standard is a benchmark that consists of tests and other measures to determine a drug’s identity, purity, quality, potency, and consistency. Public standards establish the parameters by which it can be determined that a drug meets key quality attributes regardless of the manufacturer or manufacturing process. They are utilized by manufacturers and provide protection to patients throughout a product’s lifecycle from development to the patient. Unlike the private specifications developed by industry, public standards are available to anyone to use to test quality at any point in the supply chain. This is increasingly important in today’s global pharmaceutical marketplace, where the majority of drugs consumed in the U.S. come from outside the country.

**PUBLIC STANDARD**

- Developed by standards-setting organization
- Publicly available
- Can be used by any company or regulator
- Supports multiple products on market
- Establishes a single benchmark for quality and consistency regardless of manufacturer or manufacturing process
- Allows for input from multiple stakeholders during its development
- Developed using a transparent, collaborative process
- Encourages multiple entrants into the market
- Can serve as a product development tool that facilitates procedures and product development for subsequent entry products
- Once developed, is dynamic and continuously open for revision as science and the market evolve
- During product recalls/removal from the market, remains available for use and can facilitate product development and access

**PRIVATE SPECIFICATIONS**

- Developed by individual company or the regulator
- Known only to the manufacturer and regulator
- Can only be used by regulator and company that developed it
- Applies to single product on the market
- Establishes a single specification that will vary from one manufacturer to another.
- Based on proprietary knowledge and information
- Details of its development are undisclosed
- Encourages single entry into market
- Applies only to the product for which it was developed
- Once developed, remains relatively static
- During product recalls/removal from the market, is not available to any other manufacturer or other independent testing agencies

USP standards developed with input from Council of Experts comprising 5000 representatives from industry, academia, regulatory science, healthcare practice and other areas from multiple scientific disciplines.

USP standards vetted through an open comment process, in which stakeholder and public input is key.

Private standard developed with input from sole manufacturer.