

Quality: A Standard Expectation

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Our society is obsessed with instant gratification and convenience. Groceries can be packaged and waiting for our arrival where an employee graciously places them in our SUV. Apps on our phones allow us to research options, buy a birthday gift, and pay the credit card bill, all while standing around waiting for a train. Thanks to technology, there's a time-saving and seamless experience for almost everything we use or consume. We have come to demand a lot of ourselves and place even higher demands and expectations on everything in our lives.

Do we expect to make compromises in this new convenience paradigm? Of course not. Specifically, we are not willing to compromise on quality. In fact, in most instances, quality needs to be higher in order to maintain our loyalty. With an almost infinite number of businesses vying for our attention, how does any one of them earn our trust? Fortunately, in the area of medicines, there is an organization that focuses on creating standards that are made available to the biopharmaceutical industry and used to ensure quality and consistency.

Quality is the consistent answer for a demanding age

The United States Pharmacopeia (USP), is a non-profit independent organization committed to global public health through the development of standards that help address industry challenges and support quality medicines. Standards are the backbone of quality, providing the "constant" and foundation from which to ensure consistency. From research and development through the manufacturing process, standards play a crucial role in quality control and reproducibility.

As a convener, USP brings industry and regulators together for interactive discussions designed to identify areas of need and opportunity where standards that support quality initiatives will be most beneficial.

USP Biologics: a revolution in standards

The need for standards is particularly apparent in the area of biologics. Ensuring the purity, quality, and safety of these innovative treatments is paramount. With a focus on standards that broadly apply to classes or families of biologic products such as proteins and peptides, USP Biologics is committed to addressing the challenges that occur in this area of drug development.

The USP process makes the difference

When considering a standard, there are several factors that you can count on from USP Biologics. It all begins with collaboration, which involves engaging with key stakeholders to identify specific challenges where a standard would be beneficial. Once identified and development is initiated, among other things includes collaborative testing where results from multi-lab testing provide users with confidence in the standards that are developed.

The results from the various laboratories are analyzed to establish the acceptable range or tolerance to expect when integrated into real-world commercial development and manufacturing. A panel of

independent expert volunteers from industry and regulatory agencies convene to review data and make a recommendation on approving the standard to be released and made available.

Customer service is our commitment

The USP Biologics customer service team is available to answer questions and provide consultation regarding our standards. If a question cannot be addressed through the initial telephone conversation, it is triaged to the scientist who led the standard development. USP Biologics is committed to responding personally to every question in a timely manner. This is where quality truly is a standard expectation.

We are all consumers at some point, and we all demand quality products. Medicines represent the pinnacle of that demand. USP has a long-standing heritage and commitment to developing standards that ensure quality medicine are available globally and USP Biologics is extending that dedication into this growing and innovative field.

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