Proficiency Testing Program

Background

Maintaining medicine quality requires verifying the accuracy and reproducibility of test methodologies, instrumentation readings, and the competence of the analysts conducting the tests. Laboratory proficiency testing (PT) provides an objective assessment of staff competencies, specimen handling, equipment functionality, and results reporting.

Independent proficiency tests are an important tool for laboratories to show evidence of their performance and ensure their analytical results can be trusted. Accreditation agencies require analytical laboratories to participate in an appropriate PT scheme where one is available.

Opportunity to strengthen quality

The complexity of pharmaceutical manufacturing presents areas for USP to support medicine quality with products and programs in addition to our standards. One such area is the unbiased evaluation of lab staff capabilities and the accuracy of their testing results. Proficiency testing provides laboratories with an independent assessment of their performance and a way to detect and correct any unacceptably large inaccuracies. It also demonstrates a lab's commitment to quality, differentiating it from other testing labs in a highly competitive market.

USP solutions

The USP PT Program is an external quality and accuracy assessment process that evaluates lab performance. It offers 30 testing schemes in areas such as biologics, microbiology, and pharmaceuticals. Most testing schemes are available on a pre-set schedule, but some can be requested on demand.

USP operates its PT Program in collaboration with NSI Lab Solutions, an accredited manufacturing laboratory that provides certified reference materials and proficiency testing standards in chemistry and microbiology.

The USP Proficiency Testing Program webpage links manufacturers to the list of available test schemes. After manufacturers select the scheme and start date, NSI sends the testing material(s) and supporting documentation. Once manufacturers have completed the tests, they submit their results via the USP PT Portal. NSI evaluates the submission and sends a Customer Report, which is a demonstration of proficiency, along with details about their performance. For routine testing schemes, the report is available within 10 business days. For PT Express (a limited number of on-demand tests), reports are ready within 72 hours after customers submit their test results.

Why it's important

The accuracy of laboratory test results depends on the skill of its staff, the equipment and processes it uses, and its systems for controlling quality. Proficiency testing is a tool to validate a lab's analytical performance and identify gaps or areas for improvement. Along with USP public quality standards, education, and training services, the USP PT Program supports medicine quality by providing an independent, unbiased, science-based assessment of laboratory reliability.

Web resources

- https://www.usp.org/proficiency-testing
- https://www.nsilabsolutions.com/product-category/usp-pt-program/
- USP PT Portal