Call for data to support the drafting of specific applications for <72> & <73>

USP *<72> Respiration-Based Microbiological Methods for the Detection of Contamination in Short-Life Products* and *<73> ATP Bioluminescence-Based Microbiological Methods for the Detection of Contamination in Short-Life Products* are now approved and will be published in the USP 2025 Issue 2.

The methodology described in <72>and <73> has no fixed incubation times, contains an enhanced suitability approach, and includes the introduction of a safety margin for product testing. This permits the introduction of a flexible application of the method using current technologies and may be used with future improvements of existing systems or when new systems are introduced.

These chapters have been introduced with the expectation that their use will generate additional data to support updates to the methodology and evaluation criteria. The USP General Chapters Microbiology Expert Committee (MEC) anticipates that the data will facilitate the establishment of a standardized method with fixed test parameters and an expansion of the relevant product types. The evolution of these methods can only occur with scientific evaluation of a significant amount of data covering a variety of product types. Breadth and depth of data are necessary to standardize test parameters for specific applications. The MEC is inviting stakeholders to share their data and/or rationales for applications utilizing respiration-based and ATP-based microbiological methods. Discussions have identified data gaps involving respiration methods for cell based preparations and ATP bioluminescence methods for vaccines. All data and supporting validation information from other applications are also extremely useful and welcomed.

The method parameters that are the primary focus of the data review are listed below. Other test parameters may also be shared if they are available.

- Test strains used for validation or method suitability testing including inoculum size and rationales for selecting the microorganisms
- Special sample preparation step, if applicable
- Incubation time
- Incubation temperature
- Incubation oxygenation condition
- Nutrient media composition
- Sample size including rationale for the size
- Any challenges encountered

To ensure the security of any information provided, data shared that is designated as confidential will be handled and maintained in a confidential manner and will only be evaluated by onboarded participants in USP's expert bodies and relevant USP staff.

Your data may be submitted by contacting microbiology@usp.org.