The following answered questions are from the webinar 'Test Method Validation at WESTPAK' presented by Andrew Thomas, Lab Manager at WESTPAK, Inc., during the ISTA Transpack Forum 2021, Sponsorship Spotlight, on April 01, 2021.

Test Method Validation at WESTPAK

Q1. Can you briefly explain how to establish the reproducibility, repeatability, and sensitivity for Test Method Validation (TMV) with ASTM F1886 – visual inspection?

A1: For reproducibility and repeatability, we refer you to ASTM F3263, which addresses both the quantitative and qualitative aspects of attribute test methods like visual inspection for packaging TMVs. Establishing sensitivity would vary depending on the test specimen and inspection criteria.

The webinar video and slide deck can be found in Past Webinars at https://www.westpak.com/resources/webinars/

Q2. When working with a manufacturer, how do you align a WESTPAK test method and its TMV with what the manufacturer is doing? For example, is it a problem if the visual inspection performed by WESTPAK isn't exactly the same as the inspection that the seal/package gets for product release by the manufacturer?

A2. The best determination of visual inspection equivalency between two different locations or firms should begin with each performing its TMV. Many variables make the reproducibility, repeatability, and sensitivity of visual inspection particularly challenging. For visual inspection, we follow the ASTM F1886 protocol, which the manufacturer would also; therefore, the test setups and results should be similar.

Q3. I would be curious to have you elaborate on repeatability and reproducibility.

A3. We refer you to ASTM F3263 – Standard Guide for Packaging TMV, for information regarding reproducibility and repeatability, which are somewhat general terms without referencing a test method. For example, a Gage Repeatability and Reproducibility (GRR) study for measurements would differ significantly from a repeatability and reproducibility study for a visual inspection process focused on attributes.

Q4. Does Westpak maintain TMVs for the standard ISO 11607 sterile barrier test procedures? Or is it the responsibility of the device manufacturer? I know it is our responsibility, but are WESTPAK's TMVs available to reference during an audit?

A4. As a testing facility, WESTPAK has performed and maintains TMV documentation for sterile barrier tests; examples are ASTM F2096 - Gross Leak Detection and ASTM F88 - Seal Strength. The TMV records would typically be available for review during a client/partner quality audit related to TMV-supported test services.

Q5. When testing is performed for pharma product, do you follow method validation required for a medical device?

A5. Method validation is specific to the test method, not the product. The first test methods we have performed TMVs on were for medical device package testing; however, our TMV scope is

expanding rapidly. A few distribution tests, such as ASTM D999 - Loose Load Vibration, have their TMVs completed. These tests would apply to medical devices, pharma, and medical equipment packaging, for example.

Q6. Suppose there is no test method available; how to develop a test method and validate it?

A6. First, you'd have to research, determine what your test method is, write a test procedure, and do the risk analysis. It would be best if you justified everything you do and some things you chose not to do. WESTPAK works with an outside subject matter expert (SME) who helps determine sample sizes and performs the statistical analysis of TMV test data. It gets to be a very labor-intensive process and requires a significant effort, so we don't recommend attempting it alone.

Q7. Can you comment if there are regulatory expectations that each lab still needs to perform TVMs for per ASTM standards, some of which already have reproducibility/repeatability established during the method development by ASTM?

A7. Generally, the facility performing the testing and generating test data and results must do a TMV for each test performed on a product and its accessories submitted for approval. A completed TMV demonstrates that the testing laboratory can produce accurate and reliable results using their ***own*** equipment, staff, and quality management system.

Q8. Are there any special considerations for the validation of destructive test methods?

A8. The typical process for performing any TMV would be employed. Of course, you would need to be cognizant of the samples before and after testing with destructive testing, in addition to the number of samples required, since you'll use each only once.

Q9. Do your two locations provide the same services, or are there differences between them?

A9. Our two facilities, one in San Jose and another in San Diego, California, are very similar. For example, each has about 40k sq ft; both have about the same vibe & shock test capabilities. Also, we have around 100 environmental and aging chambers between the two sites. There are a few differences, too. For example, the San Jose site has a tumble tester, a product drop test machine, and a salt fog chamber. San Diego is stronger with more ICH and has HALT / HASS test capability.

Q10. For typical TMVs, how many people/operators do you typically use to establish reproducibility?

A10. A lab may need to utilize at least one engineer, an operator, and three trials to verify reproducibility. It all comes down to the data results, the risks involved, and of course, documenting your justifications.

Q11. Using F88 - Seal Strength testing as an example, do you train your staff to meet your established repeatability/reliability levels after completing the TMV?

A11. We train our staff to do the testing per the standard; then, we follow up to ensure enough consistency across the board between operators to meet the requirements.

Q12. What will be the sample size for destructive testing?

A12. Destructed samples would need to be discarded, so you'd need to have enough to do all the testing required. Please refer to the Sample Size Calculator pages on our website for assistance https://www.westpak.com/resources/calculators/

Q13. How does TMV work for testing that is random in nature (i.e., random orientation sequence drop)?

A13. Thanks for this question. A good example is ASTM D5276 - Free Fall Drop Testing, in which a bit of randomness exists in the way the container contacts the impact surface. However, the testing itself is very well defined. We handled ASTM D5276's TMV just like all the others.

Q14. Since the alignment of ISO 11607 to MDR is not yet complete, are there likely significant gaps if validation is performed now?

A14. Most likely not, however it would depend on what the gap is and the adverse risk to patient safety, if any. The situation would be like any requirement that's constantly evolving to meet the market's needs as perceived by regulators that must be incorporated by industry.

Q15. Do device manufacturers with internal test labs have to validate their testing, too, like an external test lab?

A15. Yes, ISO 11607-1 requires that all testing be validated; there are no waivers for internal test labs.

Q16. If I don't do all of the tests, do I still have to do the TMV? For example, if I don't do concentrated impact, do I need to provide TMV for it?

A16. A TMV is required only for the tests you do. If you're not doing a specific test that you would usually perform, we recommend preparing a justification for inclusion in the TMV documentation for your product and test.

Q17. If a company wanted to attempt to replicate a TMV test done at WESTPAK, ASTM F1886 – visual inspection, for example, how would they do that?

A17. We are following the ASTM standard, which the other site would also, therefore the test setups should be similar. Even if the setups were close to being equivalent, the new one would need its TMV done.

Q18. When do I need to revalidate a TMV?

A18. As mentioned, (ref: slide #12) revalidation would be required whenever something changes that might affect test data or test results. For example, if a test machine or software was updated, or a critical component like a valve was replaced, that might affect testing. It would be the same if you were developing a product and changed something; for example, a different material to seal a pouch or a redesign to a different configuration. Again, you need to document your justification.