Roundtable Q & A: Testing & FDA Compliance

Al Gale, John P. McCloy, Michael Anderson, Warren Ward-Stacey

Question 1: What tips do you have for device manufacturers to ensure their product testing processes are accurate?

Al Gale
Product and Material Engineer, DDL

Before sending a product to a third party test lab, a medical device manufacturer should be sure that what is being sent is already validated. In other words, the test methods used prior to any subsequent test methods need to be validated

John P. McCloy, PE, CWI
President, Accutek Testing Laboratory

Whoever does your tests, ensure that the test group is proficient. Using pretest “round robin” testing inside your facility or outside your facility is a good start. Of course, using an accredited outside lab is the easiest way of ensuring proficiency. Accredited labs are required to perform internal and external proficiency testing on a routine basis. Whether using internal or external laboratory resources, device manufacturers should confirm compliance with a calibration standard to ensure validity of the test results. Labs that are certified ISO 17025 and ISO 17207 are audited on scheduled intervals to guarantee that a quality control system is in place and functioning properly.

Michael Anderson, PhD
Technical Manager, Empirical Testing Corp.

Be meticulous and prompt in documenting your test methods, and recording the results. At some point in the future, you, or your successor, will need to repeat the exact testing that you are doing right now. Photographs of your test configuration will often contain minute details that don’t seem important now but will be important later. After you’ve run the test and collected the data, sometimes the temptation is to save the data file and walk away. Finish the job by writing a report that describes your methods and documents your results and conclusions.

Michael Boetzkes
Quality Manager, Life Science Division, Vaisala Canada Inc.

It’s easy to create a process that can “pass” a product. The real process you need to create is the one that catches a “fail” (especiallya borderline fail). Processes need to be tested with products that are both *obvious* pass or fail and *borderline* pass or fail. A process must tell the difference between a product that works 100% and a product that appears to work, but actually has a defect that will degrade long-term performance. A product should be assumed to be a non-working unit until it proves that *all* functions are working.

Question 2: What is a common error/oversight medical device OEMs make when it comes to preparing for validating a specific purpose?

AG: Planning ahead and scheduling for testing as part of the development process is key to avoiding mistakes due to having to rush testing and dealing with unexpected test results. Third party labs will gladly provide estimates for typical test times so that a medical device company can plan upfront. Realistic timing and expectations help all parties involved.

For custom testing, have a protocol developed which you know will satisfy regulatory requirements. Although it sounds like common sense, the protocol should be tried and proven out for feasibility. Assuming that everything will work out without actually trying it leaves room for overlooking such problems as a product that physically cannot be tested as prescribed by the protocol or setting faulty acceptance criteria.

Use of a consultant familiar with regulatory requirements is in the best interest of a medical device manufacturer when in-house expertise is not available. Among other things, this person can provide guidance on custom testing, sample sizes, and the amounts of data that are needed.

JM: Material identification is the most common. Always eliminate the obvious

sources of errors first. Is it the correct material (metals analysis)? Was it made to print (dimensional)? Is it labeled properly (visual)? Are containers labeled properly (visual)?

MA: Assuming that a change to an established process does not require validation because it is considered minor. Changes to a manufacturing or sterilization method, cleaning steps, or changing vendors of any of those services will affect the final fit and finish of a medical device. Mechanical testing (in particular, fatigue testing) will expose “weak points” in your device that may result from small seemingly inconsequential changes. If you are considering a change to your manufacturing process, ensure that you have recent baseline data on the performance of your part, do a small batch pilot run with the proposed change, and then test the pilots using the same method you used for the baseline.

Warren Ward-Stacey
Sales Director—Life Sciences, PRISYM ID

Often, companies will turn to software or other solutions to help ensure they are compliant, but a piece of software by itself cannot be compliant. Any critical software must be supported by a properly conceived and performed validation project, normally following GMP guidelines. GMP requires that the software is written and tested using a recognized lifecycle-based QA procedure; installed by following a pre-approved installation validation plan; and able to generate accurate records of every critical action performed, store records so they can be retrieved quickly, and protect records against unauthorized input, deletion, or modification of data.

Question 3: Where do medical device manufacturers run the greatest risk of running into trouble with regard to being FDA compliant?

AG: When working with a test lab, it is in the medical device manufacturer’s best interest to be familiar with the test standard and its appropriateness for the device

under test. One consideration is the use of the most recent revision of the test standard as opposed to using a previous version. Another consideration is being able to justify the use of a test standard when the product does not exactly fit within the scope of the standard.

JM: Failure to maintain evidence of conforming material identification. To be in compliance, be prepared to trace lot manufacturing, marking, and packaging/labeling with documents supporting the process (test reports, pictures, drawings, purchase orders, receiving tickets, signed work orders, and/or routing instructions).

MA: I'm going to answer this question interpreting "FDA compliant" with "obtaining FDA clearance." For a 510(k) submission, the burden of proof that you must present to FDA is that your device is "substantially equivalent" to a similar device that is currently in use. Manufacturers run into trouble when they start a round of testing without acceptance criteria in place.

WWS: The premise may seem straight-forward, but implementing FDA regulations, adhering to them, and being able to document that your organization is compliant is another matter altogether. Many companies fall short of meeting these requirements because they are using software that cannot comply to 21 CFR Part 11 and/or to quality systems regulation 21 CFR Part 820. They are also not documenting labeling standard operating procedures, not ensuring traceability in the event of a product recall, or using a labeling system that does not meet the needs of the FDA and GMP and cannot be made to meet these requirements.

Final Word: Any thoughts/comments on testing, inspection, validation, FDA compliance or another related area that you would like to share with medical device manufacturers to aid them?

JM: A great way to gain further insight on device testing and the rationale behind how the standards are written is to join ASTM and attend subcommittee meetings that govern testing for your device. The committee meetings provide an opportunity to witness and participate in the development and renewal efforts of testing specifications

MA: Ensure that you have a clear and well thought-out regulatory strategy. Will you pursue a PMA, or 510k path to approval? What devices currently for sale could you select as a predicate? What mechanical tests will you need to perform? More importantly, in what context will you present your test results? Can you tie all of the testing results together so that it is a cohesive and clear support of your regulatory strategy? Don't get lost in the minutiae of methods until your question is fully defined.

WWS: As a way to keep yourself on track, ask yourself a few questions that can help make sure you are FDA compliant.

- Is the software written "fit for purpose" for Life Sciences labeling

requirements, specifically 21 CFR Part 11?
- In the event of a product recall or FDA audit, is there an audit log going back five years?
- Does the software have full lifecycle documentation?
- Was the software installed as part of a full validation exercise?

Answering “no” to any of these questions could mean you are at risk when it comes to FDA labeling compliance.