

CASE STUDY

From Geek to Chic:

A Cosmetics Manufacturer's Journey to a Healthy Calibration Program.



Challenge

A large manufacturer in an FDA regulated industry found itself with repeated Form 483 findings as a result of using outdated practices to manage its calibration program.

Solution

Tektronix partnered with the company to determine the right type of calibration services and developed a plan to modernize the company's asset management program. Tektronix verified the company's equipment list, uploaded the information to CalWeb and began conducting regular onsite calibration events.

Benefit

With all the manufacturer's assets now in CalWeb, the company had immediate visibility of the compliance status of its asset pool as well as the ability to quickly and easily pull reports to find equipment with upcoming calibration due dates. In addition to helping the manufacturer optimize the management of its asset pool, Tektronix is providing periodic onsite calibration, which helps eliminate downtime and allows for critical pieces of equipment to be calibrated in place.

Before Tektronix

A well-known cosmetics manufacturer had received repeated Form 483 findings from the US Food and Drug Administration (FDA) and was in need of expert advice to turn around its calibration program. The manufacturer operated nearly 1,000 weight, temperature, flow and humidity instruments at its 85,000 square foot facility.

The company had received observation findings for using fading hand-written calibration labels and certificates, not listing the standards used to calibrate instruments on calibration certificates, and for operating an insufficient asset management system. A system of binders was being used to file the handwritten documents and there was no redundancy in the management of the calibration program. Gaps in record keeping could appear if service records were damaged, and the company could face serious issues in transferring the knowledge of how records were being kept if the employee running the calibration program were to leave the company. Aside from being on the wrong side of FDA regulations, the company was also generating substantial waste through inefficient manual processes.

After Tektronix

After an initial consultation, Tektronix began its engagement with the manufacturer by verifying the company's

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equipment list and recording the location of each piece of equipment. That information was uploaded into CalWeb®, a comprehensive online asset management application from Tektronix that is validated to meet FDA guidelines 21 CFR Parts 11 and 820. The company gained immediate organization-wide visibility of its calibration program. Quick and easy reporting showed the calibration status of every instrument in the asset pool, and automated calibration-due reminders could now be generated, saving countless hours of manual work. In addition to addressing the issues brought forth by the FDA, the company also opted to use periodic onsite calibration services, which reduces downtime associated with transferring instruments and allows for critical pieces of equipment to be calibrated in place.

Now, as calibrations are completed by Tektronix onsite technicians, calibration certificates and other service records are uploaded automatically to CalWeb. Records are now kept safe in a digital format and are easily searchable in the case of an audit. During the second week of onsite services, a surprise internal audit went so well that the company is considering using Tektronix at all of its manufacturing facilities. Its program now meets FDA regulations and the manufacturer can focus on making a great product without fear of product quality or non-compliance issues.

Learn more about how Tektronix can provide quality calibrations and reduce turnaround time at tek.com/calibration-services.

Accreditations



About Tektronix

Tektronix is the leading accredited calibration services provider with 75+ years of experience in serving the world's largest mission-critical manufacturers in aerospace and defense, semiconductor, automotive, medical, communications, and other industries. Tektronix works as a strategic partner, delivering tailored calibration service solutions that save time, cost, and hassle in achieving accredited and/or certificated calibrations for electronic test and measurement equipment.

