

From Geek to Chic:

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



Case Study Summary

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A large manufacturer in an FDA regulated industry found itself with repeated Form 483 findings as a result of using outdated practices to manage its calibration program.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

BENEFITS

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 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.

ABOUT TEKTRONIX

Tektronix is the world's leading multi-brand service provider of calibration, repair and related services for test, measurement and control equipment. Tektronix provides:

- Services for equipment from 9,000-plus manufacturers — far more than just Tektronix!
- Extensive global service network — more than 100 points of service.
- 1,100-plus associates — highly-skilled technicians and sales representatives.
- Superior quality — accredited calibration at ISO/IEC 17025 accredited facilities.

For more information about multi-brand calibration services, contact Tektronix today at 800-438-8165 or MVS@tek.com.

Contact Tektronix:

Australia	1 800 709 465
Austria	00800 2255 4835
Balkans, Israel, South Africa and other ISE Countries	+41 52 675 3777
Belgium	00800 2255 4835
Brazil	+55 (11) 3759 7627
Canada	1 800 833 9200
Central East Europe / Baltics	+41 52 675 3777
Central Europe / Greece	+41 52 675 3777
Denmark	+45 80 88 1401
Finland	+41 52 675 3777
France	00800 2255 4835
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Japan	81 (3) 6714 3010
Luxembourg	+41 52 675 3777
Malaysia	1 800 22 55835
Mexico, Central/South America and Caribbean	52 (55) 56 04 50 90
Middle East, Asia, and North Africa	+41 52 675 3777
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Republic of Korea	+82 2 6917 5000
Russia / CIS	+7 (495) 6647564
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