

Ensuring Accurate Particle Counting:

The Critical Importance of ISO 21501-4 Calibration

Summary

Calibration of particle counters used in controlled environments such as cleanrooms and pharmaceutical manufacturing must adhere to ISO 21501-4:2018. However, not all calibration services meet the standard's full intent. This white paper explores the importance of working with calibration providers who have direct access to the original equipment manufacturer (OEM)'s systems, processes, and firmware updates, and the latest SOPs. Only then can the calibration process be considered comprehensive, accurate, and compliant.

Why ISO 21501-4:2018 Matters

ISO 21501-4:2018 specifies the calibration and performance requirements for light-scattering airborne particle counters. These instruments are critical in industries where contamination control is paramount. The standard ensures that the data generated by these devices is accurate, repeatable, and traceable. Keeping in mind: Is all data good data?

Failure to calibrate particle counters properly can result in:

- Inaccurate data
 - Regulatory non-compliance
 - Compromised product quality
 - Risk to patient or consumer safety
 - Unwarranted Deviations and Change control
-

The Gap in Third-Party Calibration

While many service providers offer calibration services, only a subset have access to the OEM's proprietary calibration software, firmware updates, and internal procedures. Without these, third-party providers may be limited to surface-level checks or incomplete adjustments, leading to a false sense of compliance.

True ISO 21501-4:2018 calibration must include:

- Access to original calibration algorithms and firmware
 - "As found" data collection before adjustments
 - Adjustment and verification using OEM-authorised tools
 - Post-adjustment validation
-

Risks of Incomplete Calibration

Calibrations conducted without manufacturer access can result in:

- Inability to perform firmware updates critical for accuracy
- Missing procedural steps that impact instrument performance
- Invalid or unrecognised calibration certificates during audits

These risks have a direct impact on regulatory inspections and the integrity of cleanroom operations, especially in GMP-regulated environments.

Best Practice: Work with OEM-Authorised Calibration Providers

Choosing a calibration provider with full manufacturer access ensures:

- Valid calibration certificates accepted by auditors
 - Full adjustment capabilities, not just performance verification
 - Confidence that your particle counter is operating within specification
-

ISO 17025 Interlaboratory Testing: Essential for traceability, accuracy and repeatability

As a NATA Certified ISO 17025 Calibration laboratory:

- LAFtech completes proficiency testing with Lighthouse Worldwide Solutions routinely
 - This important testing continuously validates LAFtech's calibration system
 - The system is tested against the LWS system with a 1:1 comparison on traceability, accuracy and repeatability of our calibrations and technician competence
 - This ensures greater confidence in our service and the data integrity of our calibrations
-

Conclusion

ISO 21501-4:2018 is more than a standard—it's a commitment to data accuracy and product safety. To maintain true compliance, organisations must partner with calibration providers who have authorised access to the particle counter's OEM systems. This guarantees a full and accurate calibration from "as found" through to any required adjustments. Our commitment to maintaining a validated ISO 17025 calibration facility is our commitment to your data integrity and something third-party calibration can never stand up to.

LAF Technologies NATA Lab: 14755

With decades of experience and authorised partnerships with leading global instrument manufacturers, LAF tech's ISO 17025 NATA Accredited Laboratory offers industry-leading calibration services fully aligned with ISO 21501-4:2018. Our clients benefit from complete traceability, compliance assurance, factory trained technical expertise, local spare parts and total peace of mind. Many industry-leading pharmaceutical companies, GMP-compliant facilities, and healthcare organisations choose LAF Technologies as their trusted partner.

LAF Technologies supplies and supports the **Lighthouse** range of **particle counters** and **microbial impactors**, renowned for their precision and compliance with international standards.

With an extensive range of Instruments and Monitoring systems installed and instruments supported across Australia and New Zealand, LAF tech is proud to be a leading provider in cleanroom and contamination control solutions, backed by expert local service and technical support.

For more information, please contact: info@laftech.com.au | www.laftech.com.au
