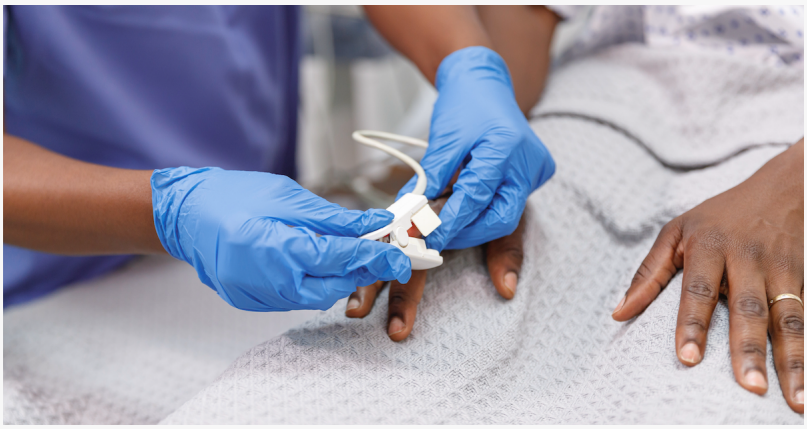
MethodSense Helps Medical Device Companies Meet FDA's Tougher Draft Guidance for Pulse Oximeters

New FDA Draft Guidance Raises the Bar on Pulse Oximeter Accuracy – MethodSense Leads the Way in Compliance, Clinical Validation, and Regulatory Strategy



New FDA Draft Guidance for Pulse Oximeters

MORRISVILLE, NC, UNITED STATES, March 5, 2025 /EINPresswire.com/ -- MethodSense, a leading regulatory and quality consulting firm, is leveraging its deep expertise to guide pulse oximeter manufacturers through the new FDA draft guidance aimed at enhancing the performance and accuracy of pulse oximeters across diverse skin pigmentations. As regulatory scrutiny tightens on pulse oximeters and demand for reliable, clinically validated devices grows, MethodSense is helping medical device companies navigate the complex FDA and international regulatory requirements, and meet the highest standards for accuracy, safety, and market readiness.

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> *Rita King, CEO of MethodSense*

Pulse oximeters have become a critical tool in both clinical and consumer health settings, particularly following the COVID-19 pandemic. However, concerns over their accuracy across diverse populations and real-world conditions have prompted the FDA and global regulators to propose higher performance expectations. Manufacturers now face increased pressure to demonstrate the clinical validity of their devices.

MethodSense's expertise in pulse oximeter compliance includes helping companies with clinical validation strategy, FDA 510(k) submissions, and compliance with international standards and post-market compliance. Having a clinical validation strategy will address FDA's expectations for accuracy across skin pigmentation and

oxygenation levels. Assistance with 501(k) regulatory submissions accelerates responses to regulatory inquiries, clearances, and FDA and international approvals. Guidance with quality system compliance ensures alignment with ISO 80601-2-61, IEC 60601, and FDA Quality System Regulations (QSR), while post-market compliance and risk management assistance supports manufacturers in surveillance and regulatory updates.

"The regulatory landscape for pulse oximeters is evolving rapidly, and manufacturers need to understand both the science and the submission process," said Rita King, CEO of MethodSense. "Based on our experience with pulse oximeters, we are helping companies bring safe and effective devices to market with confidence."

The FDA draft guidance on Pulse Oximeters expands Clinical Study Requirements by increasing the minimum number of participants from 10 to 150, increases the required data pairs from 200 to 3,000, and introduces mandatory new skin tone evaluation using the Monk Skin Tone (MST) Scale and Individual Typology Angle (ITA) assessment. The stricter performance and statistical validation criteria will improve accuracy measurement to <3%, down from 3.5%.

More information on how MethodSense can support pulse oximeter regulatory and quality needs can be found at Navigating the New FDA Draft Guidance on Pulse Oximeters.

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About MethodSense
MethodSense is a regulatory and quality consulting firm specializing in the medical device and life sciences industries. With deep expertise in FDA, EU MDR, and global regulatory pathways, MethodSense helps companies achieve compliance, accelerate market entry, and ensure product quality. Its LuminLogic® compliance management platform integrates regulatory processes, quality management, and lifecycle documentation into a seamless solution for achieving regulatory success.

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