element

BOULDER

NAVIGATE COMPLEX VALIDATION REQUIREMENTS AND ACCELERATE YOUR PATH TO MARKET

Physiological monitoring validation challenges, complex testing requirements, and stringent regulatory standards can derail even the most promising medical devices and wearables. When accurate SpO2, blood pressure monitoring, usability evaluation, and regulatory submissions demand precise clinical evidence, you need a scientific partner who transforms validation obstacles into manageable processes. Element's experts work alongside your team, delivering specialized clinical validation and human factors studies that ensure regulatory compliance while flexibly scaling with your development needs. Partner with our Boulder team to focus on your innovative health monitoring devices while we provide the expert testing that validates performance, confirms usability, supports regulatory submissions, and accelerates your path to market.

TRANSFORM CLINICAL VALIDATION FROM REGULATORY BURDEN TO STRATEGIC ADVANTAGE

PARTNER WITH ELEMENT BOULDER TO:

- Overcome regulatory challenges that threaten approval and delay market entry
- Benefit from end-to-end study management, from protocol to FDA-ready reports
- Access our extensive participant database with diverse physiologies
- Ensure quality with on-site Chief Medical Officer oversight for all studies
- Streamline IRB approvals with our established Salus IRB relationship

COMPREHENSIVE TESTING THROUGHOUT YOUR PRODUCT DEVELOPMENT LIFECYCLE

From initial protocol development through FDA-ready reporting, we handle the entire validation process so you can focus on your core innovation. Our specialized clinical validation services help you identify performance issues early, confirm user acceptance, and compile the robust documentation needed for successful submissions. Our key services include:

- SpO2/Hypoxia Studies
- Blood Pressure Monitoring Validation
- Human Factors and Usability Testing
- Method Development & Validation
- Regulatory Documentation Support

EARLY DEVELOPMENT

- Support calibration with non-blood studies
- Perform preliminary verification testing
- Design custom test protocols

REGULATORY SUBMISSION

- Conduct ISO-compliant validation studies
- Generate FDA-ready validation reports
- Meet stringent regulatory requirements

COMMERCIAL SUPPORT

- Support product modification testing
- Verify performance after device changes
- Document ongoing safety and efficacy

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SPECIALIZED EXPERTISE FOR YOUR MOST CHALLENGING VALIDATION NEEDS

Element Boulder provides specialized testing services:

SPO2/HYPOXIA STUDIES

- **ISO 80601-2-Compliant Testing -** Comprehensive validation for regulatory submission
- **Transfer Standard Methodology -** Efficient non-blood calibration development
- **Blood Validation Studies -** Gold-standard arterial blood comparison
- **Monk Skin Tone Scale Integration -** Complete demographic representation
- **Customized Protocol Development -** Tailored approaches for unique device challenges
- **Deep Subject Database -** Access to diverse physiologies and skin tones
- **Comprehensive Analysis -** Detailed accuracy and performance reporting
- **FDA-Ready Documentation -** Complete reports supporting regulatory submissions

BLOOD PRESSURE MONITORING

- **ISO 81060-2 Non-invasive Validation -** Comprehensive accuracy validation
- **Same Arm Sequential/Opposite Arm Methods -** Multiple validation approaches
- **Digital Manometer Technology -** Precise measurement capabilities
- **NIST-Traceable Equipment -** Ensuring measurement accuracy
- **IEEE 1708 Wearable Device Testing -** Specialized protocols for cuffless technologies
- **Diverse Subject Demographics -** Representation across age, BMI, and skin tones
- **FDA-Ready Documentation -** Complete reports supporting regulatory submissions

HUMAN FACTORS AND USABILITY TESTING

- **Formative Usability Studies -** Early-stage user interaction evaluation
- **Summative Validation -** FDA-compliant user interface assessment
- **Home Use Testing -** Real-world environment evaluation
- **Risk Identification -** Potential use errors and mitigation strategies
- **User Interface Optimization -** Evidence-based design improvements
- **Regulatory Documentation -** Complete HFE/UE reports for submission

SPECIALIZED MEDICAL DEVICE TESTING

- **Respiratory Rate Validation -** Specialized protocols for breathing monitoring
- **Temperature Monitoring Validation -** Precision assessment across measurement ranges
- **Sleep Monitoring Studies -** Specialized evaluation for sleep technology
- **Motion/Activity Monitoring -** Performance validation during movement
- **Low Perfusion Testing -** Evaluation under challenging conditions
- **EKG/Heart Rate Monitoring -** Comprehensive cardiac signal validation
- **Algorithm Development Support -** Data generation for improved performance

READY TO STREAMLINE YOUR PATH TO REGULATORY CLEARANCE?

Discover how Element Boulder's specialized clinical validation expertise can help ensure the performance and regulatory compliance of your medical devices and wearables. Our experienced team is ready to discuss your specific testing requirements and develop a customized solution.

Click or scan the QR code to learn more.

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