Nelson Labs®
A Sotera Health company

Expert Advisory Services

Safeguarding Global Health™
with every test we complete.

What we do

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Nelson Laboratories Expert Advisors offer an unparalleled breadth of MedTech experience to help our clients deliver safe and effective products to market. Our expert advisory services encompasses product development, facility and process validation, product performance testing as well as regulatory support.

Discovery Team

- Observation and onsite review of client processes, quality management systems, validation files and product development phase gates.
- Assessment and needs discovery related to product development to support validation for regulatory compliance and product submissions.
- Collaborative development of process changes and tailored solutions for continuous product improvement.

Education

- Onsite and client-specific training related to industry best practices, current regulatory and test guidance.
- Custom webinars for client training, regulatory updates and product-specific case studies.

Expert Advisors

- Product design file review and design phase input
- Facility validations (water systems, environmental and process controls)
- Test plans, protocols and written justifications for method selection related to:
    - Biocompatibility and material characterization risk assessments (ISO 10993)
    - Sterilization validations (EO/Steam/Radiation)
    - Packaging validations (ISO 11607)
    - Reusable and reprocessed devices (AAMI TIR12/30)
    - Product-specific validations and failure investigations
    - Development and review of product IFUs/DFUs
    - Product or family groupings
    - Unique process validations
- Regulatory support for submissions, product changes, detentions or rejection notices.

1-800-290-7552 AdvisoryServices@NelsonLabs.com

Why Choose

Nelson Labs Technical Expert Advisory Services?

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Proven Experience

- Experience with successful validation and regulatory approvals across thousands of product types in multiple MedTech industry segments (medical device, pharmaceutical, tissue, biotech).

Industry Involvement

- We remain up to date by actively participating on the standards committees working with industry and regulatory groups to shape the future of Medtech standards (AAMI/ISO/ASTM/PDA).

Thought Leadership

- Each of our advisors contributes to industry education through publications, seminars, webinars and hosted events. By combining their laboratory, regulatory and manufacturing experience and insights they give clients a full perspective on critical topics and changes.

Product Reviews | Process & Facilities | Test Plans | Regulatory Support

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We help our clients at
every phase of the product life cycle.

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Product File Review → **Process & Facility Assessments** → **Test Plans & Execution (Validations)** → **Regulatory Submission Review and Justifications** → **Regulatory Support & Post Market Surveillance**

Pre-FDA Filing Tests (Product R&D, Performance Evaluation and Validation)					**Regulatory Approval**	**Post-FDA** (Production)
R&D	**Biocompatibility ISO 10993**	**Sterilization Validation**	**Product Validation**	**Packaging Validation**	**US 510(k)** **EU CE Mark**	**Lot Release** (QC Tests)

Our highly qualified team of
Exper Advisors understand that **every product** impacts a patient's life.

Each advisor brings a unique perspective based on years of industry, regulatory, and scientific expertise. By participating in industry groups, actively working on the standards committees (AAMI/ISO/ASTM/PDA) and experience working with a broad range of MedTech companies and product types, our advisors bring a breadth of experience to each relationship. Although our lab processes over 50,000 projects each year, our advisors ensure success for our clients one project at a time.

By focusing on what matters most, we help our clients deliver life-saving products with every test through our **value-added advisory approach**.

Code of Ethics

Our advisors are committed to offering impartial, unbiased advice to clients to maintain the integrity of the services offered by Nelson Laboratories.

Request a full copy of our code of ethics at **AdvisoryServices@NelsonLabs.com.**
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