Regulatory Practice – Medtech
Medical Devices and In vitro Diagnostics

2025

AliraHealth
Patient-Enabled Solutions™

1 Alira Health

AliraHealth
Patient-Enabled Solutions™

Where Empathy Meets Science to Accelerate Life Sciences Research

Patient-enabled™ Solutions for Life Science

Local Insights.
Global Reach.

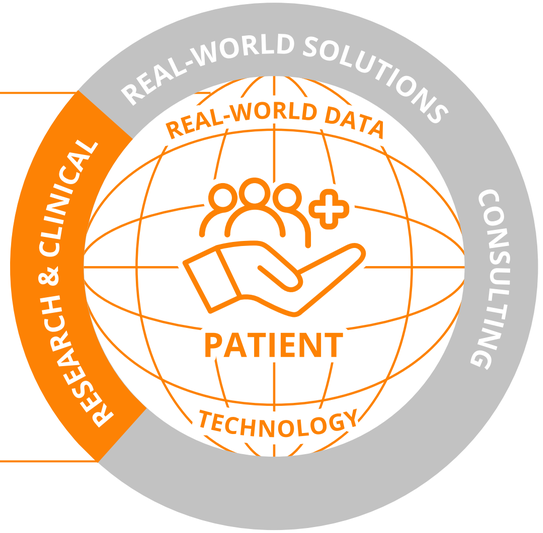
Our **local** presence and **global** collaboration allow us to deliver actionable business insights.

Our integrated team of over 800+ **Scientists, Strategists, Economists, Clinicians, and Biostatisticians** collaborate to fully understand every aspect of your business and offer an unmatched continuum of support across your full solutions' lifecycle.

Research & Clinical Development

Our team offers experienced, multidisciplinary guidance, and support for all aspects of your clinical trial. As a full-service CRO, our offering is designed to successfully execute studies, in all phases in a wide range of therapeutic areas, that deliver results ready for regulatory use.

- Clinical Operations
- Biometrics
- Medical Strategies
- Regulatory Affairs
- Chemistry, Manufacturing and Controls (CMC)

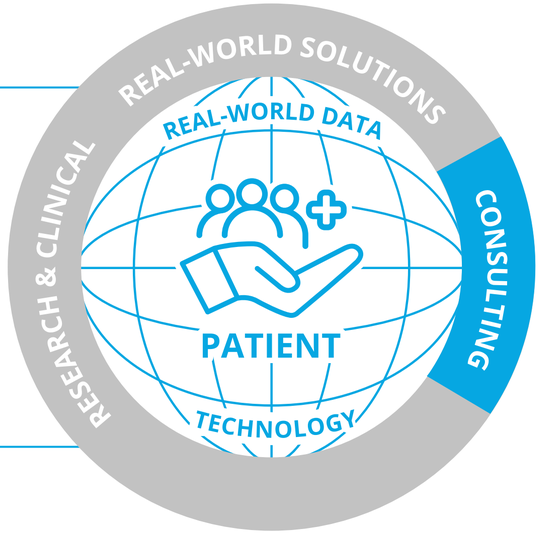


- Full spectrum of integrated in-house Clinical Development services
- Cultural & geographical proximity with your team, all as we manage global trials
- Agility & fast decision-making
- Highly specialized services provided by seasoned experts
- Patient perspective as the key driver of clinical development planning

Consulting Solutions

We put the patient's perspective at heart of our Consulting Services. As a strategic partner, we deliver more than recommendations – we create achievable strategies rooted in research, backed by advanced analytics, and supported through execution.

- Strategy & Transformation
- Market Access, Pricing & Reimbursement
- Patient Engagement
- Digital Health Services
- Transaction Advisory



- A consulting practice that intersects best-in-class market knowledge with a top-notch problem-solving process and functional expertise
- A team purpose-built to meet your needs, adapting to your level of maturity and growth ambition
- Consulting solutions that humanize healthcare

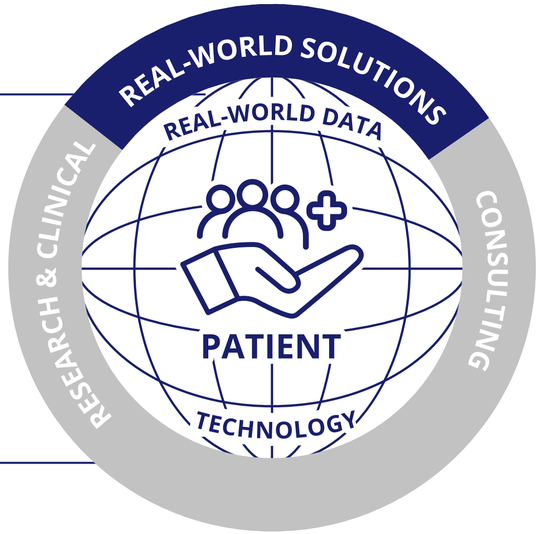
Forbes 2023
WORLD'S BEST MANAGEMENT CONSULTING FIRMS
POWERED BY STATISTA

Real-World Solutions

“Evidence generation with purpose” is our motto. We address the needs of multiple stakeholders and customers, with the participation of patients as drivers, for their ultimate benefit.

End-to-end Enterprise

- RWE Strategy
- Secondary Data Sources
- Partnership-enabled RWD Offering
- Technology-powered Patient Registries
- HEOR Strategy and Deliverables



- Integrated evidence plans to optimize access of new technologies to patients
- Global RWD studies leveraging complementary data sources
- Direct patient engagement, leveraging advanced digital solutions, enriched with clinical data to support regulatory, medical, commercial and access strategies

2 Regulatory Practice

Alira Health’s Regulatory Medtech Practice

Alira Health Medtech team delivers expert **regulatory support, strategic insights, and operational services** tailored to your needs in the **EU, US, and beyond.** Whether you’re navigating **EU regulations**, ensuring FDA compliance, or meeting local requirements in diverse markets, our team is your trusted partner in achieving global success with products such as **medical devices, in vitro diagnostics, and software-based products.**

We Ensure Tailored Strategies, Efficient Interactions and Successful Submissions

- We provide **personalized services** to meet each **client’s needs/requests** and adapt to each **stage of development** of the product.
- Our **extensive network of experts** and **key opinion leaders** addresses **specialized needs** in **numerous therapeutic areas**.
- We offer a **holistic approach** thanks to our **integrated team**, including biometrics, clinical, market access, strategic consulting, and patient engagement experts.

Medical Devices

Digital Health

Wide range of Therapeutic Areas

In Vitro Diagnostics

Combination Products

Companion Diagnostics

Strategic and Operational Regulatory Support

Alira's Health Regulatory Medtech team offers strategic and operational services to streamline the device regulatory strategy in line with the regulatory authorities, client marketing claims, indications for use and business objectives.

Strategic Development Services

> Gap Analysis
> Regulatory Strategy
> Due Diligence Assessment
> Product Classification and Categorization
> Clinical Strategy

EU Operational Services

> EU Technical Documentation Preparation
> EU Notified Body (NB) and National Authorities
> Audit Capacities

Quality Management System

> QMS Gap analysis
> QMS implementation
> Training
> Audit Capacities

US Operational Services

> FDA Meetings and Interactions
> FDA Submissions including Documentation
> Preparation

Additional Services

> Other Regions and country – specific requirements
> Go-to-market strategy
> Training and Collaborations
> Full Service Provider model

EU and US Strategic Services Detailed

Alira Health Regulatory Medtech team offers companies strategic consulting services, based in both the EU and US, designed to optimize regulatory strategies for medical devices.

Gap Analysis

- Customized report identifying the critical differences between the current state of the device development and where the company would like to be (i.e. product certification, Clinical Investigation Initiation, IVDR or MDR compliance, 21 CFR)
- Recommendations on how to solve the gaps identified and next steps to be carried out
- Recommendations on how to transit from one regulation/region to another

Regulatory Strategy

- Customized report evaluating the regulatory requirements (e.g. MDR/IVDR/FDA) and tests needed according to the applicable standards
- Define the potential development strategies and associated timing for each product, including pros, cons and risks associated

Due Diligence Assessment

- Report identifying and assessing important regulatory issues of an asset
- Conducted in multiple conditions and stages of development (e.g., FIH, prior to certification), both for licensing and for acquisition
- Provide recommendations on potential regulatory implications and requirements and go/no-go decision from the regulatory perspective

Product Classification and Categorization

- Determine main Mode of Action and product categorization (MD, IVD, Combination product, Drug, etc.)
- Classify the device according to the EU MDR and IVDR and/or the US FDA guidelines
- Review similar devices in the EU/US markets
- Provide recommendations on product claims and intended use

Clinical Strategy

- Collaborate with Medical Strategy, Biometrics and Clinical Operations divisions to design the synopsis and/or clinical trial protocol
- Ensure the clinical strategy is in line with the regulatory requirements
- Integrate reimbursement and go-to-market considerations in the trial design

EU Operational Services Detailed

Alira Health Regulatory Medtech team offers services from an operational perspective supporting the procedures that need interaction with regulatory authorities in the EU and any other operational activity.

EU Technical Documentation Preparation

- Technical Documentation (TD) preparation and/or review
- Update TD with Post Market Requirements
- Clinical evaluation/performance
- Support and prepare Clinical Evaluation/Performance (CER and PER) documents
- Advise and prepare Post Market Surveillance (PMS) strategy and documents including PMCF/PMPF
- Risk Management
- Unique Device Identifier (UDI) and EUDAMED

EU Notified Body (NB) and National Authorities

- Selection of the notified body according to the type of device and client needs
- Support and accompaniment during the evaluation and interactions with the NB
- Interaction with EU Member State National Regulatory Authorities for consultation, clinical trial approval and others
- Guidance on solving notified body on assessing non-conformities, review of CAPA plan, etc

Audit capacities

- Online and onsite Internal Audits as per MDR/IVDR.
- Third-parties audits capacity of suppliers, distributors, developers, manufacturers, and other subcontractors
- Assistance on assessing non-conformities

US Operational Services Detailed

Alira Health Regulatory Medtech team provides operational support services, facilitating interactions with regulatory authorities in the US and assisting with any other operational activities required.

FDA Meetings and Interactions

- Prepare required documentation (writing, formatting, advice on content needed) and submit documents to the FDA
- Lead and manage FDA meetings.
- Type of meetings: Pre-Submission, 513(g) Request for Classification, Request for Designation (RFD), Breakthrough Device Designation (BDD), Safety Technologies Program (SteP), Informational Meetings, Submission Issue Requests (SIRs)

FDA Submissions including Documentation Preparation

- Advise company on documentation needed
- Prepare submission package and act as primary correspondent with the FDA
- Lead and manage FDA meetings as part of the device submission
- Submissions: 510(k), DeNovo, PMA (Pre-Market Approval), Investigational Device Exemption (IDE), Emergency Use Authorization (EUA), Humanitarian Device Exemption (HDE/HUD), CLIA, LDTs

Additional Services

Alira Health Regulatory Medtech team offers to companies a wide range of complementary services.

Other Regions and Country – Specific Requirements

- Help companies transition to new frameworks for product registration in UK and Switzerland
- Identify requirements and register medical devices in APAC, Canada, LATAM
- Delineate best strategy to optimize resources & leverage data for product registry
- Identify and provide to the client the country-specific requirements that should be fulfilled (i.e. Spanish prior-to-operate license)

Go-to-market Strategy

- Elaborate go-to-market strategy for any product in the EU, US and other regions
- Full collaboration with Alira Health market access and strategic consulting practices to develop a complete & holistic strategies for market entry
- Market overview considering regulatory and clinical, but also market access, price and reimbursement requirements

Training and Collaborations

- Customized training services including specific on-site training activities for Medtech companies, investors groups, or pharma companies planning to develop MDs
- Training tailored to client needs: type of product, regulatory requirements, etc.
- Collaboration with Medtech and Regulatory clusters and associations
- Global or specific training of IVDR (2017/746), MDR (2017/745), FDA among others

FSP Model

- **Functional Service Provision**: outsourced Regulatory team as part of client's cross-functional team
- Support design and execution of the company regulatory strategy
- Support understanding of future regulatory needs
- Coordinate different stakeholders involved in product's development (toxicologist, clinicians, non-clinical experts…)

Quality Management System Service

Alira Health Regulatory MedTech team offers companies strategic services from the EU (ISO 13485), US QMSR (21CFR820), and combined regions (MDSAP) to enhance the quality management system for the development and manufacturing of any MD, IVD or Digital Health in line with the health authorities and business objectives.

QMS Gap Analysis

- Customized analysis identifying the critical differences between the current QMS and the QMS under the ISO13485, under the QMSR (21CFR820), or combined regions (e.g. MDSAP).
- Recommendations on how to solve the gaps identified and next steps to be carried out.

QMS Implementation

- Templates available for the implementation of the QMS following ISO13485, the QMSR (21CFR820), or combined regions (e.g. MDSAP).
- Support for the implementation of a system to follow quality standards in any stages of product development.

Training

- ISO13485:2016 Medical Devices Quality Management Systems global or specific training.
- ISO14971:2019 Risk Management training.
- IEC62304:2006 Software Life Cycle Process training.
- QMSR (21CFR820) global or specific training.
- Ad-hoc trainings upon request.

Audit capacities

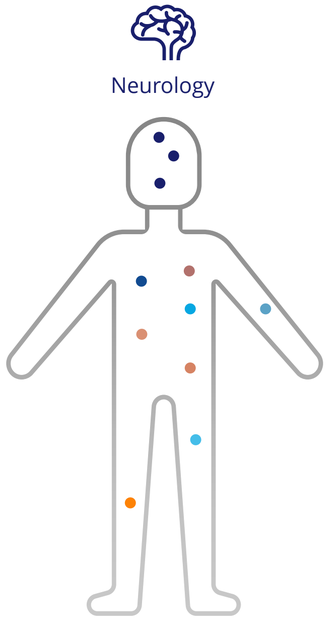
- Online and onsite Internal Audits, including MDSAP.
- Third-parties audits capacity of suppliers, distributors, developers, manufacturers, and other subcontractors.
- Assistance on assessing non-conformities, review CAPA plan, etc.

Our Experience

Our consultants have experience with different regulatory procedures for different types of devices across a wide range of therapeutic areas.

>200 medical device **certifications** in the **US** FDA and **EU**
>100 interactions with the **FDA** and **notified bodies**

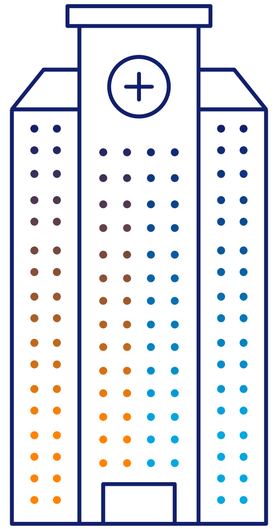
THERAPEUTIC AREAS



Neurology
Dentistry
Cardiology Cardiovascular & Diabetes
Oncology (including diagnostics)
Infectious Diseases
Orthopedics
Ophthalmology
Anaesthesia & Respiratory
Surgery, Wound Management and Transplants
Endoscopy
Dermatology

TYPES OF DEVICES

IVDs (PCR, ELISA, NGS, LFIA, CTCs)
Borderline products
Devices based on substances
Wound care, Homeostat, Dressings
Imaging devices
Implants (Knee, Heart, hip)



Active Devices
Software
Surgery devices, Accessories
Apps
Combination Products (Delivery devices, coated products)
Companion Diagnostics, In house devices, LDTs

3 Our Team

Medtech Practice Team

AINOA FORTEZA

Vice President, Regulatory Affairs

Ainoa Forteza is Alira Health's Vice President of Regulatory Affairs Medtech, working with her team on FDA and EU submissions for several different therapeutic areas and device risk classes.

Prior to joining Alira Health, Ainoa worked at Drug Development and Regulation S.L. (DDR), currently Veristat. There she managed the team focused on product strategy, manufacturer compliance, and securing CE mark for Medical Devices (MD) and In Vitro Diagnostics Regulation (IVDR).

Ainoa has almost a decade of experience in Regulatory Affairs consulting, including drug development strategy for a range of indications and EMA-related activities including scientific advice, orphan drug designation, and briefing meetings. She also worked in science communication for public entities and the pharmaceutical industry.

Ainoa is a human biologist and holds a master's degree in Pharmaceutical and Biotechnology Industry from Pompeu Fabra University, and a postgraduate degree on medical devices from the University of Barcelona (Curso de Posgrado Experto en Productos Sanitarios).

MERCÈ GUERRA

Manager, Regulatory Affairs

Mercè Guerra is Alira Health's Regulatory Affairs Manager, leading the development and regulatory activities for Medical Devices (MD) and In Vitro Diagnostics (IVDs) in the EU and U.S., and contributing to product strategy for securing CE marks and FDA clearance. Her expertise is in MD/IVD strategy and regulatory activities, including CE marks, CER, pre-RFD, 510(k), PreSubs, BDD, 513 (g), and De Novo requests. Prior to joining Alira Health in 2021, Mercè worked in MD and IVD regulatory affairs as part of Drug Development and Regulation S.L. (DDR, now Veristat). She has also worked in drug development for a range of indications and on EMA-related activities like scientific advice, orphan drug designation and briefing meetings.

She has a bachelor's degree in Human Biology and a master's degree in Pharmaceutical and Biotechnology Industry, both from the Universitat Pompeu Fabra (UPF).

Medtech Practice Team

SARA RAMIÓ
Senior Manager, Regulatory Affairs

Sara Ramió, PhD, is a seasoned expert in the development and regulatory affairs of medical devices and in vitro diagnostics, with a focus on European Medicines Agency and Food & Drug Administration submissions.
During her career, Sara has played a crucial role in ensuring companies' compliance with International Organization for Standardization (ISO) 13485 quality management systems and ISO 14971 risk management standards. Sara also made significant contributions to developing technical documentation in line with the In Vitro Medical Devices Regulation (EU) 2017/746 and gained valuable experience in software as a medical device development under International Electrotechnical Commission 62304.
Before joining Alira Health, Sara served as technical manager at GoodGut SLU, where she led the Development and Design and Manufacturing departments for various in vitro devices.
Sara's academic contributions are extensive, including numerous peer-reviewed publications and conference presentations across fields like molecular microbiology, microbial ecology, renewable resources, and digestive diseases. She has also been invited to speak at national and international conferences and has engaged in international research collaborations.
In addition to her industry experience, Sara has been an associate lecturer in the biology department at the University of Girona, where she also earned her Bachelor of Science and Master of Science in molecular biology and biomedicine, as well as a PhD with international distinction in molecular biology.

IRATI MENDIA AZKOAGA
Regulatory Affairs Consultant

Irati Mendia, PhD, with extensive experience in medtech regulatory affairs, has been instrumental in ensuring regulatory compliance for medical devices and in vitro diagnostic products. During her career, she has expertly navigated complex regulatory landscapes, led cross-functional teams, and collaborated with regulatory authorities to secure critical approvals.
Irati excels in developing technical files, overseeing the analytical and clinical validation of in vitro diagnostic products under the In Vitro Medical Devices Regulation (EU) 2017/746, and implementing International Organization for Standardization (ISO) 13485 quality management systems and ISO 14971 risk management protocols. Her commitment to regulatory excellence has consistently driven successful outcomes in the medtech sector.
Irati holds an industrial PhD in molecular biology and clinical research, which grounds her deep expertise and dedication to advancing medical technology.

Medtech Practice Team

GIACOMO BASADONNA, MD, PH.D.
CMO Medical Strategy

Dr. Giacomo Basadonna leads Alira Health's Global Medical Affairs Advisory and is Professor of Surgery at the University of Massachusetts Medical School. He has designed and obtained 16 corporate or government grants. Previously, Giacomo was the Chief Medical Officer for Z-Medica, and his prior hospital appointments include UC Davis Medical Center, Yale New Haven Hospital, and UMass Memorial Hospital.
He received his MD and PhD from the University of Milan. As a renowned transplant surgeon, he is a member of 23 national committees, three hospital committees and 14 professional societies. He has designed and obtained 16 grants, also from large companies and government departments. His previous hospital appointments included UC Davis Medical Center, Yale New Haven Hospital, and UMass Memorial Hospital.
Giacomo has presented at major conferences and on TV appearances over 80 times. His multiple publications include over 80 abstracts, 13 limited dissertations, and over 80 publications in peer review journals.

VIKY VERNA
Senior Director, Regulatory Affairs

Viky Verna is a former FDA Investigator, Compliance Officer, Reviewer who became an International Regulatory Consultant, with 15 years of experience in the Pharmaceutical Drug, Biologics, and Medical Device industries with a special interest in Digital Health, IVDs, and Combination Products.
He supports clients with their compliance challenges around the globe. Furthermore, driven by a keen interest in International Regulatory Affairs, he has also actively contributed to the mission of international regulatory organizations in the US and abroad such as the UN WHO (World Health Organization) with close attention to ICH, IMDRF and MDSAP; and also with ISO (International Standard Organizations) committees. In addition to his BS and MS in Biomedical Engineering, MS in Pharmacy, and Global Regulatory Affairs Certifications, he speaks English and French fluently.

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Thank you

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