entries
LEAN ENTRIES LTD

INSTANT ACTIONABLE KNOWLEDGE ON MEDICAL DEVICE REGULATIONS

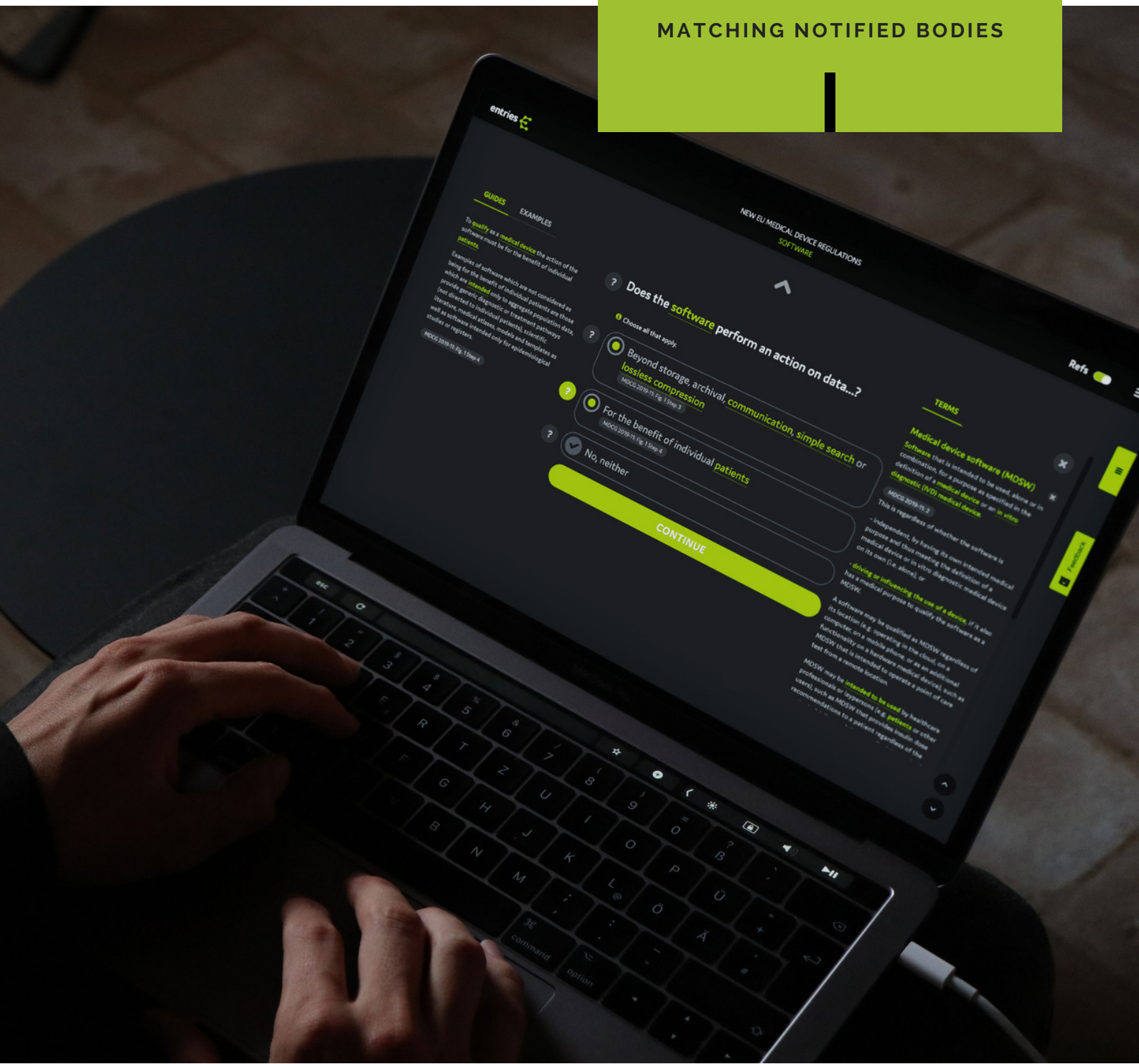
THE DIGITAL RUNWAY TOOL

INTO THE EARLY STAGE
REGULATORY PRINCIPLES
&
A PERSONALIZED
REGULATORY STRATEGY
WITH
TASKS, TIME AND COST ESTIMATES

EU MDR & IVDR:
QUALIFICATION & CLASSIFICATION
OF MEDICAL DEVICES, IN VITRO
DIAGNOSTICS AND SOFTWARE

CONFORMITY ASSESSMENT OPTIONS
AND APPLICABLE STANDARDS

MATCHING NOTIFIED BODIES



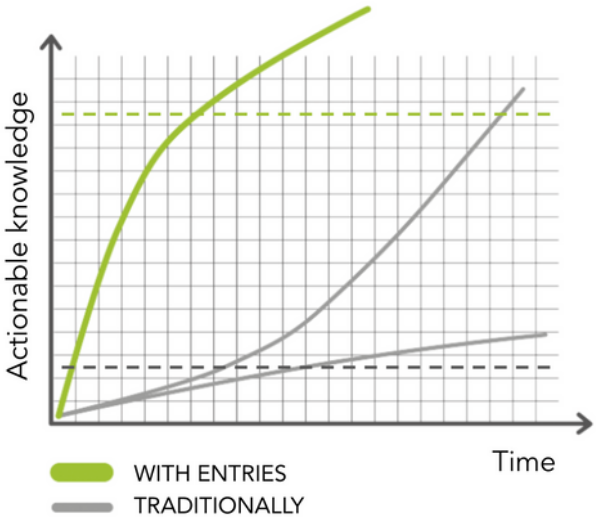
INVEST MINUTES TO SAVE MONTHS IN REGULATORY COMPLIANCE

Regulatory compliance is a struggle for Health Tech innovators and startups across the globe. AdvaMed in the USA has stated: "Medtech innovation is driven by small companies and start-ups on the cutting edge of improving patient care. In the best of times, these heavily R&D-focused firms struggle to find the financing and resources they need to navigate tough regulatory pathways in order to bring a new device or diagnostic to market"

"We are really pleased with your digital service, the **Entries**. It's easy and intuitive to use and has helped us a lot. We definitely recommend Entries for other health tech startups and innovator communities!"

Kasper Storm Køppen, CEO / Co-founder, VIOBAC, Denmark

Lean Entries has designed **Entries**, a regulatory runway tool, exploited by hundreds of health tech startups and researchers, that provides them with instant actionable knowledge on the regulatory principles. It lays the foundation for compliance and guides into turning the requirements into a business advantage for the health tech innovators, de-risking entrepreneurship. **Entries** saves weeks of their time in learning and months in reaching the global healthcare market. This unique tool, when applied from the early stages of innovation, enables the development of viable health tech to make the impact in healthcare.



"Before exploiting these regulatory tools I was daunted by the complexity of regulatory compliance. The **Entries** tool is very effective in transmitting knowledge. I have experienced nothing comparable to it as an educational hands-on application. I've certainly saved weeks worth of my time in reaching this new level of regulatory knowledge and find confidence in moving forward."

Oguz Tanzer, Urisens R2B project, Aalto University & SPARK Finland

SERVICE OFFERING

1. ENTRIES - DIGITAL REGULATORY RUNWAY TOOLS

'Regulatory Journey - Health Tech Startup' Entries tool

- For learning the regulatory basics and generating the first version of a personalized Regulatory Strategy with EU MDR / IVDR in focus and global principles for compliance included.
- For learning the effect of the following items on the path to market: Intended Purpose, Qualification & Classification, General Safety & Performance Requirements (GSPR), stage of development, regulatory know-how of the team, Person Responsible of Regulatory Compliance (PRRC), supplier control, targeted markets, Quality Management System (QMS), Clinical Evaluation and Risk Management.
- The draft Regulatory Strategy includes the above considerations with the recommended Conformity Assessment route in EU and a list of the most relevant regulations, standards and guidelines applicable to the device type. It includes work time estimates and a timeline model for the regulatory compliance tasks.

New EU Medical Device Regulations' Entries tool

- Complete Qualification & Classification of medical devices, in vitro diagnostics (IVDs) and medical device software (MDSW) according to the MDR and the IVDR in a minute format.
- Reference to all relevant EU legislation, guidelines, EU case law and the Manual on Borderline as listed in the Lean Entries library.
- Conformity Assessment options based on the device class and type.
- Automated identification of Notified Bodies that bear the scope of competence matching the device type.
- Final report with a fully referenced justification on Qualification & Classification and the other items above.

2. REGULATORY ESSENTIALS IN HEALTH TECH - TRAINING SERIES

A webinar series on the global **Regulatory Essentials in Health Tech** provided by the Labquality and Lean Entries experts in an on-demand format

- The series consists of 14 x 2-hour online sessions covering the life cycle of a medical device from the global regulatory perspective while most references are made to the EU MDR & IVDR and the US FDA requirements.
- **Entries** is exploited in the webinars as an educational tool with aligned contents.
- Most sessions provide general horizontal knowledge while some are tech specific (e.f. for software)
- Training materials and a certificate is provided from each attended session.
- The final session on the 'Person Responsible for Regulatory Compliance (PRRC)' comes with an exam.
- All sessions and contents are provided in English.

3. REGULATORY WORKSHOPS FOR STARTUPS AND TRANSLATIONAL RESEARCH TEAMS

Workshops are held on-site or online for the regional researchers and startups by our regulatory experts. They can be tailored to the specific needs of the local ecosystem. Local regulatory experts may be invited to join and contribute as trainers and mentors.

Typically two workshops are held for a group of innovators: a Kick-off Workshop and a Wrap-up Workshop some months apart from each other:

- A Kick-off Workshop introduces the **Entries** tools and the global regulatory principles.
- In a Wrap-up Workshop the innovators pitch their Regulatory Strategies to the regulatory experts and the fellow innovators according to what they've learned using the tools and trainings. This is to gain feedback, further advice and validation for their strategies. The workshop may continue in breakdown groups by device type to gain more specific advice and peer learnings.

The workshops may be followed (or substituted, depending on the regional needs) by One-on-One sessions with the innovators to address their more specific regulatory challenges. These take typically 2-3 h by the team and a regulatory expert.

COMPANY PRESENTATION & REFERENCES

Lean Entries is on a mission to light the way into compliance and other complex information for the health tech innovators. We have worked in health tech startups, large multinational companies, Notified Bodies and accredited test labs. The **Entries** platform was born for turning the piles of regulatory requirements into instant actionable knowledge and to help startups save months of time in creating viable health tech. As a result we see a growing number of innovators that turn regulatory compliance into their business advantage.

Lean Entries is part of the Labquality family of companies with a common team of ca. 70 regulatory affairs, quality assurance and clinical research professionals in Finland, Germany and Poland. We cover a vast variety of expertise from medical software and AI to biodegradable implants and in vitro diagnostics (IVDs). This includes Clinical Research Organization (CRO) services for medical devices as well as pharmaceuticals. We are an active member of Healthtech Finland chairing their regulatory affairs working group for medical device software and the special interest group for health tech startups.

The CEO & Founder of Lean Entries, **Heikki Pitkänen**, has worked in the health tech sector since 2001, including project and regulatory management roles in three startups and management roles in two Notified Bodies and accredited test labs for electromedicals, most recently at SGS. He's been active in international standardization and has represented Finland in the Advisory Board for Healthcare Standards (ABHS) of CEN-CENELEC. He is an author of a Business Finland publication European Medical Device Regulations MDR & IVDR - A Guide to Market.

Testimonials by startups, researchers and manufacturers:

Urisens R2B project, Aalto University & SPARK Finland
Viobac
Causalus
Solita

Testimonials by regional clients:

Danish Life Science Cluster
City of Helsinki
Business Tampere, Tampere University & SPARK Finland
Oulu Health

A selection of our regional clients:

MEDTECH TWENTE, ttt MED TECH, oost nl, Danish Life Science Cluster, Symbion, CPH LABS
HEALTH TECH NORDIC, SPARK FINLAND, ACCELERACE, SMILE INCUBATOR, Tampere University
INNOVATION SKÅNE, SAHLGRENSKA SCIENCE PARK, Aalto University, TERKKO HEALTH HUB, TURKU BUSINESS REGION, OULU HEALTH

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