entries
LEAN ENTRIES LTD

DIGITAL REGULATORY RUNWAYS

ABOUT LEAN ENTRIES

Lean Entries Ltd. is a group of regulatory experts in the area of global medical device regulations. We provide unique digital regulatory services (ENTRIES) and consulting for the medtech sector, from academies and startups to multinational enterprises. We've dealt with a range of innovations from medical device software and AI to biodegradable implants. We have decades worth of experience from medical device development, certification, accredited testing and standardization. We represent Finland in the Advisory Board of Healthcare Standards (ABHS) of CEN-CENELEC and provide regulatory training services in collaboration with the UK based Informa Connect. See the 1-minute video at www.leanentries.com for an introduction into our Digital Information Runway concept and mission in health tech.

"Thanks to Lean Entries and their mastery on regulations and standards, we are now an ISO 13485 certified software provider and have released our first CE-marked medical device software. We remain a happy camper on Entries, their digital service grounds, which helps us with communicating compliance to our co-operators and evaluating the regulatory status of new software in our pipeline. Entries is a great leap from analogue to digital in sharing such complicated information. "I know kung-fu!" kind of an experience, as Neo put it."

Juha Vaaraniemi, Director, Design and Advisory Services
Solita

SOLITA

"Lean Entries Ltd was hired by OuluHealth due to their intuitive digital solution (Entries) to solve the early stage regulatory challenge and their mission to empower health tech startups. In their trainings, they make the complex regulatory topic resonate with competitive gains and modern business practice. Their one-on-one regulatory clinics have put our community startups and innovators on an informed track towards compliance. As a result, the investment made by OuluHealth has already paid back after one month into the program that spans a full year."

Minna Komu, Network Director
OuluHealth

OULU HEALTH

"You're contributing in depth and highly valuable knowledge in a very user friendly way to the startups in HealthTech Nordic."

Marianne Larsson, Director New Industries
HealthTech Nordic

HEALTH TECH NORDIC.

"Having identified a pile of business risks, risking compliance was clearly not one we could afford. Everything we do for the sake of compliance, starting from risk management and clinical evaluation, translates into smart and efficient business and highly valuable marketing material. Entries now encompasses a lot of that early stage wisdom."

Pasi Heiskanen, COO & Co-founder
Noona Healthcare, an e-health startup acquired by Varian

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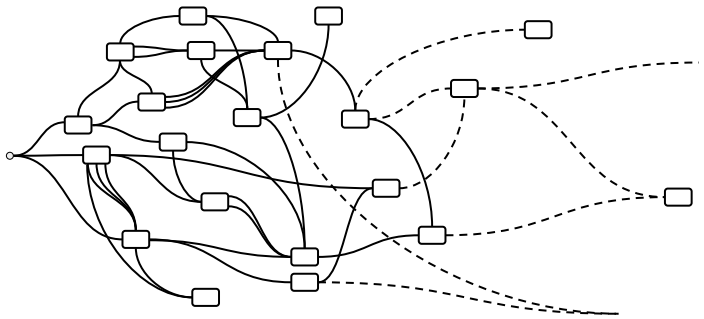
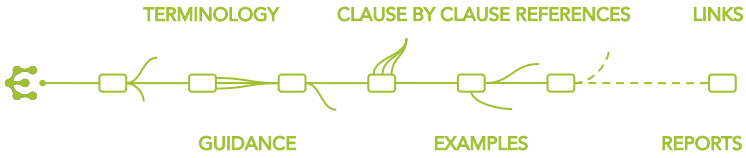


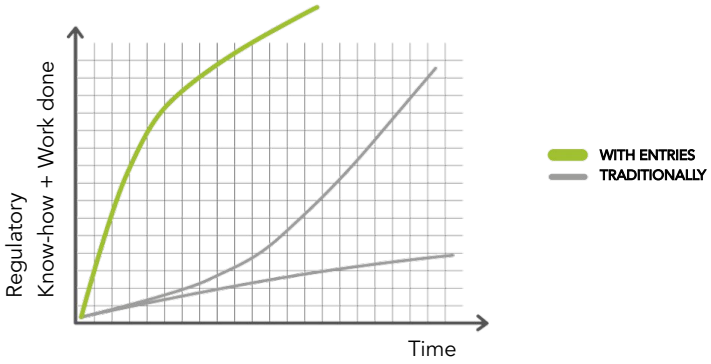
COMPLEX REGULATIONS

Health tech developers, academics and companies, define regulatory compliance as their second greatest hurdle in reaching global markets.[1] Our decades worth of experience from health tech development, certification and regulatory consulting support that finding.



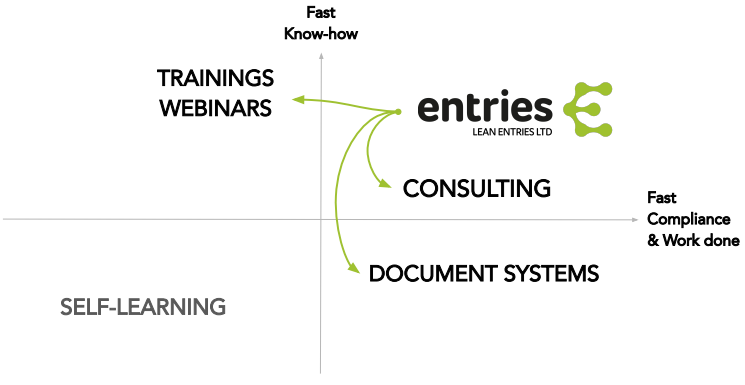
A MINUTE RUNWAY

In ENTRIES, the piles of regulatory complexity are turned into minutes of clarity in a questionnaire format (See Description of the Service). Terminology, examples and guidance from the regulatory sources light the way and the developer gains a Final Report as a rationale to move ahead.



MINIMISE THE BUSINESS RISK

Regulatory compliance is one of the foundations of a successful business. Too many health tech developers do not recognize this fact and fail slow. ENTRIES puts the developer on a steep learning curve and instant actionable knowledge regarding compliance.



COMPLY FROM DAY ONE

ENTRIES helps by turning regulations from the inevitable into an advantage, minimizing business risk and time to market. The developer may save months by spending only minutes in ENTRIES on topics that are crucial for their market entry and necessary to know from the birth of the innovation.

www.leanentries.com

1) Health Technology Industry in Finland, University of Turku and Turku University of Applied Sciences, sponsored by Business Finland, 2017

DESCRIPTION OF THE SERVICE

Lean Entries provides a **minute online regulatory tool**, ENTRIES, available at www.leanentries.com. ENTRIES guides you through the questions necessary to **determine if your product or software is regulated as a medical or in vitro diagnostic (IVD) device, and if so, what is the risk class of the device.**

Entries supports

- The current EU medical device directives: **MDD, IVDD, AIMDD** (*93/42/EEC*, *90/385/EEC*, *98/79/EC*)
- The new EU medical device regulations: **MDR, IVDR** (*2017/745*, *2017/746*)

Entries then guides you further into the following regulatory essentials:

- Conformity assessment options based on your device class and type
- Information on the general requirements and the most relevant standards and guidelines for medical device manufacturers
- Identifying the Notified Bodies that bear a scope of competence matching the device class and type, and
- Online stores to purchase internationally recognized standards.

This information is essential for any medical device developer from day one on their pursuit towards the EU and global market. Lean Entries has reorganized the hefty bit of documentation related to this task (www.leanentries.com/library) into **minute runways** that provide **clause by clause references and links to the original documents and a full rationale at the end of the path**. The service is updated accordingly as new guidelines are published by the European Commission.

When combined with training and hands-on help with the Regulatory Essentials, a medical device manufacturer will gain the crucial level of know-how for making informed decisions regarding their business.