

## Lean Entries: the view of a regulatory expert



“ The importance of the legal and regulatory aspects is inestimable. It is, therefore, definitely useful to have a directory as the eHealth HUB Platform where SMEs can find regulatory experts providing services specially designed for this sector. ”



Digital Regulatory  
Runways at Lean Entries



Heikki Pitkänen, CEO



<https://www.leanentries.com/>



Finland

### My challenges

The importance of the legal and regulatory aspects is not perceived by SMEs as compliance is considered non-affordable and is not well understood due to its complexity. Non-compliance creates a high risk for market entry for the SMEs. Start-ups should see this as an investment due to the importance of the matter, since no regulatory compliance ultimately means no commercialization.

### eHealth HUB support

**Regulatory guidance and eHealth HUB Platform.** “The creation of a network of quality and easily identifiable legal and regulatory experts and digital services can be considered a good practise and will facilitate the access to this type of expertise. The emergence of digital regulatory services provides an opportunity to cut down costs and increase efficiency in compliance for the SMEs.

In this sense, the eHealth HUB platform is very useful by providing a digital tool where SMEs can easily find regulatory experts. For us, it can serve for identifying potential clients as well. Ultimately, it raises awareness about the importance of the matter, helping SMEs to understand that is a key factor for success”

### The company

Lean Entries Ltd. is a group of regulatory compliance professionals with decades worth of know-how from the medical device sector. The company started in 2016 with a mission to light the way into compliance for every medtech developer around the world. The Entries platform was born for turning the piles of regulatory requirements into minutes of clarity for the developers.



# eHealth HUB *Stories*

## Learning points ●

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**Heikki Pitkänen**, Founder and CEO Digital Regulatory Runways at Lean Entries

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## eHealth HUB services



### Regulatory Guidance

eHealth Hub Regulatory Network helps European eHealth SMEs to be compliant with regulatory requirements and develop reimbursement strategies across the European Union.



### eHealth HUB platform

The eHealth HUB platform ([platform.ehealth-hub.eu](http://platform.ehealth-hub.eu)) is the map of European digital health. An online catalogue that identifies the key players to enhance transparency in the sector and encourage stakeholders' interaction

