The Regulatory Journey

Are you part of a MedTech start-up developing medical equipment for diagnostic purposes, treatment, or disease prevention? Do you have sufficient knowledge about the regulatory laws and regulations applying to you? This unique program will provide you with baseline knowledge on regulatory compliance and give you access to workshops and local experts. And it's all free of charge.

The regulatory journey is a program giving you access to the necessary knowledge, tools, and feedback for regulatory compliance. The program will provide detailed insight into the regulatory laws and regulations that your company and your product need to live up to in order to enter the European market. The focus will be on medical device regulation (MDR), equipment for in vitro diagnostics (IVDR), and medical software.

The program will support to ensure that the products and services you develop will fulfill the criteria for legislation, special requirements, and standards for obtaining CE marking. It is important to have the regulations in mind from the early product development stage. The activities will e.g., help you to find the right consulting services for your need and when to make use of test facilities during the product development – in order to ensure certification of your product.

Even as an early Life Science start-up you must be aware of the regulatory compliances that your product needs. This is necessary to make realistic business plan and generate interest from business partners and investors.

The program:

- Kick-off and initial workshop on 20th of September 2022 (see the program below)
- Access to the new regulatory service concept, providing you with an overview of your regulatory journey
- Online training sessions with the opportunity to ask the experts
- FInal workshop with regulatory experts on 23rd of November 2022

Deadline for signing up is 7th of September.

The challenges

Many Life Science start-ups experience the regulatory universe as confusing and as an immense challenge. The new start-ups typically do not have a particular focus on this area, instead, they focus on professional and technical product development.

Only a few start-ups have founders or employees with adequate regulatory knowledge to navigate through the regulatory universe. That often lead into pitfalls without adequate documentation for their given service or product. The product development will then be delayed and investments for development and growth will be hard to achieve. This can eventually cost valuable time and resources.

It is essential for many Life Science start-ups to add value to regulatory compliance which furthermore adds a competitive advantage. Life Science start-ups with an overview of their regulatory journey will avoid costly pitfalls and thereby reach a faster development of the regulatory compliant product.

As a new business, you would typically have to purchase consulting services within the area. Insights into the regulatory journey through this program would then, potentially, save you money and you will be prepared for when and what type of extern help for test and consulting you need for your product development. As well as what you can expect the expenses to be.

Get an overview of your regulatory journey

Danish Life Science Cluster, in collaboration with Accelerace and Symbion, strive to simplify the journey to market access for Danish health technological start-ups and research spin-outs. The innovative products and services have great potential to help patients and citizens worldwide.

The consortium is, in collaboration with Lean Entries, Labquality, and Danish consultancies with a specialty in regulations, developing a **new regulatory service concept**, to kickstart your start-up journey. The digital platform Entries, delivered by Lean Entries, will deliver an efficient introduction to the subject, and provide an overview of your regulatory journey and action points. This includes cost- and time estimates for market access.

At the same time, as a start-up, you will participate in **chosen training sessions** providing you with extensive knowledge within your category of work. This will be complemented by workshops where experienced regulatory consultants help you adjust your regulatory strategy - and you will be able to ask questions to the experts.

Feasibility Voucher

If you’re participating in The Regulatory Journey, then you can apply for a feasibility voucher for up to 75.000dkr. The funds can be used for expert consulting or the testing of your product. This could for example be market analysis or laboratory work. The funds cannot directly be used for product development or implementation. The project needs to be described in order to make a tender offer.

How to participate

It is free to participate in The Regulatory Journey. However, you are required to fill out and sign documentation for your participation. This happens during the hours you spent participating in the program's different activities.

The requirements are:

- Growth potential and ambitions

- Danish CPR-number
- Your business cannot be more than 5 years old

NEXT STEP

Life Science Incubator program
The Beyond Beta REACT-program also consists of a Life Science Incubator program. Among the other workshops, you will get an introduction to the Life Science Entrepreneurial Journey and the industry's stakeholders. As well as tools for how to build your storytelling and your pitch. As something unique, the incubator program will end with a joint stand on WHINN, where it will be possible to present your idea to the experts and audience. Apply no later than September 5th.

Accelerator program
You can apply to participate in the Accelerator program after the Incubator program. This is a longer and more in-depth program, run by Accelerace, that has helped 800+ businesses with their upscaling. The deadline for applying is September 19th.

The activity is a part of BeyondBeta REACT, financed by EU. The activity will run until June 2023. There will be 2 batches. One in fall 2022 and one in spring 2023.

DETAILED PROGRAMME FOR THE FIRST WORKSHOP:

Kick-off for Health Tech Start-ups

Date and Time: 20.9.2022, 09.00 – 16.00

Place: COBIS, Køpenhavn N

Participants:

Danish teams or start-ups selected to the program
Regulatory consultants and stakeholders from the start-up ecosystem
Business accelerators
This event is a kick-off into the Regulatory Journey service program. The concept is targeted for teams and start-ups that are in the ideation or early development phase of a product or software for the health care sector. The objective of the program is to provide the teams with the necessary baseline knowledge regarding regulatory compliance in order to save months' worth of time and effort in reaching the market. The concept combines digital, training and coaching methods which will be employed in this kick-off event and throughout the following two months of the program.

While this is the first running of the program, attendees are will be engaged to provide active feedback for the organisers and the program will be further developed based on the feedback.

AGENDA

09.00-09.15 Coffee

09:15-9:30 Welcoming words, presenting the program.
/ Signe Ulrik Holm, Danish Life Science Cluster

09.30-10.00 Round table and interview with start-ups over their regulatory challenges, discussion, feedback, experiences, stumble blocks, expectations.
/ Christian Waarst, Accelerace

10.00-10.15 Presentation of the Regulatory Journey service concept, digital + training + workshop coaching. Discussion.
/ Heikki Pitkänen, Lean Entries

10.15-10.30 – – break – –

10.30-12.00 Regulatory Essentials in Health Tech Compliance as a Business Advantage, part 1.
What to focus on from Day One? Questions & Answers.
/ Heikki Pitkänen, Lean Entries

12.00-13.00 Lunch break

13.00-14.00 Regulatory Essentials in Health Tech Compliance as a Business Advantage, part 2. Continued. Questions & Answers.
/ Heikki Pitkänen, Lean Entries

14.00-15.00 Coaching sessions with consultants: Towards the realistic regulatory plan within the business plan.

15.00-15.30 Coffee and talk: Feedback from the attendees. Expectations from the program?

15.30-16.00 Handing over the tools and schedule for the next two months. Wrapping-up.