Norwegian Health Consortium

Health Tech Regulatory Strategy

This service package offers access to Regulatory experts with extensive experience in designing regulatory strategies for healthcare companies. A structured approach will help you design and execute your market approval so that you can be confident that your innovation can be introduced to new markets.

This package will ensure that you get critical insight that will allow you to understand the regulatory requirements in order to kickstart your market approval process

Investment: 18,750kr (value 75,000kr) + travel **Duration:**~3 months

Delivered by Aleap AS in collaboration with MedQtech

Send email to info@aleap.no for ordering this package

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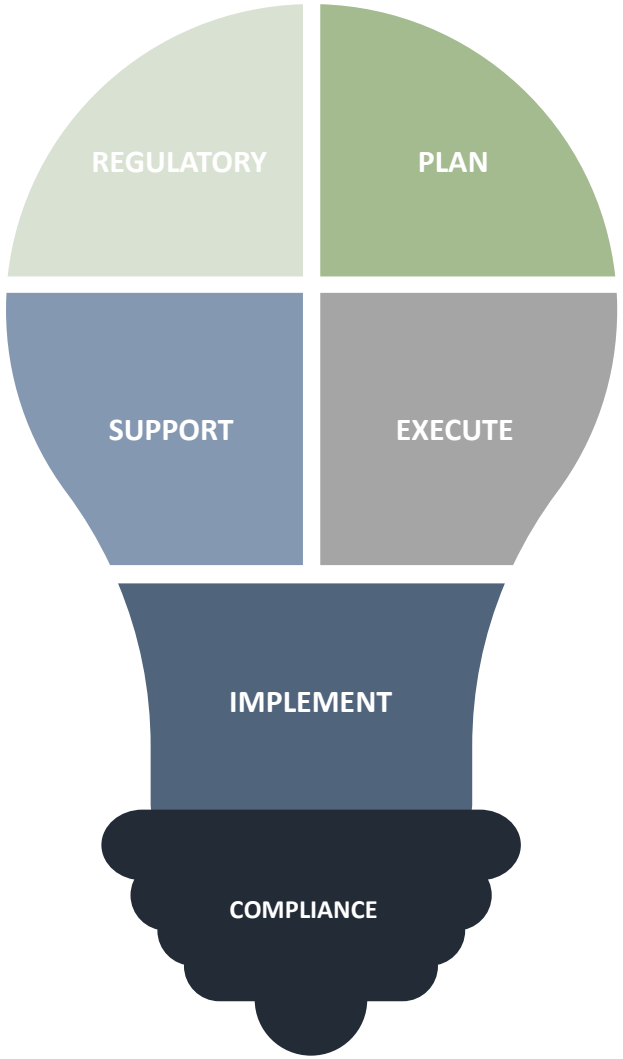
Health Tech Regulatory Strategy

NATIONAL HEALTH CONSORTIUM SERVICE PACKAGE

Aleap

for health startups

WHY REGULATORY ROADMAP?



Innovation is never easy, our experience tells us that most startups struggle with understanding the regulatory requirements for their innovation. Startups need an early understanding of the regulatory requirement in order to incorporate this into product development decision. With the new EU medical device regulations coming into force in May 2020, it becomes more and more challenging for companies to comply with regulatory requirements. Understanding the regulatory framework for your innovation can appear overwhelming, but an early regulatory roadmap giving you a basic regulatory strategy will give you the head start that you need.

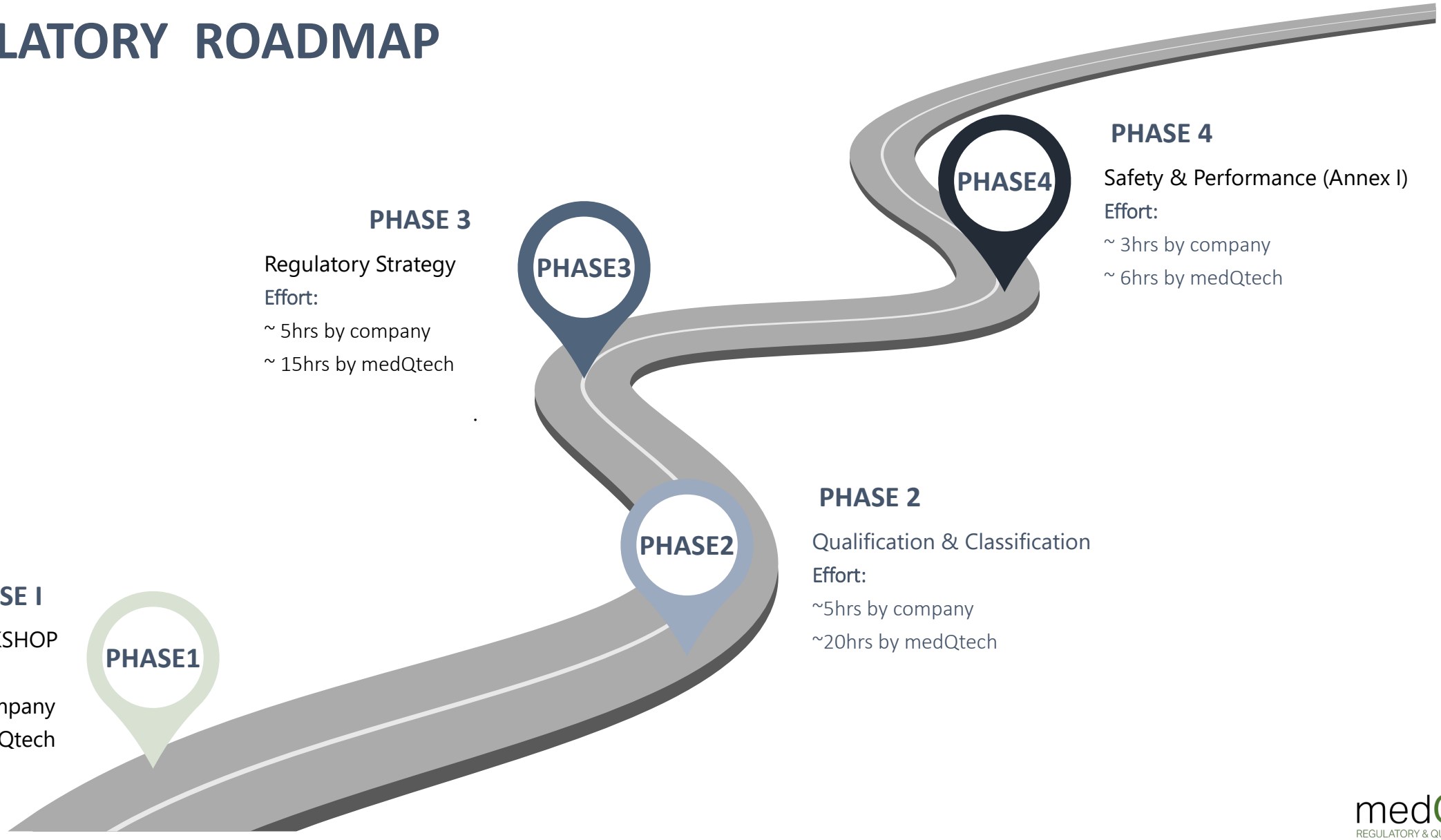
We don't want regulatory challenges to stand in the way of your great innovation. We want to ensure that you have the ability to assess the market opportunity for your innovation and a fundamental understanding of your regulatory obligations.

This service package offers access to regulatory experts with extensive experience in developing regulatory strategies for healthcare companies. A structured approach will help you design and execute your market approval so that you can be confident that your innovation can be introduced to new markets.

This package will ensure that you get critical insight that will allow you to understand the regulatory requirements in order to kickstart your market approval process

medQtech
REGULATORY & QUALITY COMPLIANCE

REGULATORY ROADMAP



PHASE I

INITIAL WORKSHOP

Effort:

~10hrs by company

~5hrs by medQtech

PHASE 2

Qualification & Classification

Effort:

~5hrs by company

~20hrs by medQtech

PHASE 3

Regulatory Strategy

Effort:

~ 5hrs by company

~ 15hrs by medQtech

PHASE 4

Safety & Performance (Annex I)

Effort:

~ 3hrs by company

~ 6hrs by medQtech

medQtech
REGULATORY & QUALITY COMPLIANCE

PHASE 1: Initial Workshop

This first phase consists of a 2-2 ½ hr workshop between the company and MedQtech to define an initial overview of the “Product Description” and “Intended Purpose (Intended Use) for the Device.

The company will be expected to share any relevant background information about their technology and market understanding prior to the workshop.

During the workshop it is expected that the company will present their product, technology and research objectives, key milestones and delivery dates that need to be met. They should also have a first proposal of a Product Description. MedQtech will facilitate a discussion the regulatory aspect of a Medical Device and present an overview of the roadmap to reach regulatory compliance.

At the conclusion of this phase the Company may identify the Overview of Product Description and Intended Use. The outcome of this phase shall be used in the next phase.

Effort:
~10hrs by company (including pre-after work in regards to the topic for workshop)
~5hrs by medQtech

PHASE 2: Qualification & Classification

This second phase consists of a 2-2 ½ hr workshop between the company and MedQtech to define a proposal of the Qualification & Classification of the device according to applicable regulations.

Based on the outcome of phase 2, MedQtech will conduct an initial qualification and classification of the device. MedQtech will prepare documentation relevant to the device's classification.

During the workshop MedQtech will present the outcome of the qualification and classification of the company's device based on the regulations (MDR 2017/745, IVDR 2017/746 and for Software MDGS 2019-11). MedQtech will facilitate and discuss the different classification rules that apply for the company´s device and discuss whether a rule is applicable or not.

At the conclusion of this phase the company will understand which class the device belongs to, the applicable rules and rationale for why that specific rule applies to the device.

Effort:
~5hrs by company (including pre-after work in regards to the topic for workshop)
~20hrs by medQtech

PHASE 3: Regulatory Strategy

This third phase consists of a 2-2 ½ hr workshop between the company and MedQtech to define a regulatory strategy for the device based on the device qualification and classification

Based on the outcome of phase 2, MedQtech will review applicable harmonized standards and guidelines that may be applicable for the device, including defining a proposal of applicable conformity route for the device to be CE-marked in EU according to MDR or IVDR.

During the workshop MedQtech will present the outcome of regulatory strategy and provide a road map of the conformity route that is applicable for the device based on regulations (MDR 2017/745, IVDR 2017/746, MDGS 2019-11). MedQtech will facilitate and discuss the conformity route and give an overview of the requirement of the regulations.

At the conclusion of this phase is the company will have a regulatory strategy document based on the outcome of the device class, that includes applicable harmonized standards and guidelines, plus any other applicable regulations.

Effort:
~ 5hrs by company (including pre-after work in regard to the topic for workshop)
~ 15hrs by medQtech

PHASE 4: General safety & Performance Requirements

This fourth phase consists of a 2-2 ½ hr workshop between the company and MedQtech to review ANNEX I and define what General safety & Performance Requirements are applicable for the device.

The purpose is also for the company to gain knowledge in the regulatory requirements and the documentation evidence that is required by reviewing the General safety & Performance Requirements.

At the conclusion of this phase the company will have started the process to show compliance to the regulations. The Safety and Performance characteristics checklist is a significant document in the Technical documentation of a device to demonstration compliance to regulations (MDR/IVDR).

Effort:
~3hrs by company (including pre-after work in regard to the topic for workshop)
~6hrs by medQtech

REGULATORY ROADMAP

DOCUMENT OUTCOME & EFFORT

PHASE 1

PRODUCT DESCRIPTION

INTENDED PURPOSE

PHASE 2

QUALITIFICATION & CLASSIFICATION

PHASE 3

REGULATORY STRATEGY.

PHASE 4

General safety & Performance Requirements Checklist

CONCLUSION

Total Effort:
~23hrs by company
~46hrs by medQtech

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REGULATORY & QUALITY COMPLIANCE

Want to learn more?

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