Environment for Medical Devices in Rehabilitation
- An Industrial Perspective -

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Abstract

This presentation will start by short introduction of Össur company. Then the challenges to get a new device through the regulatory framework will be discussed and advices given on how to approach that work. Finally some areas of potential advances will be mentioned.

The presentation has the main aim of introducing the regulatory environment that medical device producers face with emphasis on the situation in Europe and will therefore not be technical.

Recommended references with the talk

The following sites (and many more) contain regulatory information and other useful information regarding how to get a medical device to the market.

www.europe.eu.int

www.meddev.info

www.mhra.gov.uk

www.fda.gov