Scientific/Clinical Workshop

Workshop Title

Soft-Robotic Glove: From Development to Market Uptake in Context of Medical Device Regulation

Workshop Responsible

Gerdienke Prange (Roessingh Research and Development, Enschede, the Netherlands)

Speakers

Hans Rietman, Anke Kottink, Annika Rydgard, Gerdienke Prange

Attendee Engagement

To stimulate interaction with and among the audience in the workshop, a common understanding and language is established by first informing the audience about the legislative context from the perspective of both the developers and users (clinicians, clinical researchers, patients, etc.). In addition, practical information on how to identify legislation and standards relevant for your medical device using the COVR toolkit is shared and discussed in an interactive discussion with the attendees. By taking a concrete example, the soft-robotic glove, to illustrate what is needed for uptake of rehab robots, we will kickstart discussion with and among the audience. This will be supported by specific questions directed towards the audience to leverage their input, by voting on statements and multiple-choice questions (using online voting app) as well as posing open questions to share experiences and solutions. This will be done during the presentations and at the final interactive discussion. The questions will address ideas and inspiration for how to deal with practical challenges when bringing rehab robots to the market and implementing them.

Abstract

Promoting the development and eventual uptake of rehabilitation robots means that developers have to handle specific requirements across different levels. Besides meeting the needs of its end-users, addressing practical applicability in daily life, and demonstrating effectiveness, legislation sets increasingly explicit conditions on the technology and its development process, revolving around safety. Creating a common understanding between developers (engineers) and users (healthcare professionals, clinical researchers) about the requirements for development of safe medical devices facilitates multi-disciplinary collaboration towards implementation and uptake of rehabilitation robots.

The following steps on the road to market of a rehabilitation robot will be illustrated by an example case, a soft-robotic glove supporting grip strength. Its journey through iterative testing with users in lab and clinical studies will be described from the clinical research perspective, assessing the effect of soft-robotic glove support on hand function. During these studies, a new application of the soft-robotic glove emerged [1]. A subsequent multi-center clinical trial is investigating whether assistive use of the soft-robotic glove is effective to improve hand function, as input for a potential new medical claim outside of its intended use.

This example will then be used to frame the subsequent steps for CE certification and market introduction from the manufacturer perspective. Challenges and lessons learned will be addressed (e.g. quality management process, reimbursement) and discussed with the audience, to compare

potential solutions for barriers encountered when introducing and/or sustaining rehabilitation robots on the market.

The overall aim of the workshop is to create a common understanding of the steps needed for rehab robots to achieve market readiness and list challenges matched with solutions for rehab robot uptake.