

Medical and Health Technology Development Support

Medical Device Regulatory Affairs Human Resources **Development Corporation**

Health Tech Co-Creation Foundation



Foundation philosophy

We will contribute to the advancement of medical technology by promoting collaborative development of medical devices, such as industry-academia collaboration, medicalengineering collaboration, and IT collaboration. We will also train personnel who will take on the role of pharmaceutical specialists in order to ensure the early development and commercialization of medical devices

Business Details

(1) Coordination of Foreign Medical Devices entering the Japanese market, including manufacturing, sales, or both

(2) Human resource development project for medical device regulatory development

- Operation of the "Pharmaceutical Affairs School" training course for new regulatory affairs personnel
- "Medical Device Regulatory Affairs Coordinator" training project

Commonly known as the M-RAC (Medical Regulatory Affairs Coordinator) certification system (3) Medical device co-development support project (industry-academia collaboration, medical-engineering collaboration, IT collaboration)

Corporate Overview

♦ Corporate Name: Health Tech Co-Creation Foundation

○Representative Director: Hideki Fujitsuka (CEO, Expartner Japan Co., Ltd.)

Director: Shinya Miike (CEO, Neuroceuticals Co., Ltd.)

Yoko Ide (Career Consultant)

○URL: www.htcf.or.jp



Representative Director Hideki Fujitsuka

We run a training program for medical device regulatory professionals called the "Regulatory Affairs School."

Now in its 21st year, the program has trained about 2,900 participants from more than 1,500 companies.

The school aims to quickly and effectively develop skilled regulatory staff and help companies strengthen their regulatory capabilities. Participants now include not only regulatory teams but also members from development and quality assurance.

The program is useful both for beginners and for those with experience who want to update their knowledge.

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