

Many staffs here have specialized knowledge related to medical device development.

We support the use of simulators at seminars and trainings for healthcare and clinical professionals.

















animal treatment with an emphasis



As specialists of medical devices and surgical practices, we confirm safety and fficacy of testing.

products to electromagnetic noise release and electromagnetic

We perform tests to confirm that no





→ Facilities

Various non-clinical tests designed for product development can be performed.

Biological safety testing





Complex vibration test

equipment



Water-proof test

Angio-hybrid



MRI (1.5T)

Constant-temperature,





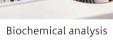


Pathological examination











Inductively coupled and humidity chamber plasma mass spectrometer



EMC test (10 m method radio wave darkroom)

Many patient model dum-

Improving skills of novice

nurses and carrying out

case studies that simulate

actual medical settings

mies and simulators





Conference room

Large conference room : 100-person capacity Small conference room 1:80-person capacity Small conference room 2:70-person capacity

- The capacities are for theater style rooms. Each conference room can be connected by removing the partitions.
- Small conference room 1 can be used as a model of a patient room (medical gas, suction equipment attached)
- The capacities are standard amounts.Please feel free to contact us for details.



Simulators

Fukushima Prefecture is one of Japan's top prefectures for medical device production

The shipment value of medical device parts shipment value is 28.0 billion yen. No.

201.3 billion No.3 in Japan

Production of medical machines



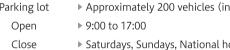




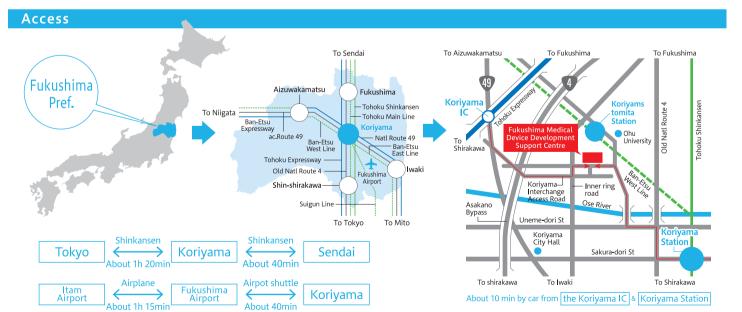
Facility overview

and devices

Established by ▶ Fukushima Prefecture Designated manager Fukushima Medical Device Industry Promotion Agency Total floor area Facility structure ▶ 2 stories (partly 3 stories), partly earthquake-proof ▶ Approximately 200 vehicles (including large sized buses)







Contact Information



Medical Device Development Support Centre

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Fukushima Medical Device Development Support Centre



Beyond regions, connected in Fukushima





Matching

Human resource development/training

We provide support focusing on 4 functions essential to

medical device development.

Medical devices are Cardiac pace To save people's lives.

Cardiac pace

Oximeter

Heart-lung machi

Medical device development progressing

Create new business by matching across disciplines

The Council for Fukushima Medical & **Nelfare Device Industry**

We vitalize planning and interactions and develop human resources for business expansion and enhancement of technology bases help companies enter the medical welfare device industry field. Fukushima Medical Device Development Support Centre





Launching safe medical devices **Safety Evaluation**

High-reliability facility that has obtained certifications to international standards, ISO/IEC17025 and medical devices GLP

Prevent effects on human body

Biological safety testing

We evaluate the safety and efficacy of prototypes of medical devices used directly for human bodies using large animals. Since we have obtained the certification of Medical Device GLP test data can be used for applications of medical devices in foreign countries. We are also fully accredited from AAALAC International regard-





Does it Meet strict standards? Is it durable enough? Electrical, physical, analysis safety testing Withstand voltage testing, leakage current testing, and EMC testing

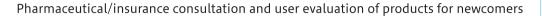
checks electrical safety, effects of interference by electromagnetic waves, etc. This facility is one of the few facilities that have a radio wave darkroom with X-ray shielding function. Physical property testing including waterproof testing and drop testing measure durability and strength against impacts under various usage environ-

ments, storage methods, and transportation conditions. Chemical analysis detects substances that are harmful to human bodies.

bridges for industry - government - academia, and medical-engineering collaboration.

Acquiring information required for medical device development





Professional support tailored to the development phase and the entry type

Integrated support

•How to enter the medical device industry
•How to proceed with acquiring marketing authorization, registering as a manufacturer, and obtaining ISO13485 certification
•How to understand the Pharmaceutical and Medical Device Act, QMS Ordinance, etc.



als, experts, medical device manufacturers, etc.

viability of the medical device under development, we provide opportunities to exchange opinions with healthcare profession-



Design/development, safety evaluation consulting

xperts and examining body workers provide advices and instructions for procedures of risk management and safety testing of medical devices which are under development.





Laws/specification adoption consulting

Regarding medical devices which will apply for approval, consultants and experts provide advice for procedures and methods of application, and how to correspond to international standards.



We provide advice on collaboration business and public relations regarding participation in exhibitions and academic meetings, market expansion,

and overseas operations



from development to commercialization of medical devices Connecting people involved in medical device development

Matching Support for developments and commercialization through events that act as linking

Function as a bridge for medical device manufacturers,

manufacturing companies, and healthcare professionals

Medical Creation Fukushima

We display exhibitions of technologies that the manufacturing industry excels at, the latest medical devices from medical device manufacturers at the same time, and plan and hold seminars with themes of the latest topics, state-of-the-art technologies, and human resource development in the medical device industry.







Nurturing people who use and manufacture medical devices

Human resource development, training

A wide range of training under environments that fits clinical settings for human resources contributing to medical care are available.







Other seminars useful for medical device development, including pharmaceutica affairs and quality control



