

Fukushima Medical Device Development Support Centre

Safety evaluation

Consulting

Matching

Human resource development/training

We provide support focusing on **4 functions** essential to medical device development.

Past

Cardiac pacemaker



Oximeter

Heart-lung machine

Photos courtesy :
Inzai City Inba
Medical Instrumental
History Museum

**Medical devices are
To save people's lives.**

**Medical device
development progressing
day by day.**

Now

Oximeter

Cardiac pacemaker

Heart-lung machine



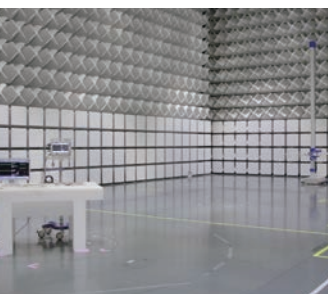
Launching safe medical devices Safety Evaluation

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 regarding animal welfare.



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



Connecting people involved in medical device development Matching

Support for developments and commercialization through events that act as linking bridges for industry - government - academia, and medical-engineering collaboration.

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.



Create new business by matching across disciplines

The Council for Fukushima Medical & Welfare Device Industry

We vitalize planning and interactions and develop human resources for business expansion and enhancement of technology bases to help companies enter the medical welfare device industry field.

Fukushima Medical Device Development Support Centre



Acquiring information required for medical device development Consulting



Pharmaceutical/insurance consultation and user evaluation of products for newcomers

Professional support tailored to the development phase and the entry type

Consultation items

- 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.

SUPPORT 01

Judge of market and needs

Regarding the marketability and viability of the medical device under development, we provide opportunities to exchange opinions with healthcare professionals, experts, medical device manufacturers, etc.



SUPPORT 02

Design/development, safety evaluation consulting

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



SUPPORT 03

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.



SUPPORT 04

Other

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



Integrated support
from development
to commercialization
of medical devices

①Market research/design and development
②Validation/evaluation
③Production/distribution
④Proper use/training

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.

Training for healthcare professionals



Hands-on seminars for junior doctors



Training for novice nurses

Events for companies



Seminars on new entry to the medical field
Other seminars useful for medical device development, including pharmaceutical affairs and quality control

Events for general public and students



Events in which people from children to adults can experience medical work

