Biomedical Engineering

The most advanced technologies in the service of health

ISIFC Génie Biomédical — UFC Université de Franche-Comté

What is Biomedical Engineering ?

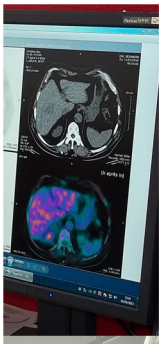
Biomedical Engineering is the art of applying the most advanced sciences and technologies for conception of diagnostic equipment or tools of treatment for assistance (called **Medical Devices***) and for developing of information systems. The aim is to improve the quality of care for patients and to develop safe and practical solutions to medical problems.

The field of activities of biomedical engineering is very large: concept of devices (scanner, prostheses, dressings ...), validation of a device before its introduction to the market, assistance to medical staff, and participation in clinical research. ISIFC biomedical engineers work in companies of medical devices or of software for health or in hospitals and care facilities.

The ISIFC training in biomedical engineering is necessarily multidisciplinary. It is based on three cultures: technical (mathematics, physics, chemistry, information technology and communication ...), medical (biology, medicine ...) and regulatory.

The biomedical sector is experiencing a significant growth internationally both economically (increasing and aging of population) and in terms of research (new developments of coupling mechanical device - drug).

*** Medical devices** : instrument, apparatus, appliance, material, product, except for the products of human origin, or other article, whether used alone or in association, including accessories or software for its functioning, intended by the manufacturer to be used in humans for medical purpose and whose principal intended action is not achieved by pharmacological or immunological means or by metabolism, but whose function may be assisted by such means.



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The main disciplines of Biomedical Engineering at ISIFC

Biomedical instrumentation and implants

It is the application of technics and measurement principles to development of medical devices. The spectrum of applications is very large between device employed in a single-use instrument and the design of a complex medical system as for example the artificial heart (Carmat, France).

Regulatory affairs and quality systems

The main targeted skills are the knowledge and the mastery of quality systems and of technical and regulatory aspects of medical devices and all the process of the accreditation in order to access a specific market.

Biomechanics and microsystems

It is mechanics applied to living (blood circulation or respiratory system, body movements ...). It allows the design of implants (stents, pins, protheses, ...) or handicap assistance devices. The development of micro-technologies led to the design of micro devices from the molecular or cellular level to organ level (micro-needle, active micro capsule for exploration of the gastro-intestinal wall...).

Bioengineering

This is the part of biomedical engineering dedicated to health biotech with recent innovative developments in products of biotherapy or in cellular and tissular engineering. This domain is booming because it links more and more implants and drugs.

Communication systems and e-health

This is a rapidly developing field for our societies which increasingly integrate digital technology in their daily lives. If the first remote monitoring of patients has been successful, they generate many questions. What practices for e-health ? How to coordinate the actors of this e-health? How can physicians, surgeons, pharmacists, biologists, manufacturers, patients and payers work together?

Clinical investigations

Any biomedical device should be subject to clinical evaluation adapted to the expectation of the institutions which are invited to give an authorization for an access to the market. The quality of the proposed clinical protocol and clinical trials should allow collecting usable clinical data from the first patients.

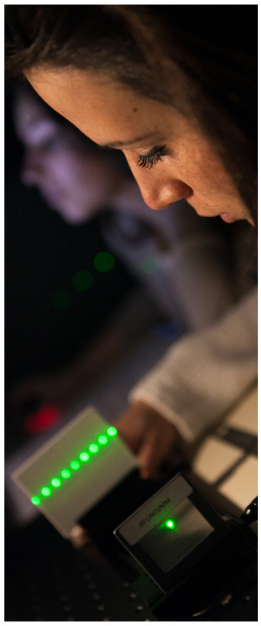
Medical imaging

This methodology includes means for acquiring and restoring images of the human body from various physical phenomena such as X-ray absorption, magnetic resonance, ultrasound reflection, radioactivity and techniques of optical imaging such as endoscopy.

Functions and activities of an ISIFC biomedical engineer

A job with a high expanding

Biomedical engineer often needs to work with experts in other fields (biologists, surgeons, technical specialists …)



Project manager, studies-research-design engineer

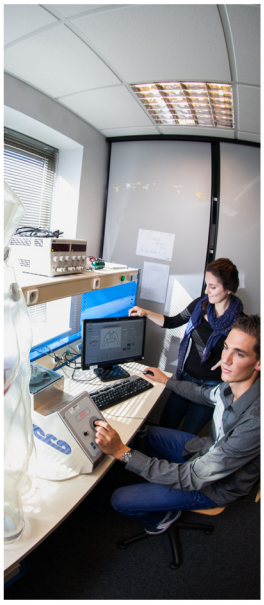
He develops medical devices taking into account first the assessed needs with international marketing and then regulatory constraints. This feature requires a good overview of the situation of the new device.

Engineer of validation, quality, methods, processes and regulatory affairs

For each medical device, he elaborates and leads the technical file for getting the authorization of market access. He supervises and controls the quality of processes and products. He ensures regulatory compliance and prepares submissions.
Regulatory affairs engineer's role is very large : it begins in the R&D with clinical trials and extends to approvals of premarket, to manufacturing, labeling, advertising, post market surveillance ...

Application engineer

He provides technical advice to the hospital engineers and he ensures the training to the users (doctors, medical staff) during the commissioning of the equipment. His presence is especially important when this equipment is sophisticated. He is a technical support for marketing, sales, design and development activities. He collaborates directly with customers.



Clinical engineer

Very close to medical teams, he participates in clinical research projects or in clinical validation projects. After the technical validation (all laboratory tests demonstrating the reliability and the specificity of the device), a clinical validation implements a scientific study in hospital to assess the efficacy and safety of the device and establish its clinical utility. Clinical affairs engineers are also considered as regulatory professionals.

Biomedical engineer in hospital

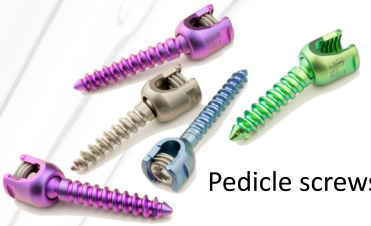
He manages all medical equipment, advices on their selection and use. With a team of technicians under his command, he oversees maintenance and replacement.

Health information systems engineer

In software publishing companies for health, he provides design, development and integration of applications. In institutions managing health, he carries assistance to project management of medical information systems (functional and technical expertise) and he may also be responsible and coordinator of health information systems (networks of care).

Examples of medical devices

Knee prosthesis



Pedicle screws

Endoscopic camera

Dental drill

Hip prothesis