T3.3.Research regarding non-allergic materials and comfortability close to the skin.
Investigation of possible materials that correspond to FDA requirements to avoid skin irritation. Comfortability tests of materials on skin on test persons. Consultation of the academic hospital Sahlgrenska hospital in Gothenburg, Sweden.

Conclusions on how we will approach the FDA certifications regarding CapMouse

The U.S Food and Drug Administration (FDA) do not approve materials for use in medical devices nor does it keep a list of materials used to manufacture medical devices. That's because the appropriateness of a material depends on the application. They approve devices, not materials.

If the device is considered a Medical Device or a Radiation-Emitting Product it has to go through a procedure to be approved by the CDRH, The Center for Devices and Radiological Health, which is a branch of the FDA responsible for the premarket approval of all medical devices. CDRH also oversees the safety performance of non-medical devices which emit certain types of electromagnetic radiation.

In the configuration CapMouse will appear for the PRO users, we don't think CapMouse need to go through FDA for approval, since it is neither a medical device nor a radiation-emitting product. Although it will need to be registered with the FDA

For the HMC user, CapMouse could have Bluetooth- or other wireless connection, and in that case it might need to go through FDA for approval as a radiation-emitting product. But probably not as a medical device.

CapMouse can be considered a medical device in other configurations and applications, and then fit in to the definition of a medical device, but not within the objectives of the AAL project.

When choosing materials for production, we will specify to the material supplier that we want non allergenic materials and materials that correspond to the requirements for different certifications.

If CapMouse not goes under the definition of a Medical Device or a Radiation-Emitting Product, it does not have to go through the FDA for any certification.

Allergies and materials

Contact allergy is an allergy caused by direct contact with an allergenic substance. The allergens that trigger symptoms are often simple chemicals. Approximately 700 substances have been classified as a skin sensitizer. Materials are classified as allergenic if they contain at least 1 percent of allergy-causing substance.

In complex materials such as plastic, the basic polymer can be the same but different additives are used, some of which may be allergenic, some are not.

Allergenic metals to avoid are for example nickel, gold, chromium and cobalt. Also rubber chemicals, epoxy and other thermosetting resins, polyester and uncured plastics can be allergenic.
Titanium and materials without nickel, such as stainless steel, is non allergenic.

FDA Quality System Regulation

If a product is considered as a Medical Device or a Radiation-Emitting Product it needs to go through a procedure to be approved for marketing in the US.

CDRH's definition of a medical device includes products from the simple toothbrush to complex devices such as pacemakers. Before a medical device can be marketed in the USA a marketing application must be submitted to the FDA and clearance obtained. There are three regulatory classes for medical devices, which are based on the degree of control necessary to assure the various types of device are safe and effective.

If CapMouse would be considered as a Medical Device, in the case of the PRO user, it will probably fall into Class 1. Class 1 includes everyday items such as toothbrushes which are unlikely to cause serious consequences if they fail. Manufacturers are required to follow what are called "general controls" which closely match ISO 9000 requirements.

Examples of Class 2 devices include powered wheelchairs and some pregnancy test kits. CapMouse might fall in to this classification when targeted to the HMC user.

Class 3 devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. This class is estimated to be excluded for CapMouse. In the case of controlling a Permobil with a CapMouse it could be considered to fall into this class, but this case is not an objective for the AAL project.

Most Class 1 devices and a few Class 2 devices are excluded from the requirement for submission of a marketing application. However, these devices are not exempt from other general controls. All medical devices must be manufactured under a quality assurance program, be suitable for the intended use, be adequately packaged and properly labeled, and have establishment registration and device listing forms on file with the FDA.

We have had correspondence with Connie Daly from CDRH regarding the FDA regulations. She says:

"There is no such thing as a list of approved medical materials. CDRH does not approve materials for use in medical devices nor does it keep a list of materials used to manufacture medical devices. That's because the appropriateness of a material depends on the application. For example, stainless steel is OK for fracture fixation plates, but would not be OK for your decubitus ulcer mattress. CDRH approves devices, not materials.

It is up to the manufacturer to determine the appropriate materials used to do appropriate Biocompatibility testing. The biological testing requirements also depend on the application. The firm needs to conduct biocompatibility testing in accordance with the specific intended use of the device."