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Animal Testing Program

Quality for life

1. Overview

Ottobock recognizes the importance of high-quality animal care and welfare. To minimize the potential harm to animals and the environment, Ottobock has a clear program in place and is committed to ensuring the quality and safety of its products worldwide without conducting animal testing. In rare cases, however, animal testing is still required by law as part of the registration process of medical devices. The standard ISO 10993-1 norm necessitates a biological evaluation of medical devices that is based upon in-vitro and ex-vivo test methods and upon animal models.

2. Initiatives to replace Animal Testing

Ottobock requires that all studies within the company and its subsidiaries that are designed to assess the safety of a medical product in non-clinical models, such as biocompatibility studies for medical devices, need to be conducted according to the following guidelines:

1. Animal testing is not permitted in the company unless specifically required by law.
2. If animal testing is required by law, the research studies must minimize and optimize the number of tested animals as well as evolve the procedures to suppress or reduce the suffering and discomfort of animals.
3. For each study and medical registration process, it is mandatory to check whether animal testing is still required by law and whether alternative testing methods have been approved. All animal tests should be replaced within six months of an alternative testing method being legally permitted.
4. In-vitro or similar testing methods must be used whenever possible to replace the required biocompatibility testing practices that involve animal models.
5. Ottobock is committed to actively engaging with industry associations and regulators to convince the authorities to abandon animal testing and allow alternative testing options that verify biocompatibility.

3. Reporting on Animal Testing

Animal Testing, from project submission to study conduct, must be documented and archived. The appointed Study Director needs to have comprehensive knowledge about the test items and be aware of all events that may affect the quality or integrity of the testing. The study results must be analyzed and reported by the Study Director. In addition to the outcomes, any confounding or contributing factors that could result in misinterpretation of study results must also be explained in the test report. Based on the test reports, regular audits have to be carried out to ensure that the test series are carried out in a way that respects high-quality animal care and welfare.

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4. Accountability

Ottobock has anchored responsibilities for animal testing issues at the highest board level. At Ottobock, direct accountability for the animal testing program lies with the Chief Technology Officer. All animal testing activities must be reported to him. The management and all executives are responsible to act in accordance with this program. They guide all employees as a role model and through their behavior.

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