Joint Expertise on Biological Evaluation of Medical Devices

SENZA GEN

VitroScreen

SenzaGen and VitroScreen guide you through the comprehensive process of biological evaluation of medical devices:

Product identification
In vitro approaches to demonstrate the mechanism of action by using 3D reconstructed human tissues.

Substance-based medical devices classification
In vitro penetration, distribution and absorption studies to comply with MDR and Rule 21.

Risk identification
GAP analysis and Biological Evaluation Plan (BEP).

Risk mitigation
In vitro biocompatibility testing according to ISO 10993-1 and permeation, distribution and absorption studies according to OECD TG 428.

Evaluation of results
Biological Evaluation Report (BER), including toxicological risk assessment, safety margins calculation and biological testing interpretation.

SERVICES SUMMARY

***In vitro* biocompatibility testing**
Our GLP-certified laboratories provide *in vitro* biocompatibility testing addressing the three endpoints that all medical devices are subjected to assess: cytotoxicity ISO 10993-5, irritation on skin and other epithelia according to ISO 10993-23, and skin sensitization according to ISO 10993-10 with GARD®.

Mechanism of action on 3D reconstructed human tissues
In vitro testing protocols on 3D reconstructed human tissues and pharmacological expert reports are provided to confirm that the medical device acts at the superficial level and the principal mechanism of action is physical, mechanical, or chemical and not linked to pharmacological, immunological, or metabolic effects.

***In vitro* penetration, distribution and absorption**
Protocols for penetration and absorption studies are established according to medical device class and type, formulation and intended use, and performed to quantify selected ingredients' penetration, absorption and local distribution. This data is used to support classification/re-classification of existing devices according to the MDR and the classification of new products that are applied to the skin, introduced into the body via body orifices, or with intended purpose in the stomach or lower gastrointestinal tract.

Tailored consultancy services
The *in vitro* testing and pharmaco-toxicological consultancy services provide expert advice during product development and/or to respond to regulatory requirements: for product identification as medical devices and medical device classification, risk identification, risk mitigation by *in vitro* testing and evaluation of results in the Biological Evaluation Report (BER).