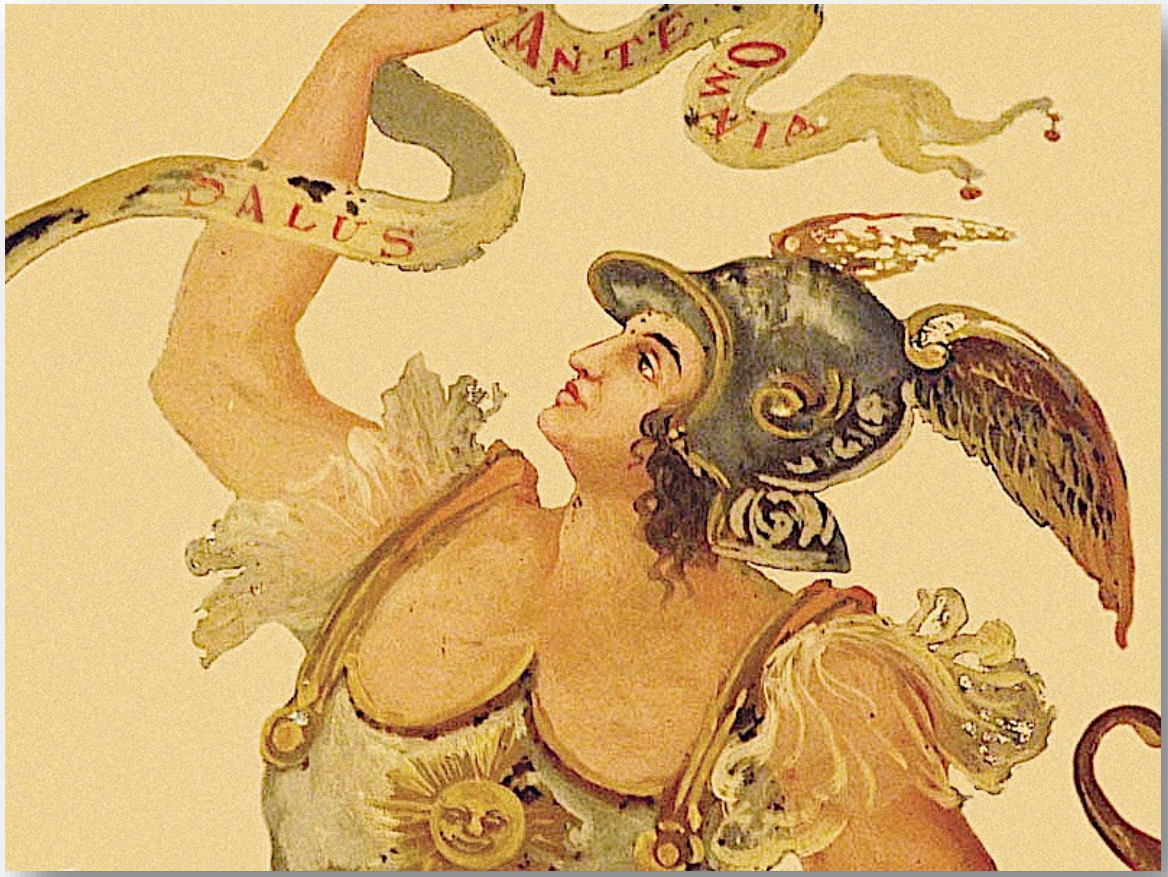
In Vitro Consultancy Unit



Salus Ante Omnia
Farmacia Meloni, 1907

VitroScreen
Leading Innovation in Pre-Clinical Testing

In Vitro Consultancy Unit

Consistently with the new safety requirements introduced in many Regulations, an expert and deeper knowledge of the applicability domain of *in vitro* testing approaches is today highly recommended.

VitroScreen is proud to announce the establishment of the ***In vitro* Consultancy Unit** with the mission of providing its Customers with high level *In Vitro* Testing Strategies for Hazard and Risk Assessment, coupled with an independent pharmaco-toxicological expert judgment.

The Consultancy Unit's deliverables focus on a more accurate, more ethical approach and supports Customers in high level strategies related to regulatory in vitro toxicology for a sustainable classification of chemicals (including mixtures and polymers), pesticides, agrochemicals, new secondary raw materials and in the safety assessment of pharmaceuticals, medical devices and cosmetics.

The Consultancy Unit supports the Medical Devices industries facing the new MDR's requirements, in particular to comply with Rule 21. It also avails a collaboration with **SenzaGen**, to address skin and respiratory sensitization potential by the high predictive and accurate GARD® technology.

Through these partnerships, VitroScreen aims to further contribute to a sustainable and ethical development of pre-clinical testing, based on human relevant data and mechanistic high content information.

To be compliant with MDR 2017/745

- Biological Evaluation Plan and Design input within a risk management process in accordance with ISO 14971:2007 and Gap analysis to ISO standards.
- MD Raw Materials toxicological characterization and safety assessment according to EN ISO 10993-1:2018 and following the process of an in-depth literature review as indicated in Annex C.
- Risk assessment on absorption, penetration and local distribution of devices composed of substances or of combinations of substances, that are intended to be introduced into the human body via a body's orifice or applied to the skin as required by Rule 21 of MDR 2017/745.
- Toxicological expertise on the results of *in vitro* percutaneous absorption studies (OECD TG 428 and EFSA 2017 guidelines). Assessment of systemic exposure for the identified use and calculation of safety margins.
- Toxicological risk assessment of residual impurities from the manufacturing process (ISO 10993-18), products' degradation (ISO 10993-13/14/15) and substances extracted and/or released by the primary packaging in the MD (ISO 10993-17) including polymers (plastic/silicon), solvents, elemental and genotoxic impurities and definition of their safety limits.
- Biocompatibility Test Plan strategy development following 3R principles thus avoiding animal testing using Alternatives, and *in silico* prediction.
- Interpretation of the results obtained in the biocompatibility and the overall biological safety in accordance with EN ISO 10993-1:2009 and the subsequent amendments.

VitroScreen and SenzaGen Partnership

Since December 2019, VitroScreen is a non-exclusive distributor of SenzaGen's GARD test platform which includes highly versatile genomic-based *in vitro* tests:

- **GARD®skin**
- **GARD®potency**
- **GARD®skin Medical Device** (on extracts)
- **GARD®skin Dose-Responce**
- **GARD®air**

GARD® test methods are recognized for accuracy, high sensitivity and specificity to support:

- product development
- quality control after product/production changes
- REACH registration
- classification into CLP categories
- extrapolation to LLNA EC3 values and/or human potency
- marketing claims

GARD®skin and GARD®potency are under EURL ECVAM validation and included in the OECD Test Guideline Program (TGP 4.106). The results of both tests can already be used in REACH dossiers in a weight of evidence approach to meet data requirements under REACH.

Thanks to the partnership established with SenzaGen, VitroScreen aims to further contribute to a sustainable and ethical development of pre-clinical testing including innovative and robust genomic approaches as GARD®. In particular, the GARD®air is the only *in vitro* test available for the identification of respiratory allergens and can highly support research on environmental toxicology, a definitively hot topic related to urban pollution.

SENZA GEN

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