



F. Medeiros^{1,6,7}, R. Damiani¹, T.C. Feitosa¹, V. Dakic², J.V.M.A. Silva⁵, T.F. Cunha^{1,7}, N. Alépèe³, C. Pellevoisin⁴, L.B. Balottin⁵, R. De Vecchi²

Animal-free safety assessment for children's articles

the first successful implementation of Reconstructed Human Epidermis (RhE) model as an in vitro test for regulatory purposes in Brazil



Company

Biosintesis is a private lab specialized in preclinical studies and supports the R&D and regulatory safety assessment of health and life science products.

In operation since 2008 in Sao Paulo (USP), we are committed to create and implement innovative solutions on Alternative Methods for Animal Science in Brazil: GLP certified test facility (full in vitro) and RENAMA member since 2014.



IN VITRO PROTOCOLS AND BIOLOGICAL MODELS FOR EFFICACY AND SAFETY



TISSUE ENGINEERING



GLP Scope:

Toxicity, Mutagenicity and Cytotoxicity Studies

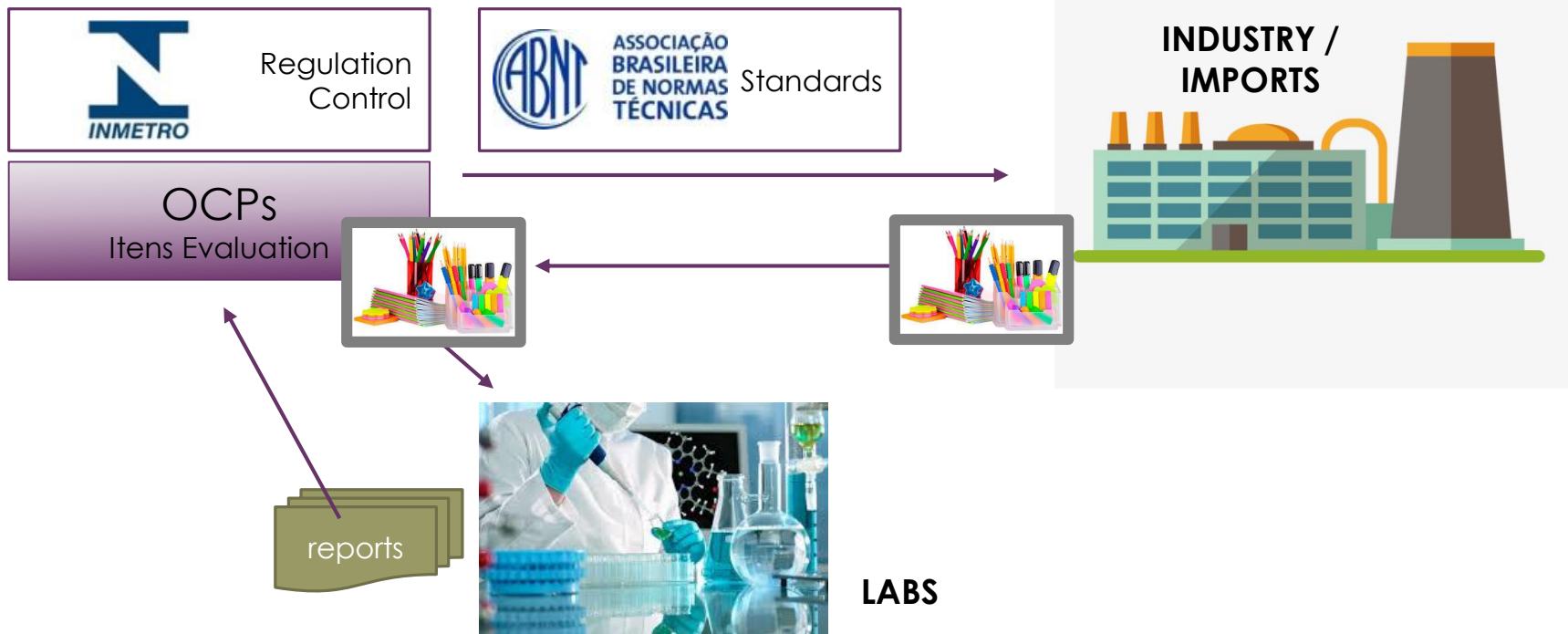
- OECD TG 129 – Acute Toxicity
- OECD TG 431 – Skin corrosion
- OECD TG 439 – Skin Irritation
- OECD TG 487 – Micronucleus Genotoxicity

ISO 10.993 – Biological Evaluation of Medical Devices
ABNT NBR 15.236 - Schools Articles Safety

A young girl with long brown hair, wearing a white shirt and an orange knit vest, is focused on painting. She is using a paintbrush to apply blue and yellow watercolor to a piece of paper. In front of her is a white watercolor palette with various colors like yellow, green, blue, red, and purple. Her hands are stained with paint. The background is softly blurred, showing a wooden table.

LESSONS LEARNED: SAFETY OF CHILDREN ARTICLES

Background



Background for children's articles



Biological safety with *in vivo* assays



Concea resolution for 17 alternative methods

ABNT committee Update with Concea resolution methods

ABNT update: NBR 15236:2016

2012

2013

2014

2015

2016



Background for children's articles



Biological safety with *in vivo* assays



Concea resolution for 17 alternative methods

ABNT committee

Update with Concea resolution methods

ABNT update: NBR 15236:2016

2012

2013

2014

2015

2016



FULL REPLACEMENT



ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS

Schools Articles Safety Brazilian Technical Committee (CEE 102), Brazilian Association of Technical Standards




NORMA BRASILEIRA

ABNT NBR 15236

Segurança de artigos



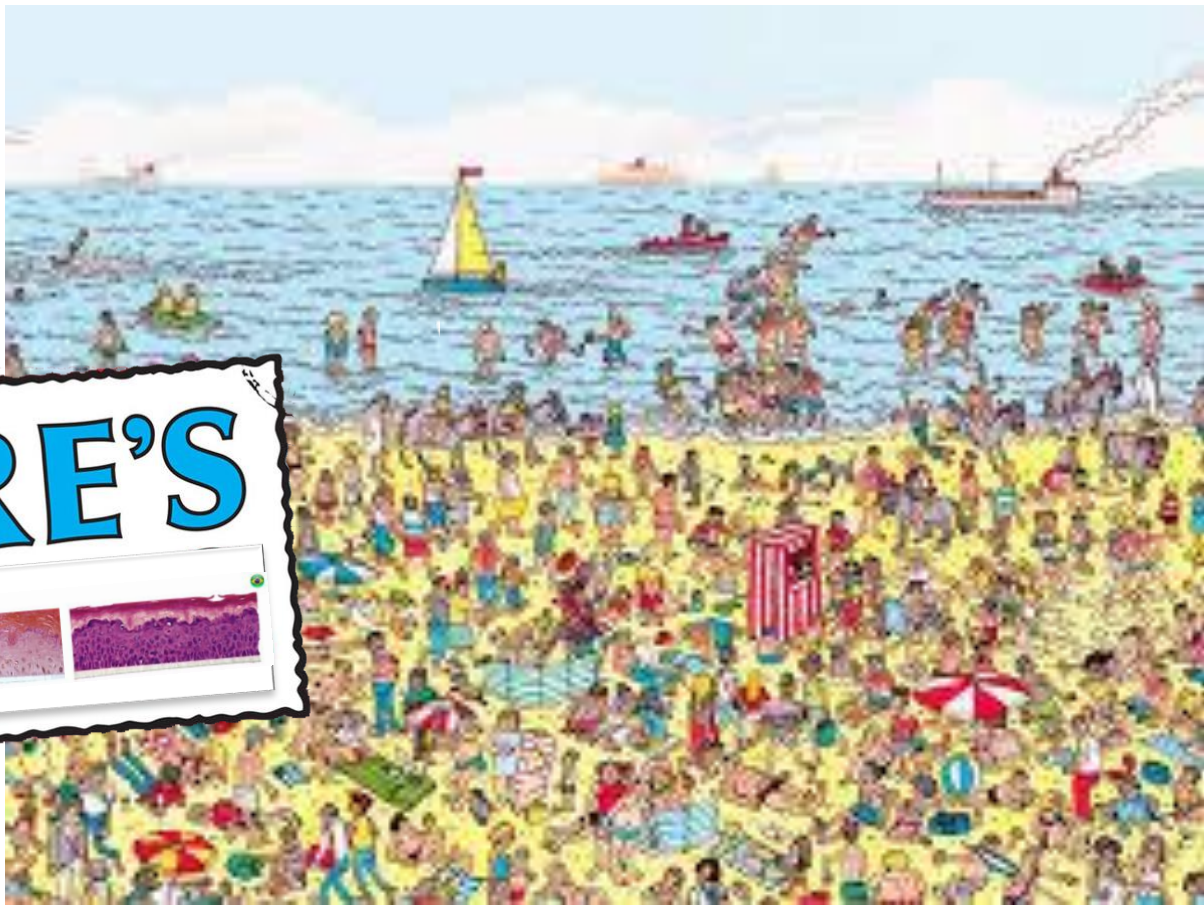
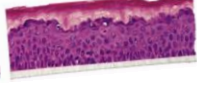
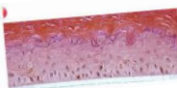

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WHERE'S

RHE ??



1st STEP – FEBRUARY 2017 - RENAMA NETWORK



GLP Test Facility on Research and Innovation of Vitro Methods



National Institute of Metrology, Quality and Technology



Brazilian National Alternative Methods Network

L'ORÉAL EPISKIN

Research & Development



ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS

Schools Articles Safety Brazilian Technical Committee (CEE 102), Brazilian Association of Technical Standards



Biotechnology Department, Nuclear and Energy Research Institute

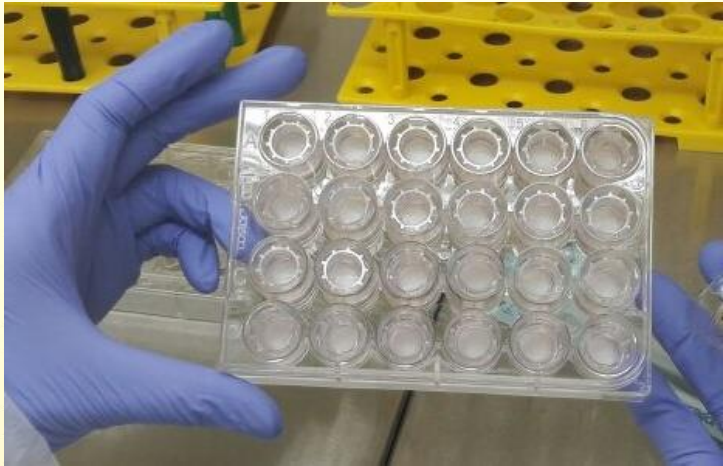


2ND STEP – MARCH – MAY 2017:

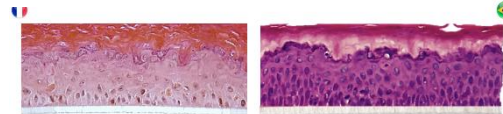
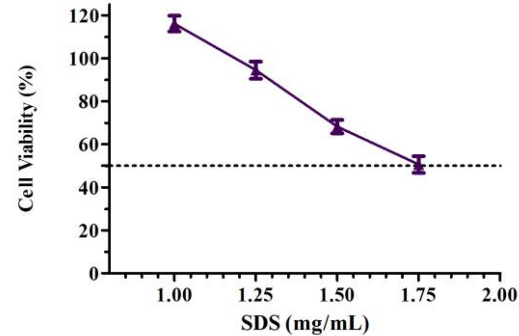
Training and Implementation of SkinEthic™ RHE model

Phases

- 1) Shipped over distance RJ –SP
- 2) Tissues conditions (Receipt)
- 3) RHE model - acceptability range for IC50 SDS

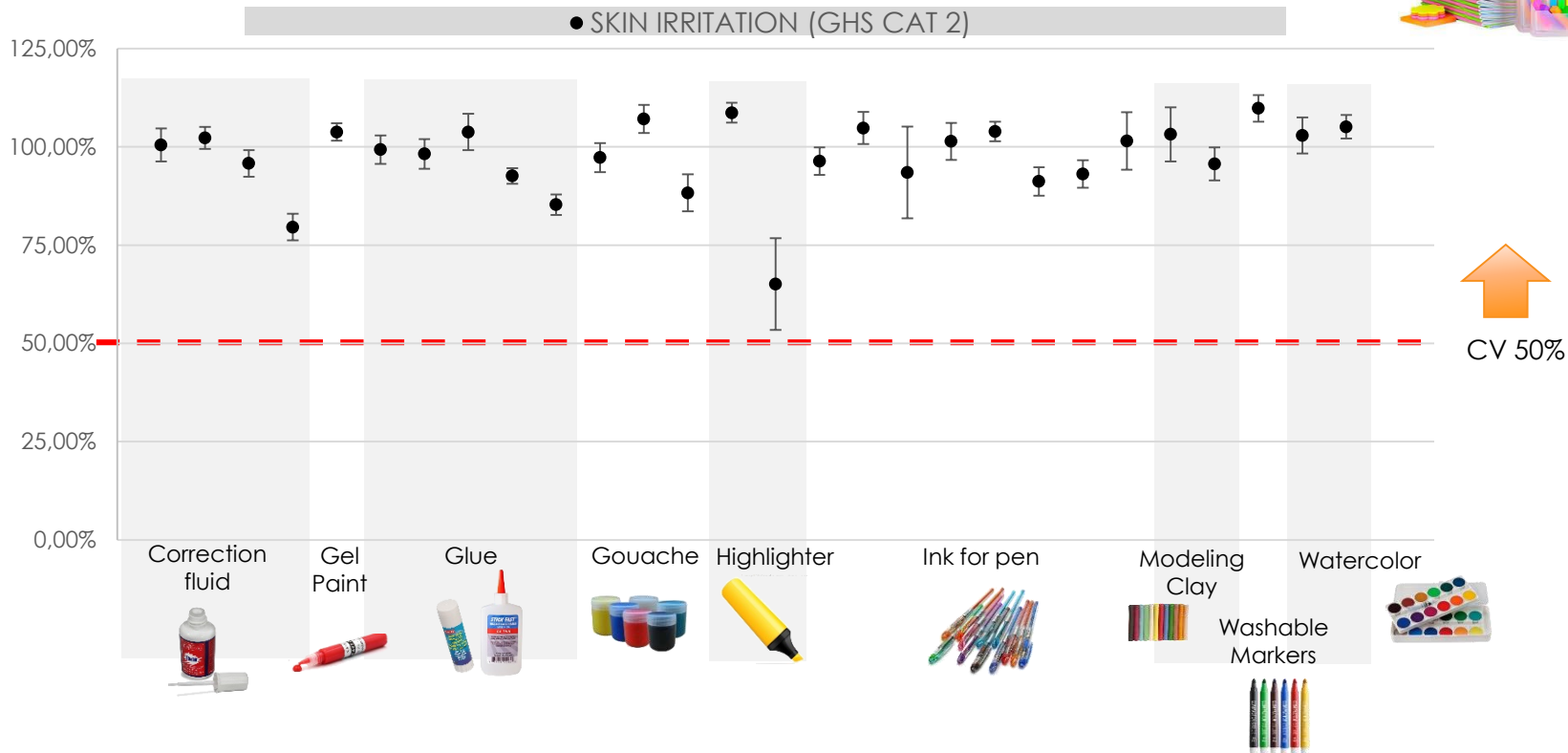


Two Technical Practical
Trainings:
April – 2017
May - 2017

3th STEP – MARCH – JULY 2017

Assays for children's articles using SkinEthic RHE



4th STEP – AGO – SEPTEMBER 2017

RHE Test Method included as GLP principles – ANVISA and INMETRO

Federal Republic of Brazil
Ministry of Industry, Foreign Trade and Services
National Institute of Metrology, Quality and Technology - INMETRO

General Coordination for Accreditation
Brazilian Compliance Monitoring Authority for the Principles of Good Laboratory Practice – GLP



Statement of GLP Compliance

GLP Recognition No. GLP 0043 Inicial Recognition: September 01st 2014

Laboratório Biosintesis P&D do Brasil Ltda
Centro de Biotecnologia - Estudos Biológicos In Vitro
Avenida Professor Lineu Prestes, 2.242 - Centro de Biotec. - Butantã - Cidade Universitária - São Paulo – SP – Brasil

General Coordination for Accreditation of Inmetro grants to the above mentioned test facility the recognition of compliance with the OECD Principles of Good Laboratory Practice as part of the Brazilian GLP Monitoring Program to carry out non-clinical health and environmental safety studies, as described in the scope below:

| Areas of expertise | Categories of Test Items |
|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Toxicity studies; Mutagenicity studies; Cytotoxicity studies | Pharmaceutical Products; Cosmetics; Veterinary Products; Industrial Chemical Products; Health Products |

Note: Categories of test items "pesticides", "pharmaceutical products", "cosmetics", "wood preservative", "feed additives", "veterinary products", "sanitizers", "remedial for treatments of effluents and natural ecosystems" and "industrial chemical" are covered by Brazil's full adherence to the OECD Council Acts related to the Mutual Acceptance of Data (MAD) on Good Laboratory Practice.


Aldoney Freire Costa
 General Coordinator for Accreditation Substitute

Assinado de forma digital por
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The recognition status shall be checked at the address http://www.inmetro.gov.br/monitoramento_BPL/certificados

GLP Scope

Toxicity, Mutagenicity and Cytotoxicity Studies

OECD TG 129 – Acute Toxicity

OECD TG 431 – Skin corrosion

OECD TG 439 – Skin Irritation

OECD TG 487 – Micronucleus Genotoxicity

ISO 10.993 – Biological Evaluation of Medical Devices

ABNT NBR 15.236 - Schools Articles Safety



TODAY



Validated RHE according
OECD and specific guidelines

GLP compliance

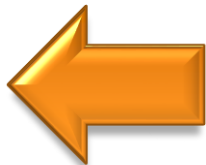
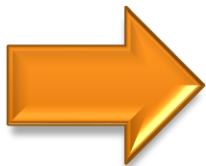
Interlaboratorial (INMETRO)

evaluation of other children
products (toys, cosmetics)

Looking forward

REGULATORY

- Harmonization between legislations and segments
- Agencies joint efforts



INDUSTRY

- Use of validated RHE protocols here in Brazil

cosmetic



med devices



pharma



Agro



children







Marcio Faber

New Projects

marcio@biosintesis.com.br

**Animal-free safety assessment for
children's articles**

The logo for the 2nd PAN-AMERICAN Conference for Alternative Methods features a blue silhouette of the Americas. To the right of the map, the text "2nd PAN-AMERICAN Conference for Alternative Methods" is written in blue, with "PAN-AMERICAN" in a larger, bold font. Below this, the dates "August 23-24, 2018" and the location "Rio de Janeiro" are listed in a smaller blue font.

2nd
PAN-AMERICAN
Conference for Alternative Methods
August 23-24, 2018
Rio de Janeiro