

Institute for In Vitro Sciences, Inc
30 W Watkins Mill Road #100
Gaithersburg, Maryland 20878

Curriculum Vitae
GERTRUDE-EMILIA COSTIN

Education

- 2019** ATS, Fellow of Academy of Toxicological Sciences (Certification), Raleigh, NC, USA
- 2019** ERT, European Registered Toxicologist (Certification), Hellenic Register of Toxicology, Greece
- 2010** MBA, Aspen University, Denver, CO, U.S.A.
- 2001** Ph.D. (Biology) (CUM LAUDE), Institute of Biochemistry of the Romanian Academy, Bucharest, Romania
- 1998** M. Sc. (Molecular Biology), Faculty of Biology, University of Bucharest, Bucharest, Romania
- 1997** B. Sc. (Biochemistry), Faculty of Biology, Biochemistry Department, University of Bucharest, Bucharest, Romania

Current position

2019 – present

(September) Director, Laboratory Services
Program Leader, Skin Sensitization Department
Study Director

Provide scientific and regulatory oversight for the laboratory-based programs. Design *in vitro* bioassay programs for corporate clients to evaluate toxicology profiles, safety and efficacy of raw ingredients/finished products. Develop and oversee assay validation programs. Study Director primarily for GLP-compliant *in vitro* dermal and mucosal irritation assays. Responsible for operational aspects of the laboratory, for Study Directors' training, workload assessment, annual reviews; supervisor of members of two Departments, 3D Dermal and Skin Sensitization, respectively.

Professional Memberships

- 2004 – present: PanAmerican Society for Pigment Cell Research (PASPCR) – *Honorary member as of October 2019*
- 2008 – 2019 – Editor - PanAmerican Society of Pigment Cell Research (PASPCR) Newsletters
- 2009 – Member of the National Organizing Committee of the 15th PASPCR Meeting (The Pigmentary System: Securing a Place Under the Sun), Memphis, TN, September 4-7, 2009.
- 2012 – 2014– Member - Council of PASPCR

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- 2011- Society of Toxicology – regular member
2016-2018 – Editor – National Capital Area Chapter of the Society of Toxicology (NCAC-SOT) Newsletter
- 2014- SOT Dermal Toxicology Specialty Section – regular member
- 2014- The National Capital Area Chapter of the Society of Toxicology – regular member; 2015-2018 Newsletter Editor and member of the Executive Board
- 2014- American Society for Cellular and Computational Toxicology – regular member
2016-2018 – Council Member

Selected Scientific Awards and Recognitions

- 1998. The prize for the best **poster** presented at the 1st International Meeting of the Romanian Society of Biochemistry and Molecular Biology (RSBMB) – September 24th-26th, Bucharest, Romania
- 2010 Florence R. Sabin Educational Achievement Award presented by Pearson’s Higher Education – June 26th, Denver, CO, USA
- 2014 2014 3Rs Innovation Award for the application entitled “Conversion from *In Vivo* to a Tiered *In Vitro* Method for Assessment of Skin Irritation for BMS Molecules” submitted by: Caren Villano and Janet Gould (R&D EHS, Bristol-Myers Squibb), Christina Risatti (Early Phase Chemical Development, Bristol-Myers Squibb) and Non BMS contributors: Neil Foglio (Rutgers); Nathan Wilt and **Gertrude-Emilia Costin** (Institute for In Vitro Sciences); Andrew Grant Robertson (Charles River Laboratories).
- 2017 The poster award of the Japanese Society for Alternatives to Animal Experiments (10th World Congress on Alternatives and Animal Use in the Life Sciences) for the poster entitled “Introducing the 3Rs Concepts into Pre-college Classrooms” by N. Green, G.-E. Costin, A. Miller, S. Leary and K. Lewis.
- 2019 Taylor & Francis Prize for the Outstanding Paper in Dermal Toxicology Published in the Cutaneous & Ocular Toxicology in 2019 to the manuscript by: Jessica C. Graham, Nathan Wilt, Gertrude-Emilia Costin, Caren Villano, Jackie Bader, Lindsay Krawiec, Elizabeth Sly and Janet Gould and entitled “Evaluation of a tiered *in vitro* testing strategy for assessing the ocular and dermal irritation/corrosion potential of pharmaceutical compounds for worker safety”, Cutaneous and Ocular Toxicology 37 (4): 380-390. Prize presented during the Society of Toxicology Meeting, Dermal Toxicology Specialty Section (DTSS) meeting.

Patents

- 2003. **Targeted drug delivery**, Stefana M. Petrescu, **Gertrude-E. Costin**, Mihaela Trif, Norica Nichita, Raymond A. Dwek – International application published under the Patent Cooperation Treaty (PCT) – international publication number WO 03/032946 A2 (international application number PCT/IB02/04691; international publication date April 24th, 2003)

Invited lectures

- 2009 | Part of the Washington, D.C. area Coalition for the Public Understanding of Science (DC

- 2014** A new, non-animal based, hazard identification strategy for ocular irritation of antimicrobial cleaning products – the Chemical Watch Global Antimicrobials/Biocides Conference – September 25th-26th, Washington DC, USA – *expert panelist*
- 2015** 21st century methods – assessing acute toxicity while avoiding animals. Western Plant Health Association Summer Regulatory Conference – August 28th-29th, Sacramento, CA, USA.
- 2015** **Invitation to write a letter celebrating 25 years for the Romanian Society of Biochemistry and Molecular Biology as a long-standing member:** http://www.biochim.ro/ib/photos/2015_srbbm/letter_Emma-Costin-RSBMB-member.doc.
- 2016** *In vitro* testing systems and strategies used in toxicology. Current status of the field and emerging trends, University of Maryland, BioEngineering Society – February 25th, College Park, MD, USA.
- 2016** *In vitro* testing systems and strategies used in toxicology. Translating an idea into a labeled product, Institute of Biochemistry of the Romanian Academy – July 1st, Bucharest, Romania.
- 2016** Current political climate – Global acceptance of *in vitro* methods: 2nd Annual US/Global Biocides (Antimicrobials) Regulation Conference – July 11th-12th, Washington DC, USA – *expert panelist*
- 2016** Optimization of the validated *in vitro* Skin Irritation Test (OECD TG 439) to address the assignment of EPA hazard categories. 5th ASCCT Annual Meeting – September 29th, Research Triangle Park, Durham, NC, USA.
- 2017** Modernizing the “six-pack” testing strategy: influx of modern *in vitro* techniques, Northern California Chapter of SOT Fall Symposium: the 3Rs – September 28th, Sacramento, CA, USA.
- 2018** Development of a non-animal method for biocompatibility assessment of personal lubricants under the US FDA’s MDDT Program) at the 7th Annual Meeting of the American Society for Cellular and Computational Toxicology – September 11th, Bethesda, MD, USA.
- 2018** Modernizing predictive toxicology for regulatory decisions: Influx of modern non-animal testing technologies and strategies) at the National Capital Area Chapter of the Society of Toxicology (NCAC-SOT) Fall Symposium – October 25th, Bethesda, MD, USA.
- 2018** Non-animal testing technologies and strategies used for chemical hazard and risk assessment, Spring Meeting of the Society of Chemical Hazard Communication – April 25th, Orlando, FL, USA.
- 2018** Be(coming) a Study Director: The sum of all Talents. NCARSQA Study Director Training Course – October 9th, Gaithersburg, MD, USA.
- 2018** Non-animal testing technologies and strategies: Supporting global product stewardship, Product Stewardship Conference – September 29th, Washington, DC, USA.
- 2019** Non-animal testing technologies and strategies used for chemical hazard and risk assessment Applied *In Vitro* Toxicology Course – April 14th-19th, Bucharest, Romania.

- 2019** | Non-animal skin irritation and corrosion testing technologies and strategies: risk assessment, regulatory classification and labeling, New Approach Methodology Use for Regulatory Application (NURA): Evaluating Toxicology Information using Modern Science – May 20th-21st, Gaithersburg, MD, USA.

Webinars

- 2014** | **Costin G.-E.**, Rovidia C. Skin irritation and corrosion – hosted by Chemical Watch and the PETA International Science Consortium, Ltd. – 11 November 2014 – *the webinar focused on alternative methods and testing strategies that can be used to meet REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) requirements. Prepared and presented the technical part of the webinar (half of it), prepared for distribution the answers for the Q&A document; over 700 registrants, ~350 online participants.*
- 2017** | **Costin G.-E.**, Randhawa M. Skin tone modulation: *in vitro* pre-clinical and clinical efficacy testing strategies and innovative solutions in cosmetics. 29 June 2017. Available at: <http://iivs.org/2017/06/30/view-our-webinar-on-skin-tone-modulation/>.
- 2017** | **Costin G.-E.** *In vitro* assays used for safety assessment: skin irritation and corrosion. Replacing regulatory experiments on animal webinar series. The webinar was recorded for the 2017 course “Replacing regulatory experiments on animals: an introduction to *in silico* models and *in vitro* test methods”. The course was co-hosted by PETA India and the Institute of Home Economics, University of Delhi. October. Available at: <https://www.piscltd.org.uk/replacing-regulatory-experiments-course/>. *I was the coordinator of this activity commissioned by PETA – coordinated 5 lectures from IIVS (by Hans Raabe, Nathan Wilt, Allison Hilberer, Tinashe Ruwona and myself) to share about in vitro toxicology assays with students from Delhi.*
- 2018** | **Costin G.-E.** and Rovidia C. Skin irritation and corrosion webinar. REACHing for alternatives to animal testing. A new webinar series on modern testing strategies for REACH organized by the PETA International Science Consortium and Chemical. 25 January 2018. Available at: <https://www.piscltd.org.uk/reaching-alternatives-animal-testing/>.
- 2018** | **Costin G.-E.** Taiwan FDA Webinar: *In vitro* assays for dermal safety and efficacy testing for regulatory and non-regulatory purposes hosted by PETA International Science Consortium. 25 April 2018. Pre-recorded, translated for the audience. Available at: http://nehrc.nhri.org.tw/toxic/in_vitro.php and <https://www.piscltd.org.uk/training-videos-webinars/>.

Published manuscripts

Peer-reviewed

- 2020** Costin G.-E., Miller A. Emerging trends in science and education: Introducing the 3Rs concepts into pre-college classrooms. *J. Biol. Educ.* DOI: 10.1080/00219266.2020.1748688.
- 2020** **Costin G.-E.**, Hill E., Brown J., Clippinger A.J. Qualification of a non-animal vaginal irritation method admitted as nonclinical assessment model (NAM) in the Incubator Phase of the United States Food and Drug Administration (US FDA) Medical Devices Development Tool (MDDT). *Toxicol. In Vitro.* 2020. Feb; 62: 104680. doi: 10.1016/j.tiv.2019.104680. Epub 2019 Oct 15.
- 2018** Graham J.C., Wilt N., Costin G.-E., Villano C, Bader J, Krawiec L, Sly E, Gould J. Evaluation of a tired in vitro testing strategy for assessing the ocular and dermal irritation/corrosion potential of pharmaceutical compounds for worker safety. *Cutan. Ocul. Toxicol.* 2018, 37(4), 380-390.
- 2017** **Costin G.-E.** Advances in science: next generation of lab tools, models and testing platforms used in predictive toxicology. *Molecular Life* 2017; 1(1), 22-28, doi: 10.26600/MolLife.1.1.3.2017. Available at: <http://molecular-life.org/wp-content/uploads/2017/07/Advances-science-next-generation-lab-tools-modelstesting-platforms-used-predictive-toxicology.pdf>.
- 2017** Birlea S.A., **Costin G.-E.**, Roop D.R., Norris D.A. Trends in regenerative medicine: repigmentation in vitiligo through melanocyte stem cell mobilization. *Med. Res. Rev.* 2017, 37(4), 907-935.
- 2016** Walters R.M., Gandolfi L., Mack M.C., Fevola M., Martin K., Hamilton M.T., Hilberer A., Barnes N., Wilt N., Nash J.R., Raabe H.A., **Costin G.-E.** *In vitro* assessment of skin irritation potential of surfactant-based formulations using a 3-D skin reconstructed tissue model and cytokine response. *Altern Lab Anim.* 2016, 44, 523-532.
- 2013** Baldea I., **Costin G.-E.**, Shellman Y., Kechris K., Olteanu E. D., Filip A., Cosgarea M.R., Norris D.A., Birlea S.A. Biphasic pro-melanogenic and pro-apoptotic effects of all-trans-retinoic acid (ATRA) on human melanocytes: time-course study. *J. Dermatol. Sci.* 2013, 72(2), 168-176.
- 2013** **Costin G.-E.**, Raabe H. Technical challenges associated with dosing devices used for topical treatment of three dimensional reconstructed pigmented tissues. *Rom. J. Biochem.* 2013, 50(2), 81-91.
- 2013** **Costin G.-E.**, Raabe H. Optimized *in vitro* pigmentation screening assay using a reconstructed three dimensional human skin model. *Rom. J. Biochem.* 2013, 50(1), 15-27.
- 2012** Cameron D.M., Donahue D.A., **Costin G.-E.**, Kaufman L.E., Avalos J., Downy M.E., Billhimer W.L., Gilpin S., Wilt N., Simion F. A. Confirmation of *in vitro* and clinical safety assessment of behentrimonium chloride-containing leave-on body lotions using post-marketing adverse event data. *Toxicol In Vitro* 2013, 27(8), 2203-2012.
- 2012** **Costin G.-E.**, Birlea S.A., Norris D.A. Trends in wound repair: cellular and molecular basis of regenerative therapy using electromagnetic fields. *Curr. Molec. Medicine* 2012, 12(1), 14-26.

- 2012** Costin G.-E., Birlea S.A., Norris D.A. Trends in wound repair: cellular and molecular basis of regenerative therapy using electromagnetic fields. *Curr. Molec. Medicine*. 2012, 12(1), 14-26.
- 2011** Costin G.-E., Raabe H. A., Priston R., Evans E., Curren R. D. Vaginal irritation models: the current status of available alternative and *in vitro* tests. *Altern. Lab Anim*. 2011, 39(4), 317-337.
- 2010** Costin G.-E. How I became a biochemist? *IUBMB Life* 2010, 62(9), 703-705.
- 2009** Costin G.-E., Raabe H., Curren R. *In vitro* safety testing strategies for skin irritation using 3D reconstructed human epidermis models. *Rom. J. Biochem*. 2009, 46(2), 149-163.
- 2009** Birlea S.A., Costin G.-E., Norris D.A. New insights on therapy with vitamin D analogs targeting the intracellular pathways that control repigmentation in human vitiligo. *Med. Res. Rev*. 2009, 29(3), 516-546.
- 2008** Vavilikolanu P., Lazaro C., Mun G., Hilberer A., Hyder M., Raabe H., Curren R., Costin G.-E. Experiences in the development and utilization of an *in vitro* safety testing program for hair conditioners. *Proc. 6th World Congress on Alternatives & Animal Use in the Life Sciences, AATEX 2008*, 14 (Special Issue), 529-534.
- 2008** Birlea S.A., Costin G.-E., Norris D. A. Cellular and molecular mechanisms involved in the action of vitamin D analogs targeting vitiligo depigmentation. *Curr. Drug Targets* 2008, 9(4), 345-359.
- 2007** Valencia J.C., Rouzaud F., Julien S., Chen K.G., Passeron T., Yamaguchi Y., Abu-Asab M., Tsokos M., Costin G.-E., Yamaguchi H., Miller Jenkins L.M., Nagashima K., Appella E., Hearing V.J. Sialylated core 1 O-glycans influence the sorting of Pmel17/gp100 and determine its capacity to form fibrils. *J. Biol. Chem*. 2007, 282(15), 11266-11280.
- 2007** Costin G.-E., Hearing V.J. Human skin pigmentation: melanocytes modulate skin color in response to stress. *FASEB J*. 2007, 21(4), 976-994.
- 2007** J. C. Valencia, F. Rouzaud, S. Julien, K. G. Chen, T. Passeron, Y. Yamaguchi, M. Abu-Asab, M. Tsokos, G.-E. Costin, H. Yamaguchi, L. M. Miller Jenkins, K. Nagashima, E. Appella, V. J. Hearing, Sialylated core 1 O-glycans influence the sorting of Pmel17/gp100 and determine its capacity to form fibrils. *J. Biol. Chem.* **282** (15), 11266-11280 (2007).
- 2006** G.-E. Costin, S. A. Birlea, "What is the mechanism for melasma that so commonly accompanies human pregnancy?" *IUBMB Life*, **58** (1), 55-57 (2006).
- 2006** F. Rouzaud, G.-E. Costin, Y. Yamaguchi, J. C. Valencia, W. F. Berens, K. G. Chen, T. Hoashi, M. Bohm, Z. A. Abdel-Malek, V. J. Hearing, Regulation of constitutive and UVR-induced skin pigmentation by melanocortin 1 receptor isoforms, *FASEB J.* **20** (11), 1927-1929 (2006).
- 2006** S. Birlea, M. Birlea, D. Cimponeriu, P. Apostol, R. Cosgarea, L. Gavrila, S. Tigan, G.-E. Costin, P. K. Das, Autoimmune diseases and vitamin D receptor *Apa-1* polymorphism are associated with vitiligo in a small inbred Romanian community, *Acta Derm. Venereol.* **86** (3), 209-214 (2006).

- 2005** H. Ando, Z.-M. Wen, H.-Y. Kim, N. Salem Jr., J. C. Valencia, **G.-E. Costin**, H. Watabe, K. Yasumoto, Y. Niki, H. Kondoh, M. Ichihashi, V. J. Hearing, Modulating the intracellular composition of fatty acids affects the post-Golgi degradation of tyrosinase and elicits its retention in the endoplasmic reticulum by hyper-ubiquitination and proteasome inhibition, *Biochem. J.*, **394** (1), 43-50 (2005).
- 2005** **G.-E. Costin**, J. C. Valencia, K. Wakamatsu, S. Ito, W. D. Vieira, Y. Yamaguchi, A. L. Milac, F. Rouzaud, A.-J. Petrescu, M. L. Lamoreux, V. J. Hearing, Mutations in the mouse *Dct* gene induce a reduction of eumelanin and an increase in the level of pheomelanin produced by melanocytes in culture, *Biochem. J.*, **391** (2), 249-259 (2005).
- 2005** E. Greggio, E. Bergantino, D. Carter, R. Ahmad, **G.-E. Costin**, V. J. Hearing, J. Clarimon, A. Singleton, J. Eerola, O. Hellström, P. J. Tienari, D. W. Miller, A. Beilina, L. Bubacco, M. R. Cookson, M. R., Tyrosinase exacerbates dopamine and α -synuclein toxicity but is not genetically associated with Parkinson's disease, *J. Neurobiochem.*, **93**, 246-256 (2005).
- 2004** **G.-E. Costin**, "What is the advantage of having melanin in parts of the central nervous system (e.g. substantia nigra)?" *IUBMB Life*, **56** (1), 47-49 (2004).
- 2004** **G.-E. Costin**, W. D. Vieira, J. C. Valencia, F. Rouzaud, M. L. Lamoreux, V. J. Hearing, Immortalization of mouse melanocytes carrying mutations in various pigmentation genes, *Anal. Biochem.*, **335** (1), 170-174 (2004).
- 2003** F. Rouzaud, J.-P. Annereau, J. C. Valencia, **G.-E. Costin**, V. J. Hearing, Regulation of melanocortin 1 receptor expression at the mRNA and protein levels by its natural agonist and antagonist, *FASEB J.*, **17** (14), 2154-2156 (2003).
- 2003** **G.-E. Costin**, J. C. Valencia, W. D. Vieira, M. L. Lamoreux, V. J. Hearing, Tyrosinase processing and intracellular trafficking is disrupted in mouse primary melanocytes carrying the *underwhite* (*uw*) mutation. A model for oculocutaneous albinism (OCA) Type 4, *J. Cell Sci.*, **116** (15), 3203-3212 (2003).
- 2003** T. Kushimoto, J. C. Valencia, **G.-E. Costin**, K. Toyofuku, H. Watabe, K. Yasumoto, F. Rouzaud, W. D. Vieira, V. J. Hearing, "Makoto Seiji memorial lecture": The melanosome: an ideal model to study cellular differentiation" (review), *Pigment Cell Res. (Proceedings of the XVIIIth International Pigment Cell Conference (IPCC))*, **16** (3), 237-244 (2003).
- 2002** **G.-E. Costin**, M. Trif, N. Nichita, R. A. Dwek, S. M. Petrescu, pH-sensitive liposomes are efficient carriers for endoplasmic reticulum targeted drugs in mouse melanoma cells, *BBRC*, **293** (3), 918-923 (2002).
- 2002** K. Toyofuku, J. C. Valencia, T. Kushimoto, **G.-E. Costin**, V. M. Virador, W. D. Vieira, V. J. Ferrans, V. J. Hearing, The etiology of oculocutaneous albinism (OCA) type II: the pink protein modulates the processing and transport of tyrosinase, *Pigment Cell Res.*, **15** (3), 217-224 (2002).
- 2001** **G.-E. Costin**, S. M. Petrescu, Inhibitors of N-linked glycoproteins biosynthesis and processing, *Rom. J. Biochem.*, **38** (2), 233-249 (2001).

- 1999** G. Negroiu, N. Branza-Nichita, **G.-E. Costin**, H. Titu, A.-J. Petrescu, R. A. Dwek, S. M. Petrescu, Investigation of the intracellular transport of tyrosinase and tyrosinase related protein (TRP-1). The effect of endoplasmic reticulum (ER)-glucosidases inhibition, *Cell. Mol. Biol (Melanocytes and Melanogenesis)*, **45** (7), 1001-1010 (1999).
- 1998** **G.-E. Costin**, C. Fatu, M. Bostangiu, Tumoral markers in cancer, *Stud. and Res. of Biochim.*, **41** (1-2), 89-96 (1998).
- 1998** **G.-E. Costin**, C. Fatu, Molecular mechanisms and therapeutics concerning acquired immunodeficiency syndrome, *Stud. and Res. of Biochim.*, **41** (1-2), 73-87 (1998).

Book chapters

- 2016** **Costin G.-E.** and Norman, K.G. Use of In Vitro Methods in Pre-clinical Safety Assessment of Skin Care Products. In: *Textbook of Ageing Skin* (Eds. M.A., Miller, K.W., Maibach, H.I.). 2016, pp. 1503-1521.
- 2014** **Costin G.-E.** and Raabe H.A. *In vitro* toxicology models. In: *The Role of the Study Director in Non-clinical Studies. Pharmaceuticals, Chemicals, Medical Devices, and Pesticides.* (Eds. William Brock, Barbara Mounho and Lijie Fu), John Wiley and Sons. 2014, pp. 145-170.
- 2013** **Costin G.-E.** and Raabe H.A. *In vitro* Toxicology Models for Acute Eye and Skin Irritation Assessment. In: *Reducing, Refining and Replacing the Use of Animals in Toxicology Testing* (Eds. David Allen and Mike D. Walters), RSC Publishing. 2013, pp. 215-243.