

Institute for In Vitro Sciences, Inc.
30 West Watkins Mill Road, Suite 100
Gaithersburg, MD 20878

Curriculum Vitae

Allison Hilberer

Education

May 2019 to Present	Clinical Toxicology Graduate Certificate Program University of Florida College of Pharmacy, Gainesville, FL
May 2011	Master of Science, Biology George Mason University, Fairfax, VA
December 2001	Bachelor of Arts, Biology Keuka College, Keuka Park, NY
May 1999	Associate in Science, Liberal Arts and Sciences Finger Lakes Community College, Canandaigua, NY
April 2016	Mid-America Toxicology Course Kansas City, MO

Professional Certifications

2016-2026 (recertified 2020)	Diplomate of the American Board of Toxicology (DABT) Certification
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Experience

January 2021 to Present
Phototox, &
Senior Toxicologist/ Study Director/ Program Leader BCOP, 96well assays
Institute for In Vitro Sciences, Inc.

Additional responsibilities to those listed below for the Toxicologist II/Study Director/ Program Leader. Represent International Council on Animal Protection in OECD Programmes (ICAPO) for eye/skin and sensitization assays. Oversee photoallergy program including integration and optimization of multiple assays at IIVS. Assume Study Director responsibility for additional assays including photoDPRA, UV-VIS Analysis, KeratinoSens, and LuSens. Organizing and/or participating in other IIVS programs as assigned.

March 2019 to Present
96-well Present
Toxicologist II/ Study Director/ Program Leader BCOP, Phototox, & Assays
Institute for In Vitro Sciences, Inc.

Additional responsibilities to those listed below for the Toxicologist II/Study Director: responsible for the training and oversight of Biologists working in the BCOP, Phototoxicity, and 96-well Cytotoxicity Assays.

January 2017 to March 2019
Toxicologist II / Study Director
Institute for In Vitro Sciences, Inc.

Assist clients in developing appropriate *in vitro* toxicology programs for their products. Interact with industry, animal welfare groups, and government, as necessary, to examine use of *in vitro* methods and interpretation of data. Oversee *in vitro* toxicology assays including: the 3T3 Neutral Red Uptake (NRU) and 3-Dimensional Phototoxicity Assays to evaluate phototoxicity hazard/risk assessment; the Short Time Exposure (STE) Test, the Bovine Corneal Opacity and Permeability (BCOP) Assay, the Trans Epithelial Passage (TEP) Assay, and the Human Corneal Epithelium (HCE) Assay to assess eye irritation; and the EpiDerm™ Assays to evaluate skin irritation potential. Ensure compliance of assays, documentation, and data under Good Laboratory Practices (GLPs). Participate in identifying, developing, and commercializing novel *in vitro* toxicology assays. Participate in IIVS' Education and Outreach activities, including coordination of and conduct of international workshops (in the US and on location in the People's Republic of China) with focus on OECD compliant and/or validated *in vitro* test methods.

January 2015 to
January 2017

Toxicologist I / Study Director
Institute for In Vitro Sciences, Inc.

Assist clients in developing appropriate *in vitro* toxicology programs for their products. Interact with industry, animal welfare groups, and government, as necessary, to examine use of *in vitro* methods and interpretation of data. Oversee ocular, dermal *in vitro* toxicology assays that address irritation, corrosion, and photosafety and compliance of assays, documentation, and data under Good Laboratory Practices (GLPs). Participate in identifying, developing, and commercializing novel *in vitro* toxicology assays. Participate in IIVS' Education and Outreach activities, including coordination of and conduct of international workshops (in the US and on location in the People's Republic of China and Vietnam) with focus on OECD compliant and/or validated *in vitro* test methods.

July 2011 to
December 2014

Study Director/ Laboratory Supervisor
Institute for In Vitro Sciences, Inc.

Manage the laboratory activities and personnel; research activities and testing schedules; manage daily activities of the laboratory personnel, equipment, supplies, and resources; assure adherence to current protocols, SOPs, GLPs, client-specific documents, etc.; manage the scientific and regulatory currency of protocols and SOPs; prepare/review regulatory compliant written reports of the study methods, results and interpretations; execute and review studies and resulting data; provide scientific interpretations of the client studies; stay current with regulatory requirements; assist the Laboratory Director in developmental phase projects; oversee specific assays as the Study Director and contractually responsible for the conduct of the studies, as well as the presentation and interpretation of the study data. Transfer the STE Test into IIVS (including preparation of documentation tools, cell banks, assay training); participate in inter-laboratory STE validation effort; assist with editing/review of OECD STE draft test guideline used to create OECD TG 491. One of two instructors chosen to provide hands-on training to academic and regulatory toxicologists in Goiania, Brazil, and to toxicology regulators in Beijing, P.R.C.

November 2009 to
July 2011

Laboratory Supervisor/ Training Specialist
Institute for In Vitro Sciences, Inc.

Supervises, plans and conducts commercial toxicology studies, as well as plans, conducts and coordinates a broad range of toxicology research and development projects. Often communicates directly with clients concerning the design and interpretation of their studies. Oversees the daily operation and

scheduling of the laboratory, including conduct of the assays, and maintenance of lab equipment. Reviews technical SOPs, provides updates as necessary, and assures adherence to GLPs and other applicable regulations. Monitors the performance of the lab staff and generates reviews with lab management. Coordinates the development and presentation of experimental data and assists in the development of protocols. Continues performance of responsibilities associated with Biologist and Training Specialist. Lead Technician for the EpiOcular™ Eye Irritation Test (EIT) validation study leading to its acceptance as an OECD Test Guideline (OECD TG 492). Trained special delegations of toxicologists from China and Russia in *in vitro* methods.

July 2008 to
November 2009

Senior Biologist/ Training Specialist
Institute for In Vitro Sciences, Inc.

Apply specialized lab skills and exceptional technical proficiency in conducting *in vitro* toxicology assays and lab leadership. Interact with the Laboratory Supervisor to plan, conduct, and coordinate assays. Communicate and interpret results to industry clients on specialized projects. Conduct and evaluate a broad range of research or testing projects (EST assay and assays using the ATP endpoint); make independent technical decisions; coordinate the development and presentation of experimental data; assist in the development of protocols and draft periodic reports; record, compute and analyze test data; prepare test reports. Coordinate training and development program at IIVS: prepare objectives for new employees; cross train biologists in new assay systems; coordinate work assignments of trainees; and provide follow-up to Team Leader and management. Assign and oversee laboratory equipment and technician laboratory responsibilities to ensure efficient laboratory functioning and compliance with GLPs.

November 2006
to July 2008

Biologist III
Institute for In Vitro Sciences, Inc.

Primarily performs *In Vitro* alternative assays (as a lead technician): BCOP, CORROSITEX®, EpiOcular™, Neutral Red Phototoxicity Assay in Balb/c 3T3 Mouse Fibroblasts, NHEK and 3T3 NRU Bioassays, EpiDerm™ assays, the P30 Assay using A-253 and A549 cells, and ELISA Assays (TNF α , IL-1ra, IL-1 α , IL-6, IL-8). Lead technician of the EpiOcular™ validation study: REACH (European Community Regulation on chemicals and their safe use Registration, Evaluation, Authorisation and Restriction of Chemical substances). Assists with the EpiDerm™ (R-38) validation study (OECD TG 439). Lead technician for the 56-chemical NRU Assay in 3T3 Mouse Fibroblasts- A Screen for Low Toxicity. Assist management with preparation of presentations via photography and

videotaping assay critical steps. Prepare and edit assay-related posters for SOT, World Congress, and other *In Vitro* presentations. Assist with IIVS' website updates by compiling and editing laboratory sections. Collaborate with management in the introduction of Administaff training programs for employees.

November 2005 Biologist II
to November 2006 Institute for In Vitro Sciences, Inc.

Primarily perform *In Vitro* alternative assays (as a lead technician): BCOP, CORROSITEX® Continuous Time Monitor, EpiOcular™, Neutral Red Phototoxicity Assay in Balb/c 3T3 Mouse Fibroblasts, and Adenosine Triphosphate Cytotoxicity Bioassay in Normal Human Epidermal Keratinocytes (NHEK) Cells, NHEK Neutral Red Uptake (NRU) Bioassay, and EpiDerm™ assays. Lead technician for the AcuteTox validation studies using a Neutral Red endpoint with NHEK (normal human epidermal keratinocytes) and 3T3 cells. Perform routine sterile tissue culture techniques maintaining cell lines and primary human cells (NHEK).

November 2004 Biologist I
to November 2005 Institute for In Vitro Sciences, Inc.

Performs *In Vitro* alternative assays (as a lead technician): BCOP Assay, CORROSITEX® Continuous Time Monitor, EpiOcular™, and Glycation in Bovine Corneas. Performs routine sterile tissue culture techniques maintaining rodent cell lines (L929 and Balb/c 3T3). Assist in non-critical steps in other assay systems. Use of sterile tissue culture techniques, including antibiotic free culture and preparation of sterile tissue culture media. Review study data and workbooks to ensure adherence to study protocol and compliance with GLPs. Assist with training technicians for ocular assay systems and aseptic cell culturing. Participate in annual workshop through demonstrations and presentations. Receipt and log-in of test articles using StarLIMS software. Assist with creating and editing protocols for new assays. Responsible for the receipt and cataloging of histology slides. Assist histology personnel by compiling histology reports for sponsors' final reports. Assist Head of Quality Assurance in workbook and data auditing of NTP validation study. Assist in administrative duties, including archiving. Perform all assays in accordance with SOPs and GLPs. Generate and analyze assay-specific workbooks, data, and study reports using Word and Excel.

Affiliations

Society of Toxicology
American Society of Cellular and Computational Toxicology
Phi Theta Kappa National Honor Society

Selected Published Work

Takayuki Abo, Allison Hilberer, Christine Behle-Wagner, Mika Watanabe, David Cameron, Annette Kirst, Yuko Nukada, Takuo Yuki, Daisuke Araki, Hitoshi Sakaguchi, Hiroshi Itagaki. Predictive performance and inter-laboratory reproducibility in assessing eye irritation potential of water- and oil-soluble mixtures using the Short Time Exposure test method. *Toxicology in Vitro*. 2018. Volume 48, 78-85

Gamson, A., Herpel, T., Lamm, M., Sadowski, N., Sheehan, D., Hilberer, A. The Assessment of Phototoxicity Using the 3T3 Neutral Red Uptake (NRU) Phototoxicity Assay and a Modified Photo-Direct Peptide Reactivity Assay (DPRA). Presented at the Annual Society of Toxicology Meeting in San Antonio, TX March 2018

Kostrubsky V., Herpel T., Hilberer A. Evaluation of Phototoxicity of Ocular Medical and Combination Devices. Presented at the Annual Society of Toxicology Meeting in San Antonio, TX March 2018

Russel M. Walters, Lisa Gandolfi, M. Catherine Mack, Michael Fevola, Katharine Martin, Mathew T. Hamilton, Allison Hilberer, Nicole Barnes, Nathan Wilt, Jennifer R. Nash, Hans A. Raabe, & Gertrude-Emilia Costin. *In vitro* assessment of skin irritation potential of surfactant-based formulations using a 3-D skin reconstructed tissue model and cytokine response. *ATLA*. 2016 Dec;44(6):523-532

D. Sheehan, A. Pidathala, A. Hilberer. Evaluation of New Solvents for the Use in the Multi-Dose Reconstructed Human Epidermis (RhE) Phototoxicity Assay. Presented at the Annual Society of Toxicology Meeting in New Orleans, LA March 2016

H. P. Behrsing, L. E. Haswell, A. M. Hilberer, D. W. Sheehan, E. A. Sly, M. D. Gaça and H. A. Raabe. Effect of Acclimation Conditions on 3D Human In Vitro ALI Airway Models: Exposure-Induced Inflammatory Response and Sampling Location - Specific Results. Presented at the Annual Society of Toxicology Meeting in New Orleans, LA March 2016

Hilberer, A. Webinar: In Vitro 3T3 Phototoxicity Assay Practical Experiences Assay Optimization & Challenges. April 2015 (https://www.youtube.com/channel/UCvt_e0lolkcFvm5SNgO-TYw)

Raabe, Hans, Barnes, Nicole, Hilberer Allison. Evaluation of a Reconstructed Human Oral Buccal Tissue Model as a Testing Platform for Determining the Oral Irritation Potential of Tobacco Products. Presented at the Assessment of In Vitro COPD Models for Tobacco Regulatory Science Workshop in San Diego, CA March 2015

Carrao A; Norman K; Cameron D; Mun G; Wilt N; Hilberer A; Avalos J; Simion FA. Testing Framework for Prediction of Ocular Irritation Using the Bovine Corneal Opacity and Permeability (BCOP) Assay and Chorioallantoic Membrane Vascular Assay (CAMVA) Presented at the Annual Society of Toxicology Meeting in Phoenix, AZ March 2014

Raabe H, Barnes N, Hilberer A, Natsch A, Norman K, Wilt N, Curren R. Validation and Application of the KeratinoSens Assay, a Novel In Vitro Skin Sensitization Assay. Presented at the Japanese Society for Alternatives to Animal Experiments Meeting in December 2013

Liebsch, M. and Hilberer, A. Webinar: In Vitro Phototoxicity Assays. Presented June 2013 (https://www.youtube.com/channel/UCvt_e0lolkcFvm5SNgO-TYw)

Abo, T. and Hilberer, A. Webinar: The Short Time Exposure STE Assay Method and Use. Presented March 2013 (https://www.youtube.com/channel/UCvt_e0lolkcFvm5SNgO-TYw)

Bader J, Costin GE, Hilberer A, Mun G, Nash J, Norman K, Wilt N, Raabe H. Surfactant Responses in the Bovine Corneal Opacity and Permeability Assay: Points to Consider for In Vitro Eye Irritation Testing. Presented at the Annual Society of Toxicology Meeting in San Antonio, TX in March 2013

Abo T; Hilberer A; Heppenheimer A; Watanabe M; Ooshima K; Cameron D; Kirst A; Nukada Y; Sakaguchi H; Nishiyama N. The inter-laboratory reproducibility of the STE test for assessing eye irritation of cosmetic products. Presented at the Annual Society of Toxicology Meeting in San Antonio, TX in March 2013

Natsch A., Bauch C., Foertsch L., Gerberick F., Norman K., Hilberer A., Inglis H., Landsiedel R., Onken S., Reuter H., Schepky A. and Emter R (2011). The intra- and inter-laboratory reproducibility and predictivity of the KeratinoSens assay to predict skin sensitizers in vitro: Results of a ring-study in five laboratories. *Toxicol In Vitro*. Apr;25(3):733-44

Wurzburger, L., P. Kazmi, T. Re, A. Alonso, B. Bertino, N. Barnes, A. de Brugerolle de Fraissinette, A. Hilberer, H. Raabe, N. Wilt, and V. Srinivasan. Evaluation of an Oral Care Product Safety Screening Program Utilizing the In Vitro SkinEthic Human Gingival Epithelium (RHG) and Oral Buccal (RHO) Models. Presented at the 50th Annual Society of Toxicology Meeting, Washington D.C. March 6-10, 2011

Liebsch, Manfred, Gamer, Armin, Curren, Rodger, Frank, Jürgen, Genschow, Elke, Tharmann, Julia, Remmele, Marina, Bauer, Britta, Raabe, Hans, Barnes, Nicole, Hilberer, Allison, Wilt, Nathan, Lornejad-Schäfer, Mohammad Reza, Schäfer, Christine, Spiller, Erin, Hayden, Patrick, Kandárová, Helena. (2009) International validation of an *in vitro* skin irritation test protocol (EpiDerm-SIT) to replace the *in vivo* rabbit test for hazard identification of chemicals. 189: S83. Toxicology Letters: Abstracts of the 46th Congress of the European Societies of Toxicology

Prieto Pilar, Raabe Hans, Curren Rodger, Hilberer Allison, Whelan Maurice, Coeke Sandra, Gibson Rosemary, Compagnoni Anna, Hartung Thomas, Kinsner-Ovaskainen Agnieszka. Preliminary Results from the ECVAM Follow-Up Validation Study in the Predictive Capacity of the 3T3 Neutral Red Uptake Assay to Identify Substances with Acute Oral LD50 > 2000 mg/kg b.w. European Commission Joint Research Centre. Presented at the 7th World Congress on Alternatives and Animal Use in the Life Sciences, Rome, Italy, August 30- September 3 2009

Raabe H, Burdick J, Hanlon E, Hilberer A, Inglis H, Kong A, Majewski S, Mcnamara M, Mun G, Nash J R, Wilt N. Eye and Skin Irritation in 3-D Human Tissue Constructs Using MTT and ATP Endpoints. Presented at the 7th World Congress on Alternatives and Animal Use in the Life Sciences, Rome, Italy, August 30-September 3 2009

Vavilikolanu, P, Lazaro, C, Mun, G, Hilberer, A, Hyder, M, Raabe, H, and Curren, R. The Utilization Of the EpiOcular™ Human Tissue Model To Assess and Compare the Irritation Potential Of Multiple Surfactant Systems Used In Shampoos and Facial Cleansers. Presented at the 47th Annual Society of Toxicology Meeting, Seattle, WA, March 16-20, 2008

Raabe, Hans A.; Kelly, Jeffrey; Rybina, Irina; Hilberer, Allison; Moyer, Gregory O.; Curren, Rodger D. Estimating Systemic Toxicity *in vitro* Using an Adenosine Triphosphate Cytotoxicity (ATP) Assay in Normal Human Epidermal Keratinocytes. Presented at the 46th Annual Society of Toxicology Meeting, Charlotte, NC, March 25-29, 2007