

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

Curriculum Vitae

Nathan R. Wilt

EDUCATION

May 2000 **Bachelor of Science in Biological Sciences**
University of Maryland, College Park, MD

EXPERIENCE

March 2019 to **Toxicologist II/ Study Director/ Program Leader - EpiOcular**
to present

Additional responsibilities to those listed below for the Toxicologist II/
Study Director: responsible for the training and oversight of Biologists
working in the EpiOcular Assays.

January 2018 **Study Director / Toxicologist II**
to March 2019

Responsible to assist commercial clients to develop appropriate *in vitro*
toxicology programs for their products. Interacting with industry, animal
welfare groups and government as necessary to discuss use of *in vitro*
methods. Assuming Study Director responsibilities for the following *in vitro*
toxicology assays: screening assays using three dimensional
reconstructed tissues such as EpiOcular and EpiDerm, (from MatTek
Corporation). Also responsible for Eye Irritation Assays using EpiOcular
tissues, Skin Irritation Test using EpiDerm tissues, Bovine Corneal
Opacity and Permeability (BCOP) assay, and Corrositex assay.
Participate in identifying, developing, and commercializing novel *in vitro*
toxicology assays. Assist in producing posters and/or manuscripts
detailing IIVS' scientific activities. Organizing and/or participating in
other IIVS programs as assigned.

January 2015 **Study Director / Toxicologist**
to January 2018

Assist commercial clients to develop an appropriate *in vitro* toxicology program for their products. Assume Study Director responsibilities for one or more *in vitro* toxicology assays. Participate in selected *in vitro* method development programs, especially those involving new tissue engineered models, so that new or existing *in vitro* assays become useful tools for industrial safety or efficacy programs. Interact with industry, animal welfare groups and government as necessary to discuss use of *in vitro* methods

Develop appropriate product safety evaluation literature emphasizing *in vitro* methods that will assist industrial scientists in understanding and utilizing *in vitro* assays. Stay current with scientific requirements; maintain close interactions with current clients; provide schedule and scientific interpretations of the client's studies; stay current with regulatory requirements; and assist the Scientific Officer in developmental phase projects.

**June 2011 to
January 2015**

Study Director / Lab Manager

Manage the laboratory activities and personnel (1) research activities and testing schedules; 2) daily management of the laboratory personnel, equipment, supplies, and resources; 3) assures the strict adherence to current protocols, SOPs, GLPs, client-specific documents, etc., as required; 4) manages the scientific and regulatory currency of protocols and SOPs; 5) prepares/reviews regulatory compliant written reports of the study methods, results and interpretations). Execute and review studies and resulting data. Function as the Study Director on specific studies and is contractually responsible for the conduct of the studies, as well as the presentation and interpretation of the study data.

Stay current with scientific requirements; maintain close interactions with current clients; provide schedule and scientific interpretations of the client's studies; stay current with regulatory requirements; and assist the Laboratory Director in developmental phase projects.

**January 2010 To
June 2011**

Laboratory Manager

As the Laboratory Manager, Nathan is responsible for the oversight and management of personnel, daily operation and scheduling of the laboratory. In this role, the Laboratory Manager will participate in the execution and review of studies and resulting data. He will assure that time and resources are available for assays and specialized projects in

order to maintain productivity. The Laboratory Manager assures that

standard procedures are adhered to, and provides supplemental training or instruction when needed to maintain proper performance in the lab. In addition he oversees preparation for workshops held at IIVS and assures that materials and presentations are complete and accurate.

**January 2009 To
January 2010 Laboratory Supervisor**

As the Lab Supervisor, Nathan is directly responsible for the daily operation and scheduling of the laboratory, conduct of the assays, and maintenance of the equipment at the IIVS. The Laboratory Supervisor both supervises and conducts studies performed in the laboratory, as well as plans, conducts and coordinates a broad range of research or testing projects. He maintains technical SOPs and updates as necessary, and assures adherence to GLPs and other applicable regulations. He monitors the performance of the lab staff and generates reviews. He coordinates the development and presentation of experimental data and assists in the development of protocols. The Lab Supervisor also, trains and coordinates work assignments for the laboratory staff.

**April 2007
To January 2009 Team Leader
Institute for In Vitro Sciences, Inc.**

As the Team Leader, Nathan is responsible for overseeing laboratory activities in one or more well-defined areas of research or testing. He works mostly independently and has the responsibility of scheduling and overseeing the work of staff members classified as Biologist I, Biologist II and Biologist III. The position requires specialized lab skills and exceptional technical proficiency in the areas of responsibility and team management. The biologist must possess lab experience sufficient enough to make scientific judgements on how to handle priorities and problems.

**April 2005
To April 2007 Senior Biologist
Institute for In Vitro Sciences, Inc.**

The position of Senior Biologist, at the Institute For *In Vitro* Sciences requires specialized lab skills and exceptional technical proficiency in the area of responsibility. The biologist must possess lab experience sufficient

enough to make scientific judgements on how to handle priorities and problems. Under minimal supervision, independently performs nonroutine assignments of some complexity and variety. The biologist is required to demonstrate leadership ability, exceptional skills, knowledge, judgement and initiative. Plans, conducts and coordinates the BCOP assay so that it is performed proficiently. Works on a broad range of research or testing projects (micronucleus and EST assays); makes independent technical decisions; coordinates the development and presentation of experimental data; assists in the development of protocols, drafts periodic reports, may conduct nonstandard tests, modify standard equipment/material to meet specific technical requirements; records, computes and analyzes test data; prepares test reports and may train and coordinate work assignments of other biologists.

**April 2004
to April 2005**

**Biologist III
Institute for In Vitro Sciences, Inc.**

Provides primary training for new technicians. Maintains a database of test article information for a specific client. Performs the Corrositex assay, and is qualified to perform the Chorioallontoic Membrane Vascular Assay. Serves as the lead technician for the hepatocyte assay. Assists in developing and performing the Long Term Corneal Assay. Performs additional assays and responsibilities as outlined in the following section under “Biologist II”.

**April 2002
to April 2004**

**Biologist II
Institute for In Vitro Sciences, Inc.
Gaithersburg, MD**

Performs *in vitro* alternative assays (EpiDerm™, EpiOcular™, BCOP, and Neutral red uptake in NHEKs). Performs portions of the assay “Gene Expression in Rat Hepatocytes”, and continues to receive training for the assay. Performs routine sterile tissue culture techniques maintaining rodent cell lines (L929, 3T3 mouse embryo). Assist in non-critical steps in other assay systems. Use sterile tissue culture techniques, including antibiotic free culture and preparation of sterile tissue culture media. Performs specific equipment maintenance. Writes SOP’s and modifies workbooks for Epiocular™. Receive and log-in of test articles using LIMS software. One of the primary shippers of dangerous goods and cell lines using training received through Fed Ex. Perform all assays in accordance with SOP and GLP regulations. Generate and analyze assay-specific workbooks, data, and study reports using LIMS, Word, and Excel.

April 2001 **Biologist I**
to April 2002 **Institute for In Vitro Sciences, Inc.**
Gaithersburg, MD

Performs *in vitro* alternative assays (EpiDerm™ and EpiOcular™). Obtained training in routine cell culture techniques using mouse fibroblast cells (L929). Assist in non-critical steps in other assay systems (BCOP). Perform specific equipment maintenance. Receive and log-in of test articles using LIMS software. Perform all assays in accordance with SOP and GLP regulations. Obtained Fed Ex certification in order to return hazardous materials to sponsors according to IATA guidelines. Generate and analyze assay-specific workbooks, data, and study reports using LIMS, WordPerfect 5.1 and Excel.

Selected Published Abstracts

Curren, R., Moyer, G., Wilt, N., Clear, M., Sizemore, A., and Mun, G. (2003) Assessment of protocol variables in cytotoxicity assays utilizing Balb/c 3T3 cells and normal human keratinocytes. *The Toxicologist* 72:157.

Raabe, H., L. Bruner, T. Snyder, N. Wilt and J. W. Harbell (2005). Optimization of an *In Vitro* Long Term Corneal Culture Assay. ABS #1630, Society of Toxicology Annual Meeting, March 7-10.

Blazka, M.E., M. Diaco, J.W. Harbell, H. Raabe, A. Sizemore, N. Wilt and D.M. Bagley (2005). EpiOcular™ Human Cell Construct: Tissue Viability and Histological Changes Following Exposure to Surfactants. ABS #2001, Society of Toxicology Annual Meeting, March 7-10.

Wilt N, Gould J, Villano C, Bader J, Krawiec L, Sly E, Costin G-E (2015). A Tiered *In Vitro* Irritation/Corrosion Testing Strategy For GHS Classification of Pharmaceutical Compounds. ABS #417, Society of Toxicology Annual Meeting, March 23-26.

Published Papers

David M. Cameron, M.S., J.D.; Douglas A Donahue, M.S.; Gertrude-Emilia Costin , Ph.D.; Lewis E Kaufman, M.S.; Javier Avalos, Ph.D.; Martha E Downey; Ward L Billhimer; Sarah Gilpin, Ph.D.; Nathan Wilt; F. A Simion, Ph.D. (2013) Validation of in vitro and clinical safety assessment of behentrimonium chloride-containing leave-on body lotions using post-marketing adverse event data. *Tox In Vitro*

Chantra Eskes, Sebastian Hoffmann, Davide Facchini, Rich Ulmer, Amy Wang, Manuela Flego, Marco Vassallo, Monica Bufo, Erwin van Vliet, Federica d'Abrosca, Nathan Wilt. (2014) Validation study on the Ocular Irritation_ assay for eye irritation testing. *Tox in Vitro*

Graham J.C., Wilt N., Costin G.-E., Villano C, Bader J, Krawiec L, Sly E, Gould J. Evaluation of a tiered 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.