ROBIN LEE GELLER, Ph.D.
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EXECUTIVE PROFILE

An accomplished scientific professional with continuously increasing responsibility inside both start-up and established global biomedical corporations. Extensive research, scientific assessment, quality, regulatory affairs and pharmacovigilance experience in Drugs, Biologics and Academia. Strong combination of analytic, strategic and technical skills provides unique insights to enhance technical development and achieve successful business solutions in complex and highly matrixed organizations.

EMPLOYMENT

Baxter Healthcare Corporation, Deerfield IL 2001-2014

DIRECTOR OF PHARMACOVIGILANCE INTELLIGENCE AND SAFETY WRITING 2011-2014

- Creation and implementation of Pharmacovigilance intelligence function
  - Collect, analyze and disseminate regulatory intelligence information concerning pharmacovigilance globally
  - Coordinate and author responses to Regulatory Authorities globally concerning proposed changes affecting PV
  - Report to PV Management Team on evolving areas of policy of strategic importance (e.g., new EU PV legislation)
  - Develop and deliver training materials to PV staff on new PV regulations and guidance documents
  - Act as Liaison for external benchmarking groups (e.g., PV Connect)
  - Privacy Officer
- Creation and implementation of strategic SOPs and CQPs for Global Pharmacovigilance
- Oversight of SOPs for PV
- Management of safety writing teams in the US and Europe
- Member of the PV Leadership team
- Lead implementation of 2010 EU PV legislation at Baxter

DIRECTOR OF RISK MANAGEMENT AND SAFETY WRITING 2009-2010

- Creation and implementation of drug and biologic risk management process

- Successful submission of >25 EU Risk Management Plans and REMS
- Oversight of risk management plans for drug and biologic products including implementation of risk minimization activities
- Creation and implementation of SOPs for Global Pharmacovigilance including CQP for Pharmacovigilance Risk Management
- Management of safety writing teams in the US and Europe

DIRECTOR OF RISK MANAGEMENT 2004-2009

- Creation and implementation of drug and biologic risk management process
- Successful submission of EU Risk Management Plans
- Oversight of risk management plans for drug and biologic products including implementation of risk minimization activities
- Creation and implementation of SOPs for Global Pharmacovigilance
- Development and implementation of signal detection process for Global Pharmacovigilance

SENIOR DIRECTOR NEW TECHNOLOGIES 2001-2004

- Manage Cellular Therapies quality and regulatory activities as the liaison with other Baxter Divisions
- Oversee North American Operations for Cellular Therapies
- Manage clinical relationship with NIH directed toward pivotal trial for use of Isolex for treatment of autoimmune disease
- Evaluate businesses and technologies for new opportunities and potential acquisitions of Biologics and Cellular Therapies
- Manage R&D projects

Cytomedix, Inc. Deerfield, IL 2000-2001

VICE PRESIDENT OF SCIENCE & TECHNOLOGY 2000-2001

- Developed and implemented all regulatory and quality strategies for both device and biologic products
- Completed 510(k) application for new medical device and pre-IND package for new biologic product
- Instrumental in negotiating acquisition of a wound care product which brought in significant intellectual property
- Instrumental in negotiating an out-licensing agreement of intellectual property with a major medical device company
- Managed the Intellectual Property Portfolio
- Directed strategies to obtain reimbursement and submitted application to HCFA for reimbursement

- Supervised 30 blood processing facilities, three QC laboratories, 3 direct reports, and 40 employees

Baxter Healthcare Corporation-Summary 1993-2000

- Developed regulatory and manufacturing strategies for recombinant product
- Led project development from initial exploratory experiments to completion of an Investigational New Drug (IND) application with the FDA in four years
- Conducted analysis of global regulatory environment concerning comparability and equivalence for biological products
- Instrumental in product planning and development, quality assurance, assay development, program management and preparation for regulatory filings for TheraCyte
- Conducted Quality System audits of Biotech facilities, participated in BLA preparation, process validation and preparation for preapproval inspection for recombinant protein product

ASSOCIATE DIRECTOR REGULATORY AND CLINICAL AFFAIRS 1997-2000

- Collaborated to develop next generation recombinant protein product including development of alternative manufacturing and regulatory strategies
- Conducted analysis of global regulatory environment concerning comparability and equivalence for biological products
- Served as corporate resource person on global developments concerning Transmissible Spongiform Encephalopathies
- Co-led team to develop global strategic sourcing plan for use of Contract Research Organizations
- Assisted in preparation for licensure of recombinant protein manufacturing facility including preparation of Master Validation Plan and Process Validation Plans
- Assessed technology of potential acquisitions for corporate business development group including regulatory and R&D strategies

SENIOR ASSESSMENT MANAGER CORPORATE QUALITY SYSTEMS 1997

- Participated in assessment teams that evaluated the adequacy and effectiveness of the quality systems implemented by the operating units, identified potential regulatory and quality risks and reported results to senior management
- Provided advice and consultation on GMP, regulatory and technical issues to operating units and senior management

SENIOR RESEARCH SCIENTIST, RESEARCH SCIENTIST GENE THERAPY UNIT 1993-1997

- Initiated studies on the use of a bioartificial organ (the TheraCyte™ system) for tumor immunotherapy which involved development of new animal models and experimental approaches

- Demonstrated that an immunoisolation device which prevents direct contact between the immunizing cells and the immune system of the host can be used both for the prevention of tumor formation and for the treatment of existing neoplasias
- Supervised the activities of two research associates and three research assistants and served as the interface with clinical and academic collaborators
- Developed project from conception to the preparation of documentation for production of GMP cell lines and for the filing of an Investigational New Drug (IND) application with the FDA to initiate clinical trials, which has been accepted. Byproducts of this work have led to the development of in vitro quality assurance assays at significant cost savings and to the development of peripherals such as loading and processing systems necessary for the clinical procedures.

University of Minnesota-Summary **1986-1992**

- Held faculty positions in the departments of Laboratory Medicine and Pathology and Pediatrics Completed contract work with Baxter Healthcare Corporation and for patent filing
- Developed monoclonal antibodies for use in understanding xenograft rejection

RESEARCH ASSOCIATE, DEPARTMENT OF PEDIATRICS 1990-1992
(In the laboratory of Dr. Jeffrey Platt, University of Minnesota)

- Developed monoclonal antibody reagents to study idiotype expression of human naturally occurring antibodies and endothelial cell activation antigens which involved both the generation of hybridomas and the screening of the resulting products by ELISA and Western blot analysis
- Initiated several projects examining the role of natural antibodies and complement in xenotransplant rejection
- Initiated and carried out the first demonstration that there was variability in the expression of major target antigens mediating xenorejection
- Supervised the activities of several undergraduate researchers and managed the day to day activities in the lab

RESEARCH ASSOCIATE AND POSTDOCTORAL FELLOW 1986-1990
Department of Laboratory Medicine and Pathology
(In the laboratory of Dr. Fritz Bach, University of Minnesota)

- Utilized an in vitro model system to examine the stepwise activation of T lymphocytes
- Developed expertise in the techniques of cellular immunology including purification and short- and long-term culture of T lymphocytes as well as the standard assays for measuring lymphocyte proliferation, cytotoxicity and cytokine production
- Established laboratory methods for the use of the FACScan

RISK MANAGEMENT PRESENTATIONS (Selected)

2013

- World Drug Safety Congress

2012

- Global Pharmacovigilance and Adverse Event Reporting Forum-presentation
- World Drug Safety Congress-workshop and panel
- DIA risk management confernce-organizing committee member

2011

- DIA Annual Meeting-presentation
- Global Pharmacovigilance and Adverse Event Reporting Forum-panel and presentation
- World Drug Safety Congress-workshop and panel

2010

- Great Lakes cGMP & Regulatory Science Forum-presentation
- World Drug Safety Congress-presentation

2009

- Pacific Drug Safety Congress-presentation
- World Drug Safety Congress-presentation
- Pharmacovigilance and Risk Management-VIB forum-presentation

2008

- European Biopharmaceutical Enterprises-presentation

OTHER PROFESSIONAL EXPERIENCE

Ad hoc reviewer	*Cancer Prevention and Detection*	1999-2005
Ad hoc reviewer	*Journal of Immunology*	1997-2005
Adjunct Assistant Professor	University of Illinois, Chicago	1996-2006
Editorial board	*Transplantation*	1996-2003
Ad hoc reviewer	*Transplantation*	2004-2006
Ad hoc grant reviewer	NIAID	1994
Book/Video reviewer	*Science Books and Films*, AAAS	1986-present
Lecturer	Calif. State Univ. Dominguez Hills	1984-1985

EDUCATION

University of CA, Berkeley, Genetics, A.B. 1976
University of WI, Madison, Molecular Biology, Ph.D. 1981
Thesis: Repair of a calcium- dependent adhesive system on embryonic neural retina cells.

POSTDOCTORAL TRAINING

Harbor/UCLA Medical Center, Medical Genetics	1981-1985
University of Minnesota, Immunology	1986-1989

HONORS AND PROFESSIONAL SOCIETIES

University of California Alumni Scholarship	1972
Graduate, U.C. Berkeley, Magna Cum Laude	1976
Wisconsin Alumni Research Foundation Fellowship	1976-1977
National Science Foundation Pre-doctoral Fellowship	1977-1980
National Institutes of Health Post-doctoral Fellowship	1983-1985
Minnesota Medical Foundation Grant	1991-1992
Transplantation Society Travel Award	1992
AAAS, Member	1985-present
American Association of Immunology, Member	1992-present
DIA, member	2005-present

PATENTS

Method of enhancing the immunotherapeutic activity of immune cells by depletion of CD8+ T cells. Patent number: US5641677. Inventors: Augusto C. Ochoa, **Robin L. Geller** and Fritz H. Bach. Issued: 1997.

Ported tissue implant systems and methods of using same. Patent number US5733336. Inventors: Steven Neuenfeldt, James Brauker, Robert Clarke and **Robin Lee Geller**. Issued: 1998.

Implantation assembly. Patent number US5964261Inventors: Steven Neuenfeldt, Joanne Daugird, James Brauker, **Robin Geller**, Scott Fredricksen, Mark Jones, Tom Loudovaris, David Maryanov and Stephanie Shors. Issued: 1999.

Implanted tumor cells for the prevention and treatment of cancer. Patent number US6156305. Inventors: James H. Brauker, **Robin L. Geller**, William Johnston, Steven Levon and David Maryanov. Issued: 2000.

Implanted tumor cells for the prevention and treatment of cancer. Inventors: James H. Brauker, **Robin L. Geller**, David Maryanov, Steven Levon and William Johnston. Application number: 08/462,252. Patent pending.

Tissue loading system for implantable biological devices. Inventors: Steven Neuenfeldt, **Robin Geller**, Tom Loudovaris and James H. Brauker. Application number: 08/464,942. Patent Pending.

Closed system for primary tumor processing. Inventors: **Robin Geller**, Steven Neuenfeldt, Mark Jones and Dave Maryanov. Application number: Not yet assigned. Patent Pending.

Implantatable Drug Delivery System. Inventors: **Robin Geller**, Ashish Jhingan and James H. Brauker. Application Number: Not yet assigned. Patent Pending

PUBLICATIONS

Grunwald, GB, **Geller, RL** and J. Lilien (1980) Enzymatic dissection of embryonic cell adhesive mechanisms. J. Cell Biol. 85:766-776

Geller, RL and J. Lilien (1983) Repair of a calcium-dependent adhesive mechanism of embryonic neural retina cells. Kinetic and molecular analysis. J. Cell Sci. 60:29-49.

Lusis, AJ, Heinzmann, C, Sparkes, RS, Scott, J, Knott, TJ, **Geller, R**, Sparkes, MC, and TK Mohandas (1986) Regional mapping of human chromosome 19: organization of genes for plasma lipid transport (APO-C1, -C2, and -E and LDLR) and the genes C3, PEPD and GPI. Proc. Natl. Acad. Sci. USA 83:3929-3933.

Geller, RL, Shapiro, LJ and TK Mohandas (1986) Fine mapping of the distal short arm of the human X chromosome using X/Y translocations. Am. J. Hum. Gen. 38:884-890.

Gromo, G, **Geller, RL**, Inverardi, L, Wee, S-L, and FH Bach (1987) Role of CD2 and IL1-? in T cell responsiveness to IL2. J. Immunol. 138:2155-2160

Gromo, G, **Geller, RL**, Inverardi, L, and FH Bach (1987) Signal requirements in the step-wise functional maturation of cytolytic T lymphocytes. Nature 327:424-426.

Mohandas, T, **Geller, RL**, Yen, PH, Rosendorff, J, Bernstein, R, Yoshida, A and LJ Shapiro (1987) Cytogenetic and molecular studies on a recombinant human X chromosome: Implications for the spreading of X chromosome inactivation. Proc. Natl. Acad. Sci. USA. 84:4954-4958.

Gromo, G, Inverardi, L, **Geller, RL**, Alter, BJ and FH Bach (1987) The step-wise activation of cytolytic T lymphocytes. Immunol. Today 8:259-261.

Geller, RL, Gromo, G, Inverardi, L, Ferrero, E and FH Bach (1987) Step-wise activation of T cells: Role of the calcium ionophore A23187. J. Immunol. 139:3930-3934.

Inverardi, L, **Geller, RL**, Gleason, J and G Gromo (1988) Anti-CD2 monoclonal antibodies and calcium ionophore A23187 modulate lytic activity in CD4+ and CD8+ alloreactive clones. J. Immunol. 140:2876-2879.

Gromo, G, Inverardi, L, **Geller, R**, Knapp, W. and FH Bach (1988) T cell activation along an alternative pathway. Annals of the New York Academy of Sciences S32:444-446.

Gromo, G, Inverardi, L, **Geller, RL**, Schoenheit, A, and FH Bach (1988) Minimal signals and step-wise maturation of cytotoxic T cells. Transplant Proc. 20:296-297.

Bach, FH, **Geller, RL**, Nelson, PJ, Panzer, S., Gromo, G., Benfield, MR, Inverardi, L., Podack, ER, Witson, JC., Houchins, JP, and BJ Alter (1989) A "minimal signal-stepwise activation" analysis of functional maturation of T lymphocytes. Immunol. Rev. 111:35-57.

Panzer, S, **Geller, RL**, and FH Bach (1990) Purified human T cells stimulated with crosslinked anti-CD3 monoclonal antibody OKT3: rIL-1 is a costimulatory factor for CD4+CD45RO+ T cells. Scand. J. Immunol. 32:359-371.

Geller, RL, Smyth, MJ, Strobl, SL, Bach, FH, Ruscetti, FW, Longo, DL and AC Ochoa (1991) Generation of lymphokine-activated killer activity in T cells: Possible regulatory circuits. J. Immunol. 146:3280-3288.

Platt JL, Lindman BJ, **Geller RL**, Noreen HJ, Swanson, JL, Dalmasso AP and FH Bach (1991) The role of natural antibodies in the activation of xenogenic endothelial cells. Transplantation. 52:1037-1043.

Nelson, PJ, **Geller, RL**, Podack, E, and FH Bach (1992) Molecular events in late stages of T cell functional maturation. Scand. J. Immunol. 35:311-320.

Geller, RL. (1992) The role of crosslinking in stepwise activation of T cells. Scand. J. Immunol. 35:327-334.

Nelson, P, **Geller, RL** and FH Bach (1992) Gene expression in CD8 and CD4 T cell populations following activation with the calcium ionophore A23187. Scand. J. Immunol. 35:611-619.

Geller, RL, Bach, FH, Vercellotti, GM, Nistler, RS, Bolman, RM, Fischel, RJ, Leventhal, J and JL Platt (1992) Activation of endothelial cells in hyperacute xenograft rejection. Trans. Proc. 24:592.

Geller, RL, Turman, M, Bach, FH and JL Platt (1992) Deposition of polyreactive antibodies in xenograft rejection: detection using anti-idiotype monoclonal antibodies. Trans. Proc. 24:595.

Geller, RL, Turman, MA, Dalmasso, AP and JL Platt (1992) The natural immune barrier to xenotransplantation. JASN. 3:1189-1200.

Geller, RL, Bach, FH, Turman, MA, Casali, P and JL Platt (1993) Polyreactive antibodies are deposited in rejected discordant xenografts. Transplantation. 55:168-172.

Geller, RL, Ihrcke, N, Maines, J, Lindman, B and JL Platt (1993) Loss of heparan sulfate proteoglycan as a manifestation of cellular immunity in vivo and in vitro. Trans. Proc. 25:144-45.

Geller, RL, Ihrcke, N, and JL Platt. (1994) The release of endothelial cell associated heparan sulfate proteoglycan by activated T cells. Transplantation. 57:770-773.

Geller, RL, Rubinstein, P and JL Platt. (1994) Variation in expression of gp115/135 on porcine platelets. Trans. Proc. 26:1381.

Geller, RL, Rubinstein, P and JL Platt. (1994) Variation in expression of porcine xenogeneic antigens. Transplantation. 58:272-277.

Carr-Brendel, VE, **Geller, RL**, Thomas, TJ, Boggs, DR, Young, SK, Crudele, J, Martinson, LA, Maryanov, DA, Johnson, RC and JH Brauker. (1997) Transplantation of cells in an immunoisolation device for gene therapy. In: Methods in Molecular Biology, volume 63 (ed. Rocky S. Tuan). Humana Press, Totowa NJ. .

Geller, RL, Neuenfeldt, S, Levon, SA, Maryanov, DA, Thomas, TJ and JH Brauker. (1997) Immunoisolation of tumor cells: generation of anti-tumor immunity through indirect presentation of antigen. J. Immunother. 20:131-137.

Geller, RL, Loudovaris, T, Neuenfeldt, S, Johnson, RC and JH Brauker. (1997) Use of an immunoisolation device for cell transplantation and tumor immunotherapy. Ann. New York Acad. Sci. 831: 699-721.