James E. McCormack, Ph.D.

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Biotechnology Consultant

Preclinical Research Assay Design Project Management Education/Training

Summary:

Consultant providing advice and assistance for biotechnology companies on a variety of issues, from basic research to regulatory filings Established manager, innovative researcher with broad scientific background 20 yr research experience, > 7 yr as supervisor/manager Expertise in immunology, molecular biology, gene therapy, animal modelling Experience with immunotherapy, autoimmunity, and inflammatory diseases Extensive experience as an educator

Education and Honors:

Ph.D. in Biochemistry

Boston University Graduate School

--Recipient of a National Science Foundation Graduate Fellowship

Bachelor of Science

Massachusetts Institute of Technology

--Certified high school teacher of physics, biology, mathematics

Professional Experience:

Independent Consultant

2000 - present

- Associate of Merchant-Taylor International, a consulting group specializing in clinical trial design and preparation of regulatory filings
- Program development, instructor coaching for Biosciences division, UCSD Extension;
 - -- Taught classes in virology, immunology
 - -- Developed course for personnel moving from academic research to industry
- Immunology training for assay development personnel at Amgen
- Technical, regulatory assistance for a client firm developing a recombinant protein; emphasis on immunology, assay development in preparation of IND filing

The Paik-Inje Memorial Institute

San Diego, CA 1999 - 2000

CONSULTANT; SCIENTIFIC DIRECTOR

Scientific and managerial direction for an independent research institute focused on immune responses in transplantation.

- Formulated a five-year plan for growth and development of this new institute
- Provided scientific direction, and served as laboratory manager
- Guided internal research program, and established external collaborations

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Chiron Technologies Center for Gene Therapy

San Diego, CA 1994 - 1998

RESEARCH SCIENTIST II

Successfully directed and executed research characterizing immune responses associated with retroviral vector gene therapy. Contributed to multiple projects in a dynamic environment.

- Directed preclinical research characterizing in vivo correlates of activity for HIV immunotherapeutic treatment.
- Managed collaborative studies testing feasibility of gene therapy for inflammatory diseases, such as rheumatoid arthritis.
- Developed protocols for analysis and prevention of immune reactions associated with gene therapy.
- Supervised postdoctoral fellows, research associates, summer interns, and vivarium staff.
- Initiated, coordinated cross-team discussion group to address issues common to R&D groups within the company
- Nine manuscripts published; two patent applications submitted

Howard Hughes Medical Institute POST-DOCTORAL FELLOW

Laboratory of Drs. Philippa Marrack and John Kappler 1987 - 1994

Research focusing on balance between T cell activation and peripheral tolerance

Further work on *in vivo* effects of superantigens; thymocyte development; thymic microenvironment

Boston University School of Medicine GRADUATE STUDENT

Laboratory of Dr. Gail E. Sonenshein 1982 - 1987

Research focusing on regulation of expression of the *c-myc* proto-oncogene

Management Training:

2000-present Project Management certification program at UCSD Extension

1997-98 Microsoft Project

1997 Trac 5000 management training

1994-1995 Zenger-Miller Frontline Leadership course

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Publications and Patents:

Patents Pending

McCormack, J.E., J. Kappler, B. Kotzin and P. Marrack, "Method of Treatment of Disease by Deletion of T Cells" (WO9423734)

- McCormack, J.E., S. Chada, and D. Jolly, "Compositions and Methods for Treating Arthritis Utilizing Gene Therapy" (WO9911292)
- McCormack, J.E., D. Jolly, et al., "Use of Submicron Oil-In-Water Emulsions with DNA Vaccines"

Publications

- Del Vecchio, M.A., H.I. Georgescu, J.E. McCormack, P.D. Robbins and C.H. Evans, "Approaches to Enhancing the Retroviral Transduction of Human Synoviocytes", Arthritis Res. **3:**259-263 ('01).
- McCormack, J.E., W. Edwards, J. Sensintaffer, L. Lillegren, M. Kozloski, D. Brumm, L. Karavodin, D.J. Jolly and J. Greengard, "Factors Affecting Long-Term Expression of a Secreted Transgene Product After Intravenous Administration of a Retroviral Vector", Mol. Therapy **3:**516-525 ('01).
- Sheridan, P.L., M. Bodner, A. Lynn, T.K. Phuong, N.J. DePolo, D.J. de la Vega, J. O'Dea, K. Nguyen, J.E. McCormack, D.A. Driver, K. Townsend, C.E. Ibañez, N.C. Sajjadi, J.S. Greengard, M.D. Moore, J. Respess, S.M.W. Chang, T.W. Dubensky, D.J. Jolly and S.L. Sauter, "Generation of Retroviral Packaging and Producer Cell Lines for Large Scale Vector Production and Clinical Application: Improved Safety and High Titer", Mol. Therapy 2:262-275 ('00).
- Boyle, D.L., K.H.Y. Ngugyen, S. Zhuang, Y. Shi, J.E. McCormack, S. Chada and G.S. Firestein, "Intraarticular IL-4 Gene Therapy in Arthritis: Anti-Inflammatory Effect and Enhanced Th2 Activity", Gene Therapy **6:**1911-1918 ('99).
- Nguyen, K.H.Y., D.L. Boyle, J. McCormack, S. Chada and G.S. Firestein, "Direct Synovial Gene Transfer with Retroviral Vectors in Rat Adjuvant Arthritis", J. Rheumatol. **25**:1118-1125 ('98).
- Hariharan, M.J., D.A. Driver, K. Townsend, D. Brumm, J.M. Polo, B.A. Belli, D.J. Catton, D. Hsu, D. Mittelstaedt, J. E. McCormack, L. Karavodin, T.W. Dubensky, S.M.W. Chang and T. A. Banks, "DNA Immunization against a Herpes Simplex Virus: Enhanced Efficiency Using a Sindbis Virus-Based Vector", J. Virol. **72**:950-958 ('98).
- Ghiviazzani, S.C., E.R. Lechman, C. Tio, K.M. Mulé, S. Chada, J.E. McCormack, C.H. Evans and P.D. Robbins, "Direct Retrovirus-Mediated Gene Transfer to the Synovium of the Rabbit Knee: Implications for Arthritis Gene Therapy", Gene Therapy **4:**977-982 ('97).
- McCormack, J.E., D. Martineau, N. DePolo, S. Maifert, L. Akbarian, K. Townsend, W. Lee, M. Irwin, N. Sajjadi, D.J. Jolly and J. Warner, "Anti-Vector Immunoglobulin Induced by Retroviral Vectors", Hum. Gene Ther. **8:**1263-1273 ('97).
- Martineau, D., W.M. Klump, J.E. McCormack, N.J. DePolo, E. Kamantigue, M. Petrowski, J. Hanlon, D.J. Jolly, S.J. Mento and N. Sajjadi, "Evaluation of PCR and ELISA Assays for Screening Clinical Trial Subjects for Replication-Competent Retrovirus", Hum. Gene Ther. **8:**1231-1241 ('97).

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Barbo, J.V., J.E. McCormack, J.W. Moorhead and R.L. Fairchild, "Reconstitution of TCR alpha-chain expression in deletion mutants restores dinitrophenyl-specific/class I MHC-restricted suppressor molecule production", J. Immunol. **154:**1551-1559 ('95).

- Vella, A.T., J.E. McCormack, P.S. Linsley, J.W. Kappler and P. Marrack, "Lipopolysaccharide Interferes with the Induction of Peripheral T Cell Death", Immunity **2**:261-270 ('95).
- McCormack, J.E., J. Kappler and P. Marrack, "Stimulation with Specific Antigen Can Block Superantigen-Mediated Deletion in vivo", Proc. Natl. Acad. Sci. USA **91:**2086-2090 ('94).
- Hugo, P., J.W. Kappler, J.E. McCormack and P.C. Marrack, "Fibroblasts can induce thymocyte positive selection *in vivo*", Proc. Natl. Acad. Sci. USA **90**:10335-10339 ('93).
- McCormack, J.E., J.E. Callahan, J. Kappler and P. Marrack, "Profound Deletion of Mature T Cells in vivo by Chronic Exposure to Exogenous Superantigen", J. Immunol. **150**:3785-3792 ('93).
- Spencer, J.S., J.E. McCormack, and R.T. Kubo, "Characterization of Defective I-A Surface Expression in a Mixed Isotype Expressing B Cell Lymphoma: Continued expression of $E\alpha^d A\beta^d$ despite competition from $A\alpha^d A\beta^d$ pairs.", Int. Immunol. **4**:905-915 ('92).
- McCormack, J.E., T. Wade, H. Morales, J. Kappler and P. Marrack, "Analysis of Class II MHC Structure in Thymic Nurse Cells", Cell. Immunol. **138:**413-422 ('91).
- Maheswaran, S., J.E. McCormack, and G.E. Sonenshein, "Changes in Phosphorylation of myc Oncogene and RB Antioncogene Protein Products During Growth Arrest of the Murine Lymphoma WEHI 231 Cell Line", Oncogene **6:**1965-1971 ('91).
- McCormack, J.E., J. Kappler, P. Marrack and J.Y. Westcott, "Production of Prostaglandin E₂ and Prostacyclin by Thymic Nurse Cells in Culture", J. Immunol. **146**:239-243 ('91).
- Marrack, P., J. McCormack and J. Kappler, "Presentation of antigen, foreign major histocompatibility complex proteins and self by thymus cortical epithelium", Nature **338**:503-505 ('89).
- Marrack, P., M. Blackman, H.-G. Burgert, J. McCormack, J. Cambier, T.H. Finkel and J. Kappler, "T-cell Repertoire and Thymus", Cold Spring Harbor Symp. Quant. Biol. **LIV:**105-110 ('89).
- Kindy, M.S., J.E. McCormack, A.J. Buckler, R.A. Levine and G.E. Sonenshein, "Independent Regulation of Transcription of the Two Strands of the c-myc Gene", Mol. Cell. Biol. **7:**2857-2862 ('87).
- Levine, R.A., J.E. McCormack, A. Buckler, and G.E. Sonenshein, "Transcriptional and Posttranscriptional Control of c-myc Gene Expression in WEHI 231 Cells", Mol. Cell. Biol. **6:**4112-4116 ('86).
- McCormack, J.E., V.H. Pepe, R.B. Kent, M. Dean, A. Marshak-Rothstein and G.E. Sonenshein, "Specific regulation of c-myc oncogene expression in a murine B cell lymphoma", Proc. Nat'l. Acad. Sci. USA 81: 5546-5550 ('84).
- McCormack, J.E., R.B. Kent, V.H. Pepe, M. Dean, A. Marshak-Rothstein, and G.E. Sonenshein, "Immune regulation of the c-myc oncogene in a murine B lymphoma", Curr. Top. Micro. Immunol. **113**:127-132 ('84).
- Sonenshein, G.E. and J.E. McCormack, "Glycosylation and secretion of an altered immunoglobulin heavy chain in mouse myeoloma MOPC 315", J. Immunol. **129:**2559-2563 ('82).