SEAMUS MCMILLAN

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Pharmaceutical Project Management, Clinical Trials, Education, Pharmacoeconomics

CAREER ASPIRATIONS

To Utilize My Diverse Background And Skills In An Interdisciplinary Environment.

- Effective Project Management across different healthcare related disciplines and perceptions.
- Clinical trials data analysis, review and management.
- Development of drug education programs for physicians, healthcare providers and third party payers, including content research, disease progression models, and authoring.
- Pharmacoeconomics, including cost effectiveness comparisons and sensitivity analyses.
- Research, analysis and strategic planning.
- Computer based multimedia programming for healthcare, including patient education, health promotion and physician CME.

SKILLS AND EXPERIENCE

Research Fellow, Development Leader and Consultant successful in diverse academic and commercial environments. Combines strong skills as a project manager with a sensitivity to the needs of both the business and academic communities. A proven technical leader with a history of identifying, developing and bringing to market valuable technologies and educational programs. Productive, innovative and committed to results. Skills and experience include:

- Commercial product development
- Pharmacoeconomic analyses and models
- Project management
- Multimedia patient and physician (CME) education
- Disease progression algorithms and models
- Technical and Customer Service management
- Content development for clinical programs
- Physician and Provider education for novel drug applications
- Team leadership and personnel management
- Marketing, strategic planning and budget planning
- Technology transfer and patent analyses
- Biomedical research and development

CAREER HISTORY

Independent Consultant, Eden Prairie, MN (1996 - Present)
Past activities have included CD-ROM content development for major pharmaceutical companies, CD-ROM programming for commercial clients in both healthcare and other industries, and web site design and development for both commercial and non-profit clients. Recent projects include a Patient Education CD-ROM program and a CME CD-ROM, both for the University of Minnesota, as well as content and algorithm development for various pharmacoeconomic analyses such as cost-effectiveness, sensitivity analyses, and risk management.

Second Source Alliance, Eden Prairie, MN (1997 - 2001)
Executive Director
Cofounded this non-profit organization. Second Source Alliance had two primary goals; the development of interactive multimedia patient education materials to support those suffering from serious chronic or incurable diseases, with particular emphasis on emotional support, and disease prevention and health promotion for low literacy groups.

Division of Health Computer Sciences, University of Minnesota, MN (1994 to 1996)

National Library of Medicine Fellow

Significant experience and learning gained in patient informatics and resources, multimedia development, patient education and support, healthcare communications for low literacy audiences, instructional design, network management, web authoring, computer interface design, and program evaluation.

Delphi Associates Inc., Eden Prairie, MN (1993 - Present)

Principal

A diversified consultancy that has steadily expanded its services and client base over the years. The company focuses primarily on healthcare applications, which include educational programming for physicians, patients and medical students, and the development of programs, models and algorithms for pharmacoeconomic cost effectiveness analyses. The latter includes drug-drug comparisons and sensitivity analyses for drug utilization.

Sanofi Diagnostics Pasteur Inc., Chaska, MN (1990 - 1992)

Director of Immunology, Research and Development

A $70 million developer and marketer of diagnostic products and instruments.

Directed all new product development and R&D support of existing products in the Immunology business group, one of the company's three major market segments, with $20 million in annual revenues. Responsible for strategic planning leading to a 30% budget increase, including review and assessment of novel technologies from academia as candidates for technology transfer. Managed three direct reports and supervised a department of 12; managed a budget of $1.7 million.

LipoGen Inc., Knoxville, TN (1987 -1990)

Director, Diagnostic Product Development (1989 - 1990)

Project Manager, Diagnostics (1988 -1989)

Senior Scientist (1987 - 1988)

A start-up company, specializing in autoimmune diagnostics and the therapeutic uses of liposomes.

One of two Project Managers responsible for the scientific development and successful commercialization of the first recombinant autoimmune diagnostic products; assumed positions of increasing responsibility for the commercialization of all diagnostic products. Responsibilities also included development of manufacturing and QC procedures (SOPs, GMP, etc.) and assistance with FDA compliance and 510k submissions. Supervised two professional groups, with a total of eight scientists and technicians. Managed a department budget approaching $1 million.

Cooper Biomedical Inc., Malvern, PA (1985 - 1987)

Scientist

An *in vitro* diagnostics company focused on automated laboratory analyzers and solid phase immunodiagnostics.

Developed solid phase (latex) enhanced immunonephelometric assay for rubella. Also worked briefly on one of the first solid phase confirmatory assays for HIV (HTLV-III) antibodies.

Scripps Clinic and Research Foundation, La Jolla, CA (1982 to 1984)

Research Associate

Responsible for the development of the first synthetic idiotypes using murine anti-dextran antibodies and synthetic peptide technology.

Stanford University School of Medicine, Palo Alto, CA (1980 to 1982)

Post-Doctoral Fellow

Jointly responsible for the first demonstration of two distinct catalytic activities on a single enzyme molecule, the *denV* UV endonuclease of bacteriophage T4.

Career also includes additional positions as a research technician and medical technologist in the UK. My graduate work focused on the mechanisms of mutagenesis and DNA repair in cultured mammalian somatic cells.

EDUCATION

National Library of Medicine Fellow (1994 to 1996), Health Informatics,
Division of Health Computer Sciences, University of Minnesota, Minneapolis.

Post-Doctoral Fellow (1980 to 1982), Laboratory for Experimental Oncology, Department of Pathology,
Stanford University Medical Center, Stanford, California.

Doctor of Philosophy (1980), Department of Experimental Oncology, Faculty of Medicine,
Victoria University of Manchester, Manchester, United Kingdom.

Master of Science (1977), Department of Experimental Oncology, Faculty of Medicine,
Victoria University of Manchester, Manchester, United Kingdom.

Bachelor of Arts with First Class Honors (1977), Faculty of Science, The Open University,
Milton Keynes, United Kingdom. **Emphasis: Biological Sciences**

General Bachelor of Arts (1974), The Open University, Milton Keynes, United Kingdom.

Higher National Certificate - Medical Laboratory Sciences (1970), John Dalton College of Technology, Manchester, United Kingdom.

Continuing Professional Education:

Includes training in management practices; finance and accounting; organizational communications; marketing strategies; quality control; and FDA regulations.

AWARDS:

Damon Runyon - Walter Winchell Cancer Foundation (New York),
Research Fellow, 1980 to 1982.

National Library of Medicine Training Grant in Medical Informatics,
Fellow, 1994 - 1996.

RECENT AND CURRENT PROFESSIONAL MEMBERSHIPS:

American Association for the Advancement of Science

American Association of Bioethics

International Interactive Communications Society.

OTHER ACTIVITIES:

Member, Minnesota Commissioner of Health's Task Force on HIV/STD Prevention Planning,
2001 - Present.

Member, Board of Directors, Twin Cities Schools Telecommunications Group, 1997 - 2001.

Member, Ad Hoc Technology Committee, Eden Prairie School District. 1996 - 1999.

Past service on various NIH SBIR Scientific Review Committees for healthcare related multimedia proposals.

INVITED PRESENTATIONS:

McMillan S., "The Patient-Computer Interface"
University of Minnesota Health Informatics Seminar Series, March 6th, 1997.

Doherty L. and McMillan S., "Human Growth and Development: A CD-ROM CME Program for Primary Care Physicians"
University of Minnesota Health Informatics Seminar Series, September 20th, 2001.

References and Publications are available on request.

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Publications

Articles:

Fox M. and McMillan S., Relationship between caffeine sensitive and resistant DNA repair, cell lethality and mutagenesis in mammalian cells after X-rays and alkylating agents.
Studia Biophysica **61** (1977) 71 - 79

Fox M. and McMillan S., Evidence for the involvement of different repair mechanisms in mutagenesis and cell killing in V79 cells.
In: "DNA Repair Mechanisms", Eds: Hanawalt P. C., Friedberg E. C. and Fox C.F.
Academic Press (1978) 723 - 727.

McMillan S. and Fox M., Failure of caffeine to influence induced mutation frequencies and the independence of cell killing and mutation induction in V79 Chinese hamster cells.
Mutation Res. **60** (1979) 91 - 107 [Abstract]

Suter W., Brennand J., McMillan S. and Fox M., Relative mutagenicity of antineoplastic drugs and other alkylating agents in V79 Chinese hamster cells; independence of cytotoxic and mutagenic responses.
Mutation Res. **73** (1980) 171 - 181 [Abstract]

McMillan S. and Fox M., Effects of metabolic inhibitors on cell lethality and mutation induction in Chinese hamster cells.
I. Inhibitors of *de novo* purine synthesis and a comparison with the effects of caffeine.
Chem.-Biol. Interactions **36** (1981) 71 - 88 [Abstract]

Brennand J., McMillan S. and Fox M., Effects of metabolic inhibitors on cell lethality and mutation induction in Chinese hamster cells.
II. The effect of post-treatment with non- toxic concentrations of thymidine.
Chem.-Biol. Interactions **36** (1981) 89 - 106 [Abstract]

Friedberg E. C., Bonura T., Love J. D., McMillan S., Radany E. H. and Schultz R. A., The repair of DNA damage: Recent developments and new insights.
J. Supramolec. Struct. Cell. Biochem. **16** (1981) 91 - 103 [Abstract]

McMillan S., Edenberg H. J., Radany E. H., Friedberg R. C. and Friedberg E. C., The *denV* gene of bacteriophage T4 codes for both pyrimidine dimer-DNA glycosylase and apyrimidinic endonuclease activities.
J. Virol. **40** (1981) 211 - 223 [Abstract]

Bonura T., Radany E. H., McMillan S., Love J. D., Schultz R., Edenberg H. and Friedberg E. C., Pyrimidine dimer-DNA glycosylases: Studies on bacteriophage T4 infected and on uninfected *Escherichia coli*.
Biochimie **64** (1982) 643 - 654 [Abstract]

Fox M., McMillan S., Durrant L. and Boyle J. M., Relative sensitivity of V79 and V79/79 cells to spontaneous and induced mutation to 6-thioguanine and ouabain resistance.
Mutation Res. **95** (1982) 339 - 352 [Abstract]

McMillan S., Seiden M. V., Houghten R. A., Clevinger B., Davie J. M. and Lerner R., Synthetic idiotypes: The third hypervariable region of murine anti-dextran antibodies.
Cell **35** (1983) 859 - 863 [Abstract]

Seiden M. V., Clevinger B., Srouji T., Davie J. M., McMillan S. and Lerner R., A synthetic peptide induces a new anti-dextran idiotype.
Ann. Immunol. **135C** (1984) 77 - 82 [Abstract]

Seiden M. V., Clevinger B., McMillan S., Srouji A., Lerner R. and Davie J. M., Chemical synthesis of idiotopes: Evidence that antisera to the same JH1 peptide detect multiple binding site-associated idiotopes.
J. Exp. Med. **159** (1984) 1338 - 1350 [Abstract]

Seiden M. V., Heuckeroth R., Clevinger B., McMillan S., Lerner R. and Davie J. M., Hypervariable region peptides variably induce specific anti-idiotypic antibodies: An approach to determining antigenic dominance.
J. Immunol. **136** (1986) 582 - 587 [Abstract]

McMillan S., Literacy and Computer Literacy: Definitions and Comparisons.
Computers Educ. **27** (1996) 161 - 170 [Abstract]

Abstracts:

McMillan S., and Fox M., The measurement of induced mutation frequencies in V79 Chinese hamster cells: a reappraisal of methodology.
Mutation Res. **53** (1978) 237.

Fox M. and McMillan S., Lack of effect of caffeine post-treatment on UV and EMS induced mutation to purine analogue resistance in V79 Chinese hamster cells.
J. Supramolec. Struct. Supp. **2** (1978) 41.

McMillan S. L. H., Radany E. H. and Friedberg E. C., Evidence that pyrimidine dimer-DNA glycosylase and AP endonuclease activities are both coded by the *denV* gene of bacteriophage T4.
Fed. Proc. **40** (1981) 1763.

Seiden M. V., Clevinger B., Srouji T., Davie J. M., McMillan S. and Lerner R., A synthetic peptide induces a new anti-dextran idiotype.
Fed. Proc. **42** (1983) 705.

Seiden M. V., Heuckeroth R., Clevinger B., McMillan S., Lerner R. and Davie J. M., Experience with five synthetic peptides demonstrates variable ability to induce anti-idiotypic reagents.
Fed. Proc. **44** (1985) 1865.

Letters:

Re: AIDS and Ethnicity, Science **271** (1996) 1480 [Link]

Manuscripts in preparation:

McMillan S., A simple method for estimating survival parameters from direct visual inspection of Kaplan-Meier plots.

CD-ROM Products and Projects:

"Intravenous Antiarrhythmic Drugs: Renaissance in Arrhythmia Management"
Cardinal Health Systems for Wyeth-Ayerst Laboratories, (Released May 1999)
Role: Content repurposing, design and programming.
Status: Final release.

"Insomnia: Prevalence, Consequences & Costs"
iCardinal for Wyeth-Ayerst Laboratories, (Released December 2000)
Role: Subject matter research and content development, initial CD-ROM program design.
Status: Final release.

"Short Stature: Human Growth & Development"
Department of Pediatrics, University of Minnesota, (Released November 2002)
Role: Content adaptation and research, CD-ROM design and programming (PC & Mac), and project management.
Status: Final release. [Support Site]

"A Patient's Guide to Moderate Hypertension"
School of Public Health, University of Minnesota.
Role: Content development, interface design, CD-ROM programming, and project management.

"A Pharmacoeconomic Cost-Effectiveness Model for Breast and Colorectal Cancers"
Medicom Digital Inc. for a major international pharmaceutical company.
Role: Content adaptation, algorithm development and validation, initial CD-ROM program design.
Status: Final release. At least one, possibly two, publications are planned and a second, expanded version is in process.

"Atrial Fibrillation and Stroke"
Medicom Digital Inc. for a major international pharmaceutical company.
Role: Content research, design and development, initial CD-ROM program design, pharmacoeconomic algorithm development and validation.
Status: CD-ROM computer programming is completed. A pharmacoeconomic model has also been completed for release in the second version of this program.

"Sensitivity Analyses for Renal Transplant Parameters"
Medicom Digital Inc. for a major international pharmaceutical company, (Feasibility completed April 2002, CD-ROM development pending)
Role: Content research, data selection, sensitivity analyses and feasibility review.
Status: This was a successful feasibility study to assess the utility of published data (USRDS*) for predictive modeling.

"An Interactive Pharmacoeconomic and Disease Progression Model for Type II Diabetes"
Medicom Digital Inc. for a major international pharmaceutical company.
Role: Content research, algorithm and model development, and validation.
Status: Algorithms and predictive model development completed for all major comorbidities. Content development finalized and CD-ROM programming commenced.

* United States Renal Data System