

**Daniel E. McLain, MS, PhD,  
DABFE, FACN, CNS**

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## Employment Experience

**Walker Downey & Associates, Incorporated**  
*Product Safety and Development Consulting*

**11/04-Present**

President

- Providing worldwide product safety and development consulting activities to the pharmaceutical, biotechnology, biologics, device and diagnostic industries in the areas of quality assurance/control, regulatory affairs, toxicology, chemistry/formulations, research and development activities, project management, statistics, and information technology.
- Medical writing in support of GHTF/SG5 and MEDDEV 2.7.1 (Clinical Evaluation).
- Providing expert witness testimony in forensic examination in toxicology.
- Manage a broad base of scientific experts (Associates) for immediate application to client needs.

**PowderJect Vaccines, Inc  
(now part of PowderMed Ltd.)**

**9/02-11/04**

Director, Preclinical Regulatory Toxicology

Reporting to the Vice-President, Discovery R&D and Site Management

- Responsible for worldwide strategy and harmonization for *in vivo* and *in vitro* product safety assessment protocols, policies and procedures by existing and developing regulatory guidelines for biologics (CBER/OVRR) and medical devices (CDRH).
  - Created and managed in-house *in vivo* and bioanalytical testing laboratories for GLP compliance, including a Quality Assurance Unit operating under 21 CFR §58.
  - Primary responsible party for product safety “concept protocol” regulatory discussions in four (4) FDA/CBER/OVRR preIND meetings and in the writing (pharmacology/toxicology section), document compilation, and full review of four (4) IND applications.
  - Developed preclinical regulatory strategies for prophylactic and therapeutic plasmid DNA vaccine products including influenza (monovalent, multivalent, and adjuvanted products), HBV, HIV (consultancy), HSV-2, and cancer (prostate-GnRH responsive [Pepscan collaboration], and NY-ESO-1-responsive colon and breast, etc.).

- Set strategy for “risk classification” of materials and components for PowderJect Vaccines’ plasmid DNA commercial delivery system (device).
- Conducted formal material risk assessments and calculated health-based-exposure-limits for plasmid DNA formulation chemical excipients. Provided assessments to FDA and collaborators (GSK).
- Provided toxicological due-diligence assessment for Pepscan collaboration (prostate cancer, GnRH responsive).
- Active toxicology and regulatory affairs contributor to ISO TC194 (Biological Evaluation of Medical Devices) and Convener to ISO10993-11 (Systemic Toxicity Evaluation).
  - As convener to ISO 10993-11, responsible for harmonizing (and achieving consensus for) the opinions of a wide range of international experts in medical device material biocompatibility, systemic toxicity, risk analysis, and chemical characterization.
- Chairman, PJV Institutional Animal Care and Use Committee (IACUC).
- Member, PJV Institutional Biohazard Review Committee (IBC).
- Supervisor, Animal Facilities and Staff
- Supervisor, Preclinical Scientific Staff

*Note: Chiron Vaccines acquired PowderJect Pharmaceuticals and all of its holdings on July 8, 2003. Chiron Vaccines transferred ownership of PowderJect Vaccines, Inc. to Chiron Corporation effective October 1, 2003. Chiron Corporation sold PowderJect Vaccines, Inc. to PowderMed Limited on May 14, 2004. PowderMed Ltd. closed PowderJect Vaccines on November 15, 2004 and moved all product development activities to Oxford, UK*

**Walker-Downey & Associates**

**2/02-9/02**

Principal and Managing Director, Product Development Consulting

- Providing worldwide product development consulting activities to the pharmaceutical, biotechnology, biologics, device and diagnostic industries in the areas of quality assurance/control, regulatory affairs, toxicology, project management, statistics, and information technology.
- Providing expert witness testimony in forensic examination in toxicology

**Quintiles, Inc. RTP, NC**

**8/01-2/02**

Director, Project Management, Clinical Development Services,  
Reporting to the Vice-President, Project Management

- General CRO responsibilities including management of large project/program team(s) and subordinate staff providing a service for external clients which can include producing integrated clinical/statistical reports from Phase I – IV clinical trials.
- Monitoring and coordinating the efforts of international clinical trial project teams
- Meet with team members regularly regarding their mission-oriented project tasks to ensure that program milestones are met.

- Support the development of the project/program statement of work project costs.

**Becton Dickinson and Company, Cary & RTP, NC**

**4/94-4/01**

Worldwide Director, International Operations.

**4/00-4/01**

Reporting to the Corporate Vice-President of Medical Affairs.

- Responsible for worldwide strategy and harmonization for *in vivo* and *in vitro* product safety assessment policies and procedures by existing FDA/CDRH and ISO guidelines for medical devices and diagnostics.
  - Established working dialogue with regulatory authorities from FDA/CDRH, FDA/CDRH/OST, KFDA (Korea), MOH (Japan), and SDA (China). [Note: Within this employment opportunity, a four-year expatriate assignment in the pharmaceutical industry in Belgium contributed to my ability to work in international cultures.]
- Facilitated international regulatory submissions by assuring compliance with existing pertinent standards.
- Active regulatory affairs contributor to ISO TC194 (Biological Evaluation of Medical Devices) and Convener to ISO10993-11 (Systemic Toxicity Evaluation).

Worldwide Director, Corporate Medical Affairs, Medical Toxicology.

**10/98-4/00**

Reporting to the Corporate Vice-President of Medical Affairs.

- Responsible for worldwide *in vivo* and *in vitro* product safety assessment of medical devices and diagnostics by existing FDA/CDRH and ISO regulatory compliance guidelines (see following Director activities below).
- Supervised department management personnel in Biological Sciences, Chemical Sciences, RA/QA, and Operations & Planning (including Finance).

Director, Corporate Medical Affairs, Worldwide Medical Toxicology.

**4/94-10/98**

Reporting to the Corporate Vice-President of Medical Affairs.

- Responsible for worldwide *in vivo* and *in vitro* product safety assessment of medical devices and diagnostics by existing FDA/CDRH and ISO regulatory compliance guidelines. Worked as a member of the Medical Director teams and reviewed Investigator Clinical Protocols.
- Contributed to 510K preparation for: Iontophoretic drug delivery device (BD Transdermal Systems - NDA with 510K component), prefilled syringe program (BD Pharmaceutical Systems – saline, heparin), and miscellaneous 510K updates.
- Supervised department management personnel in Biological Sciences, Chemical Sciences, and Operations & Planning.
- Designed, staffed, and supervised management personnel of an internal Quality Assurance Department for GLP/GMP regulatory compliance activities (21 CFR §58, §210, and §211).

**Searle Research & Development, Skokie, IL** **8/89-4/94**

Group Leader, Product Safety and Metabolism **6/93-4/94**

Reporting to the Senior Director of Regulatory Drug Safety.

- Responsible for the worldwide *in vivo* and *in vitro* assessment of drug-nutrient interactions for Regulatory Drug Safety under FDA, ICH and OECD guidelines. Corporate specialist in Nutritional Toxicology.

Senior Manager, Product Safety (Europe), Department of Toxicology **12/89-6/93**

Reporting to the Senior Director of the Department of Product Safety (Europe).

- Responsible for the *in vivo* and *in vitro* sections of Regulatory Compliance for small molecule toxicology. Pharmaceutical research and development for submissions to FDA/CDER.
- Contributed to IND/NDA preparation for: cardiovascular drug (Bidisomide – the racemic mixture, followed by individual enantiomers), AIDS drug (Protease inhibitor)

Group Leader, Product Safety and Metabolism **8/89-1/90**

Reporting to the Senior Director of Product Safety.

- Temporary assignment prior to transfer to the Searle European Development Center (Mont-St-Guibert, Belgium) as Senior Manager of Toxicology (Europe, four-year expatriate assignment). Pharmaceutical research and development for submissions to FDA/CDER.

**Baxter Healthcare Corporation** **4/85-8/89**

Senior Research Associate, Department of Toxicology

Reporting to the Director of Toxicology.

- Study Director for division-sponsored safety assessment studies; Supervisor of biomedical research efforts for product development (biologics including monoclonal, recombinant; including protein C, various cascade clotting factors, artificial hemoglobin, etc.). The majority of this work was conducted jointly with the American Red Cross for submission through FDA/CBER.

**Union Carbide Corporation** **10/83-4/85**

Senior Toxicologist

Reporting to the Associate Director of Toxicology

- Study Director of oral/dermal toxicology tests. Supervisor of the dermal oncogenicity department. Classical chemical toxicology under EPA/FIFRA guidelines.
- Completed six (6) carcinogenicity/chronic toxicity study reports

**Cornell University**

**5/83-10/83**

*Postdoctoral Fellow,*

Division of Nutritional Sciences, Institute of Comparative and Environmental Toxicology,  
Department of Molecular Toxicology.

- Project: Effects of dietary fat on the development of L-azoserine induced abnormal pancreatic acinar cell nodules.

## **Professional Affiliations**

American Society of Nutritional Sciences (ASNS) and American College of Nutrition (ACN)  
Society of Toxicology (SOT), American College of Toxicology (ACT), and MRC/SOT  
American Board of Forensic Examiners (ABFE)  
American Society for Quality Control (ASQC)  
Regulatory Affairs Professional Society (RAPS)  
Association for the Advancement of Medical Instrumentation (AAMI)

## **Education**

Cornell University, Ithaca, NY 14853, USA

Ph.D., Nutritional Toxicology/Preventive Medicine (1983)

MS, Human Nutrition/Toxicology (1981)

BS (Honors), Animal Science/Reproduction (1978)

## **Certification**

Diplomate and Board Certified (ID# 8863), American Board of Forensic Examiners (DABFE),  
Toxicology Section (since 1996). Annual recertification required.

Diplomate and Board Certified Nutrition Specialist (CNS), American College of Nutrition (ID#  
00306) – Recertified for five years in December 2005.

## **Fellowships**

Fellow, American Board of Forensic Examiners (FABFE)

Fellow, American College of Nutrition (FACN);

## **Committee Appointments**

ISO TC194 (Biological evaluation of medical devices)

*International Convener*, ISO 10993-11: Systemic toxicity evaluation (TC194/WG7)

*Voting Member*, ISO 10993-17: Methods for establishing allowable limits for leachable substances using health-based risk assessment.

*Voting Member*, ISO 10993-18: Chemical characterization

*Voting Member*, ISO 10993-7: Ethylene oxide sterilization residues

Midwest Regional Chapter Society of Toxicology (MRCSOT)

*Executive Committee, 2003-2005*  
*Chairman, Audit Committee, 2003-2005*

*AAMI/BE, Biological Evaluation Committee*

*Member, Association for the Advancement of Medical Instrumentation*

## **Personal**

Military service: Army, Infantry, Noncommissioned Officer (E5),  
Republic of Vietnam service, 1969-1970  
Hobbies/interests: Family, art/music, long distance running, nutritional/physical balance.  
Languages: English, conversation French (four years immersion)  
Citizenship: USA

## **Reference Signature**

A handwritten signature in cursive script, appearing to read "D. McLain".