



Gordon Wehner, MSc MBA

Senior Consultant, Quality Assurance & Regulatory Affairs

EXPERIENCE:

- Director of Quality Assurance and Regulatory Affairs, Pharos Life Corporation.
- Director of Operations, GeneNews Corporation.
- Director of Quality Assurance, Vasogen Inc.
- Director of Quality Control, WorldHeart Corporation
- Manager of Quality Assurance, Graphic Controls Ltd.
- Manager of Quality Systems, Mead Johnson
- Quality Assurance Superintendent, Baxter Corporation
- Regulatory Affairs Associate, Baxter Corporation
- Quality Assurance Supervisor, Baxter Corporation

AREAS OF EXPERTISE:

Devices:

- Implantable devices
- Medical devices use for delivering therapies
- Sterile devices
- Disposable devices
- Software-controlled devices

Disciplines:

- FDA Quality System Regulations – 21 CFR Part 820
- FDA 21 CFR Part 210/211
- US FDA 510(k) and PMA submissions
- CE Marking - Technical Files and Design Dossiers
- Biocompatibility and sterilization
- IEC 60601 electrical safety standards
- Pharmaceuticals:
 - Injectable solutions
 - Terminally sterilized products
 - Infant pharmaceuticals and analgesics

EDUCATION:

- MBA (1995), Strategy and Operations, Wilfrid Laurier University, Waterloo, ON Canada
- M.Sc. Biology (1985), University of Waterloo, Waterloo, ON Canada
- H.BSc. Biology with Minor in Chemistry (1982), Wilfrid Laurier University, Waterloo, ON Canada

PROFESSIONAL AFFILIATIONS:

- Voting Volunteer Member, Canadian Standards Association
- Member, Regulatory Affairs Professionals Association



TRAINING AND CERTIFICATIONS:

- RAB/QSA Lead Auditor ISO 9001

PUBLICATIONS AND PRESENTATIONS:

- Deer TR, Levy RM, Rosenfeld EL. Prospective clinical study of a new implantable peripheral nerve stimulation device to treat chronic pain. *Clin. J. Pain.* June 2010; 26 (5): 359-72.
- Yu DT, Friedman AS, Rosenfeld EL. Electrical stimulation for treating chronic post-stroke shoulder pain using a fully-implanted microstimulator with internal battery. *Am. J. Phys. Med. Rehabil.* May 2010; 89 (5): 423-28.
- Marciniak C, Rosenfeld EL. Serial electrodiagnostic studies in West Nile virus-associated acute flaccid paralysis. *Am. J. Phys. Med. Rehabil.* Nov. 2005; 84 (11): 904-10.
- Oct 26 2010, RAPS Annual Conference
Title: From Concept to Commercialization: the Real Challenge for Medical Device Entrepreneurs
- Aug 23 2010, The 2nd Canadian Quality Congress
Title: From Concept to Commercialization: the Real Challenges of Quality Thinking for Entrepreneurs
- Jul 2010, RAPS Focus Magazine
Title: From Concept to Commercialization: the Real Challenge for Medical Device Entrepreneurs
- Apr 18 2006, MEDEC Hot Regulatory Topics Conference, Toronto, Ontario
Title: Clinical Trial Competence: An Industry Perspective
- Oct 18 2005, MEDEC Medical Device Regulatory Conference, Toronto, Ontario
Title: Risk Management in the Medical Device Industry: An Industry Perspective
- May 19 2005, International Risk Management Roundtable, Toronto Ontario