

Curriculum Vitae



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Senior Consultant - Cell and Gene Therapies
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SUMMARY OF EXPERTISE

Accomplished Regulatory Expert with 12+ years experience and a proven ability to develop and implement regulatory strategies that shorten the time of entry of ground-breaking medical products into clinical trials. Has represented client interests before national regulatory authorities and guided the submittal of multiple complex regulatory submissions encompassing therapeutic vaccines, gene therapy, stem cells, medical devices and biologic-device combination products.

Respected leader, able to converse at a technical level with development scientists and advise executive management on innovative regulatory strategies. Active participant on National and International expert committees seeking to standardize global practices for medical therapies.

Areas of Expertise

- Regenerative medicine, combination products, biologics, medical device and drug regulations
- Translational research; moving concepts for medical interventions from research to clinic
- Expectations for compliance with Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) and Good Tissue Practices (GTP)
- Scientific and technical due diligence
- Regulatory compliance audits and assessments

EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant - Cell and Gene Therapies
Seattle, WA (Feb. 2004 to present)

Provides strategic scientific and regulatory expertise on development of innovative medical products; Work collaboratively with clients (industry and academia) to develop practical solutions to successfully navigate the changing regulatory landscape for novel therapies, including combination products (tissue engineering/ regenerative medicine), islet transplantation, xenotransplantation, stem cells, tumor vaccines; Conduct audits and due diligence assessments

for compliance, with GLP, GCP, GTP and GMP requirements; Serve on scientific/technical advisory boards and reviews business plans to provide insights on the product development pathway of new therapies

Key Accomplishments:

- Guided the successful submittal of multiple, complex regulatory submissions encompassing therapeutic vaccines, gene therapy, stem cells, medical devices and biologic-device combination products
- Provided training & education of academic and industry translational research teams in implementing strategic product development practices.
- Conducted due diligence and regulatory audits for both industry and academic clients encompassing GTP, GMP, GLP and GCP; for identified deficiencies identified practical approaches leading to successful corrections
- Active participant on National and International working groups seeking to establish science based standards for innovative medical products

Office of Cellular, Tissue and Gene Therapies (OCTGT), Division of Cellular and Gene Therapies, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Chief, Cellular Therapy Branch

Rockville, MD (2002 – 2004)

Management oversight for ~350 Investigation New Drug (IND) applications; Supervisory oversight of professional review staff to ensure consistency and quality of reviews; Member of Multi-Agency Tissue Engineering Science (MATES) Working group

Key Accomplishments:

- Facilitated hiring of key review staff and establishing policy priorities
- Co-chair for 2nd FDA Biological Response Modifiers Advisory Committee (BRMAC) meeting on Allogeneic Pancreatic Islet Transplantation for Type I Diabetes, October 9-10, 2003
- Authored and facilitated release of the FDA Reviewers Guidance on Somatic Cell Therapy INDs
- Formulated key FDA perspective on proposed DHHS 20/20 Regenerative Medicine Initiative.

Office of Therapeutics Research and Review, Division of Cellular and Gene Therapies, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Regulatory Review Officer

Rockville, MD (1998 - 2003)

- Expert knowledge of FDA regulations and scientific principles relevant to biological product development; Responsible for review of pre-IND, IND and BLA materials with regard to completeness and consistency of the manufacturing process, characterization and safety testing of the product and scientific rationale; Reviewed product manufacture, validation,

quality control and lot release of each IND, IDE and biologics license application (BLA) that is assigned.

Key Accomplishments

- Represented FDA to the public and other government agencies as invited speaker at internationally and nationally sponsored scientific meetings and symposia.
- Primary CMC reviewer on 88 IND, IDE and Master Files
- As member of the Multi-Agency Tissue Engineering Science (MATES) working group,
- Planned and coordinated 1st FDA Biological Response Modifiers Advisory Committee (BRMAC) Meeting on topic of allogeneic pancreatic islet transplantation
- Member of working group implementing FDA's human tissue regulations for [Human Cells, Tissues, and Cellular and Tissue-based Products](#) (HCT/P)

Office of Therapeutics Research and Review, Division of Application Review & Policy, Applications & Administration Branch Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Regulatory Management Officer (Project Manager) Rockville, MD (1996 - 1998)

- Conducted initial administrative/regulatory reviews of each assigned IND, IDE, and BLA submission; Performed administrative review of labeling for products submitted to pending or approved marketing applications; Collated comments to develop Action, Clinical Hold, and Information Request letters; Ensured that Agency/Sponsor meetings are facilitated, well organized, focused and documented.

Key Accomplishments:

- Administrative responsibility for 132 INDs and 7 Master Files encompassing cell therapy, fusion proteins, enzymes, cytokines and cell selection devices
- Issued 147 review letters to sponsors
- Coordinated 50 meetings and/or teleconferences
- Served as member on working group for electronic license applications and electronic IND pilot program.

EDUCATION

Ph.D. - *Biochemistry & Biophysics*, Oregon State University, Corvallis, Oregon

B.S. - *Molecular Biology*, The Evergreen State College Olympia, Washington

HONORS AND AWARDS

2005 U.S. Department of Health and Human Services (DHHS) Secretary's Award for Distinguished Service – For Human Tissue Action Plan Team

- 2003
1. U.S. Public Health Service (USPHS) Outstanding Unit Citation - Member of Establishment Registration and Listing Rule for Human Cells, Tissues and Cellular and Tissue-based Products Group
 2. FDA Group Recognition Award - For work as member of FDA/NIH Human Embryonic

- Stem Cell Task Force
- 2002
3. FDA Group Recognition Award - for work as member of Diabetes Care and Management; provided content for website describing FDA regulated products for diabetes
 1. USPHS Commendation Medal – For development of regulatory policy and improved FDA oversight of cellular and tissue-based therapies.
 2. FDA Commissioner's Group Award – For member of Human Tissue Establishment Registration Final Rule
 3. USPHS Unit Commendation – For planning group for Advisory Committee Meeting on Pancreatic Islets
 4. USPHS Crisis Response Service Award - 2 awards for deployments as Liaison for FEMA and DHHS Secretary's Command Center relating to 2001 Terrorist Events and Salt Lake City Winter Olympics
- 2001
1. USPHS Scientist Professional Advisory Committee "Young Scientist of the Year" Award - In recognition of outstanding accomplishments in carrying out the missions of the USPHS.
 2. FDA Group Recognition Award - For work and review as a member of the Xenotransplantation Working Group.
- 2000
- USPHS Unit Commendation - For work in developing training program on regulatory procedures for license applications
- 1999
- USPHS Achievement Medal - For industry outreach activities regarding FDA policies for licensing of biological products
- 1998
1. USPHS Citation - For high quality performance of duties and contributions in attainment of program objectives
 2. CBER Group Award - For technical excellence for coordination of computer assisted license applications (CALA)
 3. CBER Group Award - For administrative excellence as a member of the editorial board for the CBER Newsletter.

PROFESSIONAL ACTIVITIES

- International Society for Cellular Therapy (ISCT) – Member, Regulatory Affairs & Commercialization Committees
- Regulatory Affairs Professional Society (RAPS)
- United States Pharmacopoeia (USP) – Co-Chair, B&B Cell and Gene Therapy Expert Committee
- United States Pharmacopoeia (USP) – Member, Nomenclature Expert Committee
- United States Adopted Names Council (USANC) - Member and USP Delegate
- Washington Biotechnology & Biomedical Association (WBBA) - Stem Cell Technology Advisory Group

BIBLIOGRAPHY

1. **Weber, D.J.**, (2008) "Understanding and Implementing Good Tissue Practices (GTPs). Regulatory Focus 13(7): 18-28
2. **Weber, D.J.**, (2008) "Regulatory Considerations for Manufacturing and Delivery of Cell-based Therapies for Cardiovascular Indications" J. of Cardiovasc. Trans. Res. *In press*; published online 13 June 2008
3. **Weber, D.J.** and Pepperl, DJ (2007) "Biosafety and Nonclinical Assessments of Cell and Tissue-based Products in the United States". pgs. 345-372. In Nonclinical Drug Safety: Practical Considerations for Successful Registration. Edited by W.K. Sietsema and R. Schwen
4. **Weber, D.J.** (2006) "Manufacturing Considerations for Clinical Therapies Derived from Stem Cells" Methods in Enzymology vol 420:410-30; Stem Cell Tools and Other Experimental Protocols
5. **Weber, D.J.**, (2004) "Navigating FDA Regulations for Human Cells and Tissues" BioProcessing International. 2(8): 22-26
6. **Weber, D.J.**, (2004) "Biosafety Considerations for Cell-Based Therapies" BioPharm International. 17(7):48-55
7. **Weber, D.J.**, (2004) "FDA regulation of allogeneic islets as a biological product." Cell Biochem Biophys. 40(3 Suppl):19-22.
8. **Weber, D.J.**, Simek, S. Puri, R.K. "FDA Educational Partnerships to Improve the Development of Cell and Gene Therapy Products" (2003) BioProcessing Journal, 2(4): 23-25
9. **Weber, D.J.**, McFarland, RM, Irony, I (2002) "Selected Issues for FDA Regulation of Allogeneic Islets of Langerhans as Somatic Cell Therapy" Transplantation, 74(12): 1816-1820.
10. **Weber, D.J.**, McFadden, P.N. and Caughey, B. (1998) "Measurement of Altered Aspartyl Residues in the Scrapie Associated form of Prion Protein", Biochem Biophys Res Commun, 246(3): 606-8.
11. **Weber, D.J.** and McFadden, P.N. (1997) "Injury induced Enzymatic Methylation of Aging Collagen in the Extracellular Matrix of Blood Vessels" J. Protein Chemistry, 16(4): 269-281.
12. **Weber, D.J.** and McFadden, P.N. (1997) "Detection and Characterization of a Protein Isoaspartyl Methyltransferase Which Becomes Trapped in the Extracellular Space During Blood Vessel Injury" J. Protein Chemistry, 16(4): 257-267.

13. **Weber, D.J.** and McFadden, P.N. (1996) "Protein Methylation in the Nervous System", *NeuroMethods* 30. Regulatory Protein Modification. Techniques and Protocols. Hugh C. Hemmings, ed. Humana Press, Totowa, NJ. pp. 309 334.
14. **Weber, D.J.** and McFadden, P.N., (1995) "A Heterogeneous set of Urea Insoluble Proteins in Dividing PC12 Cells is Passed on to at least the Generation of Great Granddaughter Cells" *J. Protein Chemistry*, 14(5): 283 289.
15. Collodi, P., Kamei, Y., Sharps, A., **Weber, D.**, and Barnes, D. (1992) "Fish embryo cell cultures for derivation of stem cells and transgenic chimeras " *Molecular Marine Biology and Biotechnology* 1(4/5), 257 265.

INVITED PRESENTATIONS (SELECTED)

1. Regulatory Considerations for Cell Manufacturing and Cell Delivery, International Society for Cardiovascular Translational Research, 08 February 2008, San Diego, CA
2. U.S. FDA Regulatory Issues and Product Development Challenges for Cardiac Cell Therapies, GE Healthcare North American Cardiac Cell Therapy Innovation Symposium, 11-12 October 2007, Albany, NY
3. "U.S. FDA Regulations & Practices for Human Cell & Tissue-Based Products" 2007 International Symposium on Regulation of Human Cell & Tissue-Based Products, 02-03 October 2007, Taipei, Taiwan
4. Quality Expectations for Product Development CMC Activities, RAPS Annual Meeting, 23-September 2007, Boston, MA
5. "Addressing Regulatory Concerns While Translating from Research to Clinical Applications," December 11, 2006, Miami, FL, Wallace H. Coulter Center for Translational Research
6. "Lost in Translation? Addressing Regulatory Concerns While Bridging from Research to Clinical Applications of Stem Cells," February 22, 2006, San Francisco, CA, Cambridge Healthcare Institute Stem Cell Research Conference.
7. "Traversing the Regulatory Pathway for Stem Cell Therapies," Techvest, November, 5, 2005, New York, NY
8. "Perspectives on GTP & GMP Requirements for Cell Processing Facilities," June 1, 2005, ISCT-AABB Audio Conference Series.
9. "Essential Tools and Strategies for Overcoming Developmental Challenges for Cell-based Products." June 28, 2005. Washington, DC. DIA Annual Meeting
10. "Understanding the FDA's Regulatory Pathway for Regenerative Wound Healing Products." May 18, 2005. Chicago, IL. Wound Healing Society Annual Meeting.
11. "Ancillary Materials Used in Cell-Based Therapies." May 6, 2005. Vancouver, Canada. International Society for Cell Therapy (ISCT) Annual Meeting

12. "Practical Insights on Understanding the FDA's Expectations for Stem Cell-based Therapies." April 11, 2005. San Diego, CA. Stem Cells Research and Therapeutics Conference.
13. "Regulatory Considerations for the Development of Cell-Device Combination Products." May 26, 2004. Santa Clara, CA. RAPS – West Coast Conference
14. "FDA Licensing of Islet Transplantation." June 6, 2004. Orlando, FL. 65th American Diabetes Association Scientific Sessions
15. "Characterization and Comparability for Cellular and Tissue-Based Therapies: Perspectives of a Former FDA Reviewer." January 27, 2004. San Diego, CA. Williamsburg BioProcessing Conference on Characterization and Comparability for Complex Biologicals.
16. "Cell Therapy: From Lab to Market- FDA Regulatory Perspective." June 23, 2003. Washington, DC. Biotechnology Industry Organization (BIO 2003).
17. "FDA Regulatory Framework for Engineered Tissues." June 8, 2003. Orlando, FL. Defense Advanced Research Projects Agency (DARPA) Engineered Tissue Constructs Meeting.
18. "Science-based Testing for Biologics." April 22, 2003. Washington, DC. Biomedical Engineering Materials & Applications Workshop, National Academy of Sciences.
19. "FDA Regulatory Framework for Clinical Studies of Cellular and Gene Therapies, including Engineered Tissues." April 21, 2003. Arlington, VA. Defense Advanced Research Projects Agency (DARPA) Speaker Series.
20. "CBER perspective on FDA Regulation of Tissue Engineered Medical Products." March 20, 2003. Pittsburgh, PA. Engineering Tissue Growth.
21. "Regulation of Cellular & Gene Therapy Products for Cardiovascular Indications." September 25, 2002. Washington, DC. Transcatheter Cardiovascular Therapeutics Meeting.
22. "Regulation of Tissues as Biological Products." June 3, 2002. Columbia, MD. FDA/ORA Human Tissue Establishments Inspection Training Course.
23. "U.S. FDA Regulation of Human Cellular & Tissue-based Products." March 12, 2002. Kobe, Japan. Kansai Bio-Conference
24. "Overview of Xenogeneic INDs." November 29, 2002. Columbia, MD. Secretary's Advisory Committee for Xenotransplantation (SACX).
25. "FDA Regulation of Cellular Therapies." October 17, 2001. Keystone, CO. Cell Transplant Society 10th Anniversary Congress.
26. "FDA/CBER Regulatory Issues Tissue Engineered Products." June 25, 2001. Bethesda, MD. NIH - Bioengineering Consortium Mtg (BECON).
27. "Biosafety Considerations for Cell/Tissue-based Tissue Engineered Medical Products." May 10, 2001. Phoenix, AZ. ASTM - American Society for Testing Materials; Tissue Engineered Medical Products.
28. "Cellular Therapies & Tissue Engineering Initiative." May 7, 2001. Miami, FL. IUCB- Industry/University Cooperative Research Center for Biosurfaces.

29. "Product Issues for Cell & Tissue Derived Combination Products." October 2, 2000. Washington, DC. Regulatory Affairs Professional Society (RAPS).
30. "Application of FDA Regulatory Framework to Procurement, Processing & Characterization of Allogeneic Pancreatic Islets." March 20, 2000. Washington, DC. FDA Biological Response Modifiers Advisory Committee