CAPABILITIES AND EXPERIENCE
JEFF F.DOERZBACHER

WORK EXPERIENCE

Landrich Group (2019 – Present)

- Provide regulatory assistance, clinical trial design advice, protocol development, sample size estimation, statistical analysis plans, statistical analysis, clinical study reports, and manuscript preparation for clients.

Doerzbacher Consulting (2006 – Present)

- Provide regulatory assistance, clinical trial design advice, protocol development, sample size estimation, statistical analysis plans, statistical analysis, clinical study reports, and manuscript preparation for clients in the medical device, biotech, and pharmaceutical industries, with a focus on smaller medical device companies. Consultations have involved numerous therapeutic areas and device types, including:
  - Orthopedics – total joints, polymeric bone cement
  - Spine – hardware
  - Cardiology – annuloplasty device, IVD test
  - Cardiovascular – minimally invasive vascular access device
  - Otolaryngology (ENT) – RF device for nasal congestion/obstruction, IVD test
  - Pain Therapy – low-level laser therapy devices
  - Onychomycosis – low-level laser therapy device
  - Osteoporosis – whole body micro-impact platform

Vice-President, Clinical and Regulatory: Renascent Medical, Inc. (2014 – 2015)

- Participant in founding the company that was focused on reactivating an FDA-approved (NDA) drug product (chymopapain) for the nonsurgical, minimally invasive treatment of sciatica due to lumbar disc herniation and returning the product to the market.
- Evaluated the regulatory status and history of the product and current options for reentry into the market to develop the regulatory pathway for the company's strategic business plan.
- Reviewed and synthesized the extensive published clinical literature on the product.

Director, Regulatory and Clinical Affairs / Director, Regulatory/Clinical and Quality Affairs: Spinal Restoration, Inc. (2006 – 2013)

- Responsible for all aspects of regulatory, clinical, and quality for a start-up company developing a combination product (device and biologic) for treatment of low back pain. Clinical activities include writing clinical protocols, identifying clinical investigators, forecasting, and budgeting for studies, managing study implementation, data management and statistical analysis support, report writing, and oversight of Contract Research Organization (CRO). Manage quality agreements with development partners and contract auditing services. Responsible for all regulatory filings with FDA and regulatory development plans for markets outside the US. Interact with FDA to support study approvals and regulatory submissions.

EXPERIENCE HIGHLIGHTS

- Quantitatively oriented scientist with broad research, regulatory, and clinical trials experience; including applied statistical knowledge, technical writing and editing, data management and programming, clinical trial protocol development and execution, and regulatory filing experience in the medical device, pharmaceutical and biologics industries. Excellent ability to communicate statistical and quantitative concepts to a nontechnical audience. Experienced, effective in, and understand differences in the operations and needs of large international, medium-sized, and small start-up companies.

EDUCATION & ACCREDIATION

- Master of Science / Fisheries Major, Statistics Minor – Louisiana State University
- Bachelor of Science, Biology and Chemistry Majors – University of Miami
- Member of American Society for Quality / Society for Clinical Trials / American Statistical Association / Drug Information Association / American Medical Writers Association / Regulatory Affairs Professionals Society
- Stayble Therapeutics AB Consulting, Board Member since 2019