Professional Experience

Independent Consultant

Statistical, clinical, and regulatory consultations involving numerous therapeutic areas and device types, including:

Orthopaedics – total joints, polymeric bone cement

Spine – hardware

Cardiology – annuloplasty device, IVD test

Otolaryngology – radiofrequency device, IVD test

Pain Therapy – low-level laser therapy devices

Onychomycosis – low-level laser therapy device

Osteoporosis – whole body micro-impact platform

Renascent Medical, Inc.

Co-founder and Vice-President, Clinical and Regulatory

Company 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

Spinal Restoration, Inc.

Director, Regulatory/Clinical and Quality Affairs

Start-up company developing a combination product (device and biologic) for treatment of low back pain. Conducted clinical, regulatory and quality activities including submission of IND, preparation of clinical protocol, and special protocol agreement (SPA).

Abbott Spine

Clinical Project Leader

Developed clinical protocol and IDE submission for spinal device.

Smith & Nephew, Inc.

Director, Biostatistics & Clinical/Regulatory Data Management

Responsible for biostatistics, clinical and regulatory data management, and postmarketing system and study support. Responsible for design, analysis, and reporting of global clinical studies, coordination of data collection and management to support clinical studies, statistical analysis, and the support of publications and presentations for orthopaedic and trauma products.

Manager, Clinical/Regulatory Affairs

Responsible for coordination/preparation and submission of Investigational Device Exemptions (IDE) and Product Development Protocols (PDP) and all required domestic and international filings to support regulatory approval for orthopaedic products. Responsible for preparation of clinical protocols and case report forms for

regulated and unregulated clinical studies. Responsible for monitoring clinical studies to ensure compliance with applicable regulatory requirements, study protocols, investigator agreements, and corporate policies. Responsible for oversight of contract research organizations and independent consultants used to support clinical studies and regulatory submissions. Managed the Data Management group. Reviewed clinical studies and literature for the Postmarket Surveillance program.

Chiltern International, Inc.

Senior Biostatistician

Provided biostatistical and scientific expertise and leadership to project teams, including protocol development, case report form development, analysis plan development, programming advice and support, data analysis, and report writing. Project statistician for one Phase I and three Phase III/IV Spinal and Epidural Anesthetic/Analgesia studies, and two Phase III Ophthalmic Allergy studies.

PPD Development

Manager, Programming

Managed programming tasks and supervised programmers working with clinical trial data for multiple Phase III Allergic Rhinitis studies, a Phase I/II AIDS Antiviral/Anti-infective study, and a Phase III Renal Transplant antirejection study.

Sulzer Orthopedics, Inc.

Statistics Group Leader, Senior Statistician, Statistician

Developed and managed the Statistical Group of the Clinical Affairs Department. Developed Investigational Plans (protocols and case report forms) for implantable devices, including joints (hip, knee, and shoulder), spinal implants, and bone growth factors. Guided the development, maintenance, and validation of clinical databases and statistical programs. Developed SOPs to meet FDA and ISO requirements. Presented study information to investigators and staff. Directed and performed statistical analyses of clinical data. Prepared reports of statistical analyses and clinical trial results for Premarket Approval Applications (PMA), Substantial Equivalence (510k), and annual Investigational Device Exemption (IDE) report submissions to the FDA. Interacted with FDA on IDE clinical trial submissions and PMAs. Provided scientific and statistical support to other departments, including Materials Research, Engineering, Marketing, and Human Resources.

Texas Parks and Wildlife Department

Research Specialist

Coordinated processing of data collected from a coastwise monitoring program, wrote and maintained computer programs, consulted with Coastal personnel on statistical design and analysis, and performed statistical analyses. Planned and conducted fisheries research and reported the results in internal reports, peer-reviewed published papers, and at regional and national meetings.