

TERRY SHERIDAN POWELL

Senior Project Manager



Professional Experience

M SQUARED ASSOCIATES, INC. – WASHINGTON, DC

Regulatory Affairs Consultant and Senior Project Manager, January 2005 to Present: Project management activities include regulatory strategy development, 510(k), PMA, and IDE preparation, FDA meetings & negotiations, and clinical trial management. Project teams have won numerous 510(k) clearances and IDE approvals, and a PMA approval. Projects have included various Class II and III orthopedic, spinal, and bone substitute devices as well as other novel therapies.

REGULATORY AFFAIRS CONSULTANT (INDEPENDENT CONTRACTOR) – MONTVALE, NEW JERSEY

Regulatory Affairs Consultant, 1999 to 2005: Worked with major U.S. orthopedic manufacturer's product development teams to plan and execute regulatory strategies for medical devices from all risk classes: US Class I, II and III and EU Class I, Ia, IIB and III; developed 510(k), PMA and IDE submissions and shepherded through FDA review process; developed Technical Files and Design Dossiers and worked with Notified Bodies to achieve and maintain CE Mark; developed device labeling to comply with domestic and international requirements.

STRYKER ORTHOPAEDICS (FORMERLY HOWMEDICA OSTEONICS CORP. & OSTEONICS CORP.) – MAHWAH, NEW JERSEY

Team Leader – Regulatory Affairs & Clinical Research 1998-1999: Managed a team of regulatory affairs, clinical research, and clinical data management professionals responsible for all Regulatory Affairs and Clinical Research activities. Planned and executed regulatory and clinical strategies for US Class III, II, and I devices, and for EU Class III, IIB, IIa, and I devices. Managed the progress of multiple IDE studies and non-investigational-device studies. Regulatory Affairs Specialist, 1993 to 1998: Developed US regulatory filings including 510(k)s, PMAs, IDEs, establishment registration, and device listings. Developed regulatory filings for direct submission to Canadian and EU authorities. Developed international filings for submission through local affiliates for Australia, Japan, and Pacific Rim, Eastern Europe, and South American countries.

HOWMEDICA INC. – RUTHERFORD, NEW JERSEY

Regulatory Compliance Associate, 1989 to 1993: Medical device reporting, investigational device accountability, international regulatory filings.

Education

M.A. English Literature/Technical Writing, 2005 – Fairleigh Dickinson University, Teaneck, NJ

B.A. English Literature, 1989 – Manhattan College, New York, NY

Certifications and Memberships

RAC certified by the Regulatory Affairs Professional Society (RAPS) since 2001

Orthopedic Surgical Manufacturer's Association (OSMA): Board of Directors 1998-1999, Company representative for Osteonics Corp. 1995-1999.

Courses Completed

RAPS Webcast: Compliance requirements & Enforcement Regs 7/1/2003
Sponsor: RAPS

RAPS Webcast: Labeling and Promotion 7/8/2003
Sponsor: RAPS

RAPS Audio-conference: IDEs – Intro & Basics 9/17/2003
Sponsor: RAPS

FDA Audio-conference: Getting your combination product to Market, presentation and interactive discussion with Joel Falk and James Benson. Sponsor: FDA	9/16/2003
RAPS Webcast: IDE Module 3, managing study & interacting w/ FDA Sponsor: RAPS	10/1/03
Pharma Audio-conference: Off label promotion – Compliance issues and practices Sponsor: Pharma	10/2/03
RAPS Webcast: PMA Module 1: Prep&Rev of PMA Sponsor: RAPS	1/14/2004
RAPS Audio-conference: PMA Mod 2: Mfrng section Sponsor: RAPS	1/21/2004
RAPS Webcast: Overview of Canadian Regulations Module 1” Overview of drugs and biologics Sponsor: RAPS	9/8/2004
Advamed – The Politics of Reimbursement Policy Sponsor: Advamed	9/21/2001
RAPS Webcast: Overview of Canadian Regulations Module 2” Sponsor: RAPS	9/22/2004
RAPS Webcast: Overview of Canadian Regulations Module 3 Sponsor: RAPS	9/29/2004
Product Promotion: The fine line between what’s right and what’s wrong Sponsor: Arnell, Goldman, Gregory, LLP	11/10/2004