REGSOLUTIONS, LLC

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Summary of Achievements

- Thirty nine years experience in Regulatory, Quality Systems, and Clinical (RAC, FRAPS, CQA) in medical devices. Strong leadership ability managing multidiscipline/multilevel medical device projects.
- Specialize in creative regulatory strategies to achieve expedient medical device registrations in US and EU/ROW.
- Twenty six years EU registration experience with extensive knowledge CE mark process creating Technical Files and Design Dossiers for multiple medical device products for >25 different companies. Current experience in upgrades to clinical evaluation reports (CER) to compliance with MEDDEV 2.7.1 rev 4 and EU MDR requirements.
- Prepared and managed >100 FDA US regulatory submissions for medical device clearance or approvals including 510(k)s, PMA/Supplements, DeNovo. Prepared multiple IRB/Ethics Committee submissions, several successful IDEs, and one HDE.
- Thirty nine years direct interaction with FDA CDRH in Washington DC for registration submission negotiations.
- Lead liaison with FDA facility inspections. As well, lead representative for client Notified Body audits for ISO 13486 and MDD, now transitioning to EU MDR and global MDSAP.
- Over 30 years experience in FDA 483 facility site inspection responses as well as 15 years team leadership with successful warning letter CAPA remediation projects for US and international firms such as China, Canada, and Puerto Rico.
- Proficient as management representative with all internal and external contacts for regulatory, quality system, and clinical functions including FDA, Notified Bodies, Authorized Reps, CRO, IRB, Clinical DMB, Clinical Investigators, Outside Counsel, and Board of Directors.
- Thirty two years' experience in developing and implementing quality systems and SOP development compliant to FDA GMP/QSR and ISO 13485. Developed > thirty individual customized QMS for clients leading to successful FDA inspections and gaining ISO certification over the last thirteen years.

REGSOLUTIONS, LLC

Professional Experience

REGSolutions, LLC (Florida) (2007-Present)
President & CEO
Privately owned medical device regulatory/ quality systems consulting company

- Develop US Regulatory strategies and submission development including Presub, 510(k)s, PMA, IDEs, HDE, IRBs, DeNovo
- Develop EU CE mark registration strategies for EU MDR with technical files and design dossiers creation
- ISO 13485 quality system builds, implementation, NB audits and ISO certification
- FDA inspections and 483 responses
- FDA Warning Letter full remediation projects for USA and international companies for release of product detention located in China, Canada, Puerto Rico, and USA
- Regulatory and quality systems compliance gap analysis, upgrades to ISO 13485:2016 and prep for MDSAP audits, Host MDSAP audits
- Complaint Handling and AE initial process builds, consolidations and remediation record catch-up
- International registrations (Canada, Europe, Asia Pacific, Australia, New Zealand)
- Specialty knowledge include: 39 years SME for Ophthalmic medical devices – Corneal and Cataract Implants, Instruments, Laser, and Contact Lenses, Spectaces; OB/GYN - condoms, Intrauterine Tamponade Balloon, Diagnostic Fertility Device; Urology/Gastroenterology - catheters, urine bags, implants for incontinence, feeding tubes; General Surgical – syringes, sterile surgical gowns/drapes, surgical kits, suture, mesh products, HA dermal implants for aesthetic use; General Hospital - electronic software driven devices, vascular access, wound care; Orthopedics – bone screws, surgical instruments, and suture anchor; Neurological – proprietary, Tissue and biologics

CIBA Vision/Novartis (Duluth, GA) (2002 –2007)
Director, Regulatory Affairs Ophthalmic Division
Class II and III ophthalmic medical devices, international distribution

- Developed both regulatory and clinical strategies related to FDA and Rest of World registrations of new product surgical development
- Simultaneously lead five design control projects, including new materials product technology
- Developed successful strategies with OEM manufacturers to gain worldwide regulatory approvals resulting in two successful Class II product launches (glaucoma and refractive technology)
- Directed successful IDE submissions for two independent Class III clinicals following acquired technology
- Managed various successful Abbreviated, Special, and Traditional Class II 510(k) submissions for contact lenses
- Directed CRO-managed 16 investigator study, Phase III 350 subject refractive implant clinical study
- Directed CRO-managed six investigator, Phase II 100 subject therapeutic implant clinical study
- Managed in-house staff conduct five investigator, Phase I 50 subject therapeutic ocular disease study

Horizon Medical Products, Inc. (Atlanta, GA) (2000-2001)
Director, Regulatory Affairs
Class II and III vascular access medical device manufacturer, international distribution

- Directed Regulatory Affairs strategies and activities at GA and FL manufacturing facilities
- Directed FL facility Quality Control department and Compliance system activities
- Key Liaison with FDA, Notified Body, and EU Representative Contact
- Directed Adverse Event Department (EU Vigilance, US MDR reporting, Customer Medical Support)
- Consolidated two quality systems (from company purchases and facility closures) under one practical, efficient umbrella system maintaining it in compliance with FDA QSR and the Medical Device Directive
- Obtained CE Mark for all products manufactured at two facilities
- Gained FDA approvals for Special 510k and traditional Class III 510(k) submissions
- Established Design Control System resulting in four successful product development launches
- Prepared Product Registrations for non-EU customers gaining over one million in potential business
- Successfully reestablished Adverse Event Dept (hired, trained, and implemented new software)

CryoLife, Inc. (Kennesaw, GA) (1998-2000)
Manager, Regulatory Affairs
Biomedical manufacturer of human and animal tissue biologics and medical devices, international distribution
Subsidiary manufacturer of Class II vascular access medical devices in Florida, international distribution

- FDA Contact and European Notified Body Compliance Liaison for FL facility
- Developed and managed Corporate Adverse Event Dept (EU Vigilance and US MDR reporting), hired, trained, and implemented new software)
- Authored and gained concurrence of one IDE and one HDE
- Authored five Technical Files and three Design Dossiers, gaining EU approval and CE mark for FL and GA products
- Developed Design Control system for FL facility
- Directed five simultaneous product development projects in regulatory and quality
- Prepared and liaison of FL facility of successful ISO certification

C.R. Bard, Inc. (Conyers, GA) (1995-1998)
Regulatory Affairs Associate
Class II and III urological and gastroenterology medical devices, international distribution

- Managed regulatory activities for subsidiary Class II electronic manufacturing facility in MI
- Developed Technical Files for CE mark
- Participated in regulatory submissions and design control activities
- Authored seven Traditional 510(k) submissions
- Developed three successful IDE's for urological implants
- Assessed regulatory impact (for seven Bard facilities) when baseline product changes occurred
- Provided review and advisement over labeling and marketing materials

Preferred Optics (Marietta, GA) (1991-1995)
Director, Regulatory Affairs/Quality Systems
Class II and III ophthalmic medical devices

- Prepared corporate manufacturing facility for successful initial FDA inspection
- Authored one PMA, three PMA supplements, and two 510(k) submissions
- Developed Quality System and conducted GMP training

Eye Med (Atlanta, GA) (1988-1991)
Corporate Director, MIS/Inventory Systems
Corporate distribution center of Class I ophthalmic medical devices for 13 store retail chain

- Developed, implemented, and managed a proprietary intranet DBMS and LAN point-of-sale system while directing centralized purchasing, inventory control, and distribution departments

Vision Tech, Inc. (Roswell, GA) (1984-1988)
Director, Regulatory/Clinical/Quality Systems
Class II ophthalmic medical devices

- Director of Regulatory, Clinical, and Quality System departments and activities and staff
- Prepared corporate manufacturing facility for successful initial FDA inspection
- Authored two PMA, 26 PMA supplements, and one IDE submission
- Updated Quality Systems to maximize efficiency between three facilities (GA, FL, CA)

CIBA-Geigy/Novartis, (Doraville, GA) (1981-1984)
Regulatory/Clinical Department Staff Member
Class III ophthalmic medical devices

- Member of Regulatory/Clinical department in development of colored soft contact lenses

Education:

Mercer University, BS: Management Information Systems	1997
National Center for Paralegal Training, ABA: Paralegal—Litigation Specialty	1995
Southern College of Optometry, AS: Optometric Technology	1975

Certifications & Awards:

RAPS Fellows Honors	2009
Leonard Stauffer Award from RAPS	2007
Certified Quality Auditor, American Society for Quality (ASQ)	2006
British Standards Institute (BSI): ISO Lead Auditor	2005
RAPS, EU Regulatory Affairs Certification	2002
RAPS, US Regulatory Affairs Certification	1996

Affiliations:

Georgia Tech Institutional Review Board, Community Member	2009 to Present
Atlanta Chapter Chairperson for Regulatory Affairs Professional Society	2004 to Present
University of Georgia, Education Committee Member—Regulatory Program	2004 to 2017
Regulatory Affairs Professional (RAPS)	Active Member since 1996
American Society for Quality (ASQ)	Active Member since 2000
Ophthalmic Women's League (OWL)	Active Member since 2005