PENNY NORTHCUTT
A REGSolutions Company

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Summary of Achievements

- Twenty eight years experience in Regulatory, Clinical Affairs, and Quality Systems (RAC, CQA) in a top management role. Strong leadership ability managing multidiscipline/multilevel projects.
- Proficient as management representative with all external contacts for regulatory and clinical functions including FDA, Notified Bodies, Authorized Reps, CRO, IRB, Clinical DMB, Clinical Investigators, Central Test Labs, VC funding and Board of Directors.
- Twenty five years of direct interaction with FDA at federal and state levels in 8 different companies.
- Twenty five years experience with GMP/QSR audits for both internal and external audits, including pre-approval inspection (PAI) and audit response (483, warning letter, CAPA).
- Twenty five years experience in quality systems and SOP development. Includes adverse event and audit programs, recall and corrective action implementation, training, and inspection readiness per GMP/QSR/ISO.
- Fourteen years experience with product design control team activities bringing many new medical device to market.
- Specialize in creative regulatory strategies to achieve expedient product registrations.
- Led over fifteen FDA facility inspections and over twenty Notified Body audits.
- Prepared and managed close to 100 regulatory submissions and registration/device approvals over a 28 year period.
- Developed and implemented nine ISO 13485 compliant quality systems for startup companies over the past two years.
- Prepared multiple IRB/Ethics Committee submissions, several IDEs, and one HDE
- Directed CRO managed multiple investigator, greater than 300 patient Phase II and Phase III clinical studies
- Fourteen years EU registration experience with extensive knowledge of ISO certification, CE approval process creating Technical Files and Design Dossiers for multiple medical device products for 12 different companies.

Professional Experience

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

- QSR/ISO/cGMP compliance
- ISO 13485-2003 system builds, registration and certification
- FDA/ISO inspections and responses
- Regulatory status and quality compliance gap analysis
- Complaint Handling and Adverse Event system builds
- Regulatory and Quality Lead for design controls and device development/commercialization projects
- Regulatory strategies and submission development including 510(k)s, PMA, IDEs, IRBs
- International registrations (Canada, Europe, Asia)
- QSR/Personnel training
- CAPA training and system implementation

CIBA Vision (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 Registrar Compliance Liaison for FL facility
- Managed Corporate Adverse Event Dept (EU Vigilance and US MDR reporting)
- 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 products
- Developed Design Control system for FL facility
- Directed five simultaneous product development projects
- Prepared FL facility for successful ISO certification
- Successfully reestablished Adverse Event Dept (hired, trained, and implemented new software)

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
- Participated in regulatory submissions and design control project management activities in GA
- 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 labeling and advertising review and advisement

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

- Prepared manufacturing facility for successful initial FDA inspection without any 483 Observations
- 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

- Directed Regulatory, Clinical, and Quality System departments and activities, including hiring 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 and GMP compliance between three facilities (GA, FL, CA)

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

- Participated in development of colored soft contact lenses as member of Regulatory/Clinical department

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

Affiliations:

HBA Chapter Director, Volunteers	2010 to Present
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 Present
HBA Mentoring Committee Member	2008 to Present
Regulatory Affairs Professional (RAPS)	Active Member since 1996
American Society for Quality	Active Member since 2000
Healthcare Women's Business Association (HBA)	Active Member since 2008
Association of Clinical Research Professionals (ACRP)	Active Member since 2006
Ophthalmic Women's League (OWL)	Active Member since 2005

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