Martin A. Kaufman

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Resourceful, goal-focused, and accomplished executive with 20+ years' experience in the development, execution, and maintenance of Medical Device regulatory affairs and quality assurance activities at a global scale for startup and multinational organizations

Instrumental in devising effective strategies and submissions for establishing product approvals. Effective in monitoring and assessing the impact of relevant global regulations, guidance, and regulatory environment. Demonstrated success in facilitating and participating in negotiations with regulatory authorities. Adept at leading diverse teams, including Regulatory, Quality, R&D, Operations, Marketing and Sales.

Areas of Expertise

- Regulatory Affairs Management
- Quality Assurance & Compliance
- EU MDR & CE Marking
- Medical Devices & Product Development
- Technical/Quality Documentation Control
- Team Building, Motivation, & Leadership
- International Regulatory Approvals
- Process/Performance Improvement
- GXP Audit/CAPA Implementation

Career Experience

REFOCUS GROUP, INC., Aliso Viejo, CA/Dallas, TX **12/2014 – 2/2021**

Ophthalmic Scleral Implant for treatment of Presbyopia

CHIEF REGULATORY OFFICER

Directed entire regulatory affairs and quality assurance operations for expediting the approval of clinical trials, along with documentation procedures. Organized and led diverse teams to compose US IDE and PMA submissions, and EU CE-mark submissions including Technical Files. Conducted regulatory training sessions to educate management, company personnel, and clinical investigators.

- Submitted a Modular Panel-Track PMA, 2 US IDE applications, and 3 EU Design Dossiers.
- Succeeded in managing the continuation of PMA approval process despite 2 non-approvable letters.
- Successfully prosecuted an FDA Supervisory Review per 21CFR §§ 10.75 and 800.75.
- Presenter in FDA Advisory Panel Review for VisAbility™ Micro Insert System.

ALCON RESEARCH LTD, Lake Forest, CA **2/2009 – 12/2014**

Ophthalmic Cataract and Vitreoretinal Surgical Systems, Diagnostic Ultrasound Systems, Surgical Laser Systems, Intraocular Lenses, Glaucoma Therapy Devices

VICE PRESIDENT - REGULATORY AFFAIRS HEAD – CATARACT

Supervised and directed all regulatory activities. Generated US 510(k), PMA, and IDE submissions, and International Registration submissions in accordance with EU, Japan, Canada, Australia, and rest-of-world requirements. Provided registration support for International affiliates worldwide. Active member of business opportunity and acquisition review teams. Company representative for AdvaMed 510(k) Working Group.

- Oversaw the regulatory requirements of 3 Alcon manufacturing facilities and Surgical Instrumentation R&D.
- Successfully submitted 12 510(k) submissions, 2 US IDE Applications, and a US 801(e)1 Application.
- Accelerated domestic and international registrations, enabling rapid route to markets.

EDWARDS LIFESCIENCES, Irvine, CA **9/2004 – 2/2009**

Transcatheter and Surgical Heart Valve Repair and Replacement Systems

DIRECTOR OF REGULATORY AFFAIRS

Generated US and international regulatory submissions per EU and Canadian regulations. Obtained approval for clinical evaluation of novel Transcatheter Mitral Repair Device in Venezuela. Conducted training for management and production personnel on regulatory and quality guidance and procedures.

- Submitted 4 CE Design Dossiers, 3 Canadian Investigational Testing Applications (ITA's), 10 EU Investigational Testing Applications, 3 US PMA Supplements, a 510(k) submission, and a US 801(e)2 Application.
- Established KEMA as Notified Body for Advanced Technologies Group.
- Obtained CE Mark for a novel Investigational Mitral Repair Device.

GUIDANT CORP., Santa Clara & Temecula, CA **6/2002-9/2004**

Coronary Metallic/Drug Eluting Stent Systems

REGULATORY AFFAIRS MANAGER

Compiled US IDE and PMA submissions, and EU, Japan, Canada and Australia Registration submissions. Convinced FDA through direct negotiation to allow a "new" PMA submission to be submitted in the form of a PMA Supplement, saving 3 months review time. Collaborated with Australia's TGA for submission of a Drug Eluting Stent Design Dossier to be submitted in inaugural Modular format. Submitted a Drug Eluting Stent Investigational Testing Application to Canada's TPD.

- Developed guidance as company representative in AdvaMed's Combination Products Coalition in collaboration with FDA's Office of Combination Products.
- Supported Business Development Teams with due-diligence activities.
- Submitted a total of 4 IDE's, 4 PMA Supplements, 3 EU Design Dossiers, 2 Canadian ITA's and 1 Australian Design Dossier.

QLT INC., Vancouver, British Columbia, Canada **11/1998-6/2002**

Pharmaceuticals and Medical Devices used in Photodynamic and other Ocular Therapies

SR. DIRECTOR – QUALITY & REGULATORY AFFAIRS OPERATIONS

Led all Device Regulatory Affairs and Quality Assurance functions including auditing, process/software validation, facility Quality Document Management and "GXP" Training. Directed the compilation of NDA, IND, PMA, and IDE combination drug/device submissions encompassing FDA, Canadian, EU, and Japanese Registration requirements. Developed process coordinating and compiling device IDE/PMA submissions from three Medical Laser companies in conjunction with IND/NDA submissions for a combination Drug/Device product. Restructured Regulatory Affairs department to cut submission compilation time by one third, which allowed submissions to be filed ahead of schedule.

- Created a Device Quality system in conjunction with a Pharmaceutical Quality System.
- Directed the activities of Business Partners and outside consultants for translation of US PMA's and IDEs into Japanese Gaiyo for submission to Japanese MHLW.
- Drove the activities of a UK-based Medical Laser manufacturer to install an FDA-compliant Quality System which then passed a PMA approval audit.
- Submitted a total of 2 IDE's, 3 PMA's with 12 supplements, 2 IND's, 2 NDA's with 4 supplements, and 2 Canadian ITA's.
- Presenter in FDA Advisory Panel Review for Visudyne® (Macular Degeneration Therapy).

ALCON LABORATORIES, INC. Fort Worth, TX/Pomona, CA **1989-1998**

Ophthalmic Surgical Systems, Diagnostic Ultrasound Systems, Surgical Laser Systems, and Intraocular Lenses.

SR. REGULATORY AFFAIRS MANAGER - SURGICAL DEVICES 1**/**1992-11/1998

Directed all Regulatory Affairs activities, FDA Compliance, and International Registrations. Primary Regulatory Affairs oversight for 3 Alcon device manufacturing facilities and Corporate R&D. Developed a Regulatory Assessment documentation process to justify file/no-file decisions, which successfully defended against an FDA warning letter.

- Created an electronic MDR Access Database for reporting, trending and analysis.
- Developed e-mail/fax process to enable efficient ECO review for the manufacturing facilities.
- Submitted a total of 7 510(k)'s, and 2 IDE's.

QUALITY ASSURANCE/REGULATORY AFFAIRS MANAGER – IOL's 10**/**1989-1/1992

Directed and supervised an 85 personnel QA Department, including product line QA, Quality Engineering, Microbiology Lab, Metrology, and Receiving Inspection. Performed internal facility GMP audits, and audits of process vendors and component suppliers.

- Created software validation protocols for computer-controlled manufacturing equipment.
- Provided training in GMP, TQM, and ISO requirements.

PHILIPS ULTRASOUND, INC. Santa Ana, CA **5/1986-10/1989**

Diagnostic Ultrasound Imaging and Color Doppler Systems

REGULATORY AFFAIRS MANAGER

Directed all Regulatory Affairs activities including 510(k) submissions, FDA Compliance, clinical trials support, UL and IEC safety compliance testing and system/software certification. Managed the Quality Engineering Department and a Training/Certification program for Production personnel.

- Participated in Ultrasound Standards Development with FDA, the National Electrical Manufacturers Association (NEMA) and the American Institute for Ultrasound in Medicine (AIUM).
- Instituted Product Environmental Testing capability and developed Workmanship Standards.
- Submitted a total of 11 510(k)'s.

CILCO, INC., Pomona, CA **11/1982-5/1986**

Ophthalmic Surgical Systems, Diagnostic Ultrasound Systems, and Surgical Laser Systems

QUALITY ASSURANCE MANAGER

Directed and supervised an 80 personnel QA Department, including product line QA, Quality Engineering, Metrology, and Receiving Inspection. Compiled FDA Regulatory 510(k), PMA & IDE submissions and supported clinical trials.

- Coordinated relocation of a Surgical Laser company from Dallas, TX, and a Diagnostic Ultrasound company from New York City to Pomona, California.
- Co-authored a total of 5 510(k)'s, 2 IDE's, and 1 PMA.

EDUCATION AND AFFILIATIONS

BS, Electrical Engineering Technology - California State Polytechnic University, Pomona

Regulatory Affairs Professional Society (RAPS)

American Society for Quality (ASQ)