

SUMMARY

Proven clinical development experience with pharmaceuticals, Class III devices, and combination device/drug products. Expertise in clinical operations management: leading project teams, managing timelines, budgets, resources, and collecting and analyzing performance metrics. Effectively initiated and managed strategic continuous improvement programs: focusing resources to maximize impact and mitigate risks, streamlining processes to expedite study completion, maintaining quality but driving down trial costs. Experienced in cardiovascular, anti-inflammatory, oncologic and anti-infective therapeutics.

- PMA Preparation
- Site Recruitment, Training and Management
- **Clinical Team Leader**
- FDA Sponsor Audit Leader
- **Project Management**
- CRO Selection and Management
- **Budget Management**
- **Process Excellence Champion**
- **Trial Planning**
- **Requests For Proposals (RFP) Preparation**
- Staff Recruitment
- Pharmacovigilance

EXPERIENCE

Clinical Consultant

2006 to Present

Kenneth Wu and Associates, LLC

- **Interim Clinical Operations Director** (Oncology, **Cardiovascular**, CNS and Infectious Disease)
 - created program and project **timelines**; tracked trial progress, **managed trial risks**
 - developed **budgets**; **resources** requirements, **CRO** costs and contracts
 - qualified and managed vendors; prepared **RFQ**, qualified and selected CRO/vendors
 - represented clinical in program/**project team** meetings and presented status to **management**
 - organized clinical departmental at **start up** companies

Associate Director of Clinical Operations

2004 to 2006

Scios Inc., a Johnson and Johnson Company

- Optimizing **workflow in Drug Safety** on global clinical trial; reducing time for completion of SAE reports, expediting data collection and query resolution, coordinating with CRO on reporting.
- Scaled up clinical operations department by **133%**; 32 (2004) to 77 (2005), turnover 7% (2005)
- Developed **new operating model** to conduct global clinical trials with **>200 sites, enrolling >900** patients; aggressively outsourcing monitoring, site management, and site payments to CROs.
- Created **seven new groups** to improve efficiency, quality and leverage core capabilities;
 1. **Clinical accounts**: trial budgeting and forecasting, clinical site and vendor payments
 2. **Clinical supplies logistics**; labeling, packaging and global distribution, supplies forecasting
 3. **Vendor management**; create sourcing strategies, develop and negotiate vendor agreements
 4. **Process engineering**; optimize and streamline critical processes to reduce time and costs
 5. **Compliance training**; trained on new SOPs, ICH/GCP, implement new JNJ global training
 6. **Clinical Study Files**; standardized filing of study documents based on higher standards
 7. **Clinical quality and standards**; designed and implemented new quality system
- Managed increasing clinical operations budget; **~\$30M** (2004), **~\$60M** (2005), **>\$100M** (2006)
- Championed interdepartmental process improvements;
 - **Reduced packaging time by 73%** (90 to 24 days); labeling to distribution of clinical drug
 - **Reduced approval of legal agreements time by 56%** (>90 to <30 days)
 - **Expedited hiring process time by 80%** (>90 to 17 days); resume receipt to written offer
 - **Improved job offers acceptance rate; <30%** (2004) to **75%** (2006)

Clinical Research Manager

2000 to 2003

Guidant Intravascular Intervention

- Coordinated and coached clinical research associates (CRA) in creating 5 clinical development plans for new treatment indications on approved products (2001 to 2002):
 - Radiation program: **700 patients at 70 US sites, 4-year study, ~\$9M**
 - Drug/device combination programs: 1700 patients at **>90 US sites, 3-year study, ~\$20M**
- Led project management group in clinical: creating >30 new clinical project timelines, representing workload for **~100 employees** and **20 contractors**, enabling management to make informed decisions and plans about resource requirements and project progress.
- Collaborated on creating **detailed performance benchmarks** for 4 CRA levels and development milestones resulting in more equitable and consistent performance assessments for ~20 CRAs.

Director of Clinical Affairs

2000 to 2000

Eclipse Surgical Technologies

Eclipse relocated from Northern to Southern CA

- Facilitated merger of two former competitors', Eclipse's and Cardiogenesis' clinical programs in **preparation of PMA submission** of 2nd generation product and FDA site audits, and closing pivotal trial of 1st generation product.
- Initiated creation of 2 new program timelines representing workloads of **12 employees in Clinical Affairs and Data Management** with an annual budget of **~\$3M**. More accurate and timely information were available to assess project status and team performance.
- Began to collect **baseline performance metrics**: study regulatory compliance, data management processes and management capabilities of new program managers, in anticipation of creating performance targets for the department, group and individuals.

Project Coordinator/Medical Research Associate/Clinical Manager

1996 to 2000

BioEnterics Corporation

Miravant Technologies

- Initiated and organized Miravant's first **Pharmacovigilance** Committee: retrospectively investigated and collected serious adverse events (SAE) data from previous 4 years to prepare 20 comprehensive SAE investigations in 4 months. **Resulted in savings weeks in preparing IND and NDA reports, and provided more accurate and complete safety profile.**
- Gained management approval and \$1M funding to plan, lead and implement electronic data capture system. Completed Phase I (\$300K budget): collected system requirements, prepared RFP, selected vendor from 4 CROs, and created electronic case report forms and database for Phase II study.
- Led and managed clinical team of 12: site monitoring, data collection, QA audits and PMA submission for pivotal trial at 8 US sites enrolling 292 patients in 3 years. **PMA submission in 2000, panel presentation in 2000 and FDA approval in 2001.**

Clinical Research Associate

1988 to 1995

EDUCATION

Masters in Business Administration

University of Phoenix

Masters in Physiology and Biophysics

Georgetown University

Bachelors in Physiology and Psychology

University of California at Berkeley

TRAINING & CERTIFICATIONS

Regulatory Affairs Certified (RAC) by Regulatory Affairs Professional Society (RAPS) November 2002

Process Excellence Executive Champion 2006

Process Excellence Green Belt Training 2006