DAVE SELKIRK

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UNPARALLELED BUSINESS and PHARMA/BIOTECH RESEARCH VETERAN

Seasoned business executive with 3+ decades in the pharmaceutical/ biotechnology/ medical device and contract research industry. Core strengths in executive leadership, cross-functional operations, as well as alliances/business development. Experience spanning all therapeutic areas and phases of clinical trials, pre-clinical research, central & esoteric lab analyses, plus post-marketing/market access. Broad international perspective including N America, EU, APAC, & LATAM. Skilled in resolving challenging sponsor-CRO issues as well as developing methods of standardization and quality improvement.

PROFESSIONAL EXPERIENCE

WHITECHURCH PHARMA & BIOTECH CONSULTING **2020 - Present**
A pharma/biotech/device R&D consulting firm whose mission is excellence in execution and customer service.

CEO & FOUNDER (2020 – PRESENT)
Focusing on client engagement, and expansion of the business' international reputation.

- Facilitate and ameliorate the collaboration between CROs and pharma/biotech/device companies
- Expert management of studies, as well as oversight of providers (patient recruitment, SMOs, EDC, PROs, wearables, mobile phlebotomy/nursing, supply chain, IRT, central & esoteric labs, pharmacovigilance, etc.)
- Consult on protocol optimization for operational efficiency, as well as patient and site centricity
- Advise on the various options and models to decentralize clinical trials and enable virtual/digital solutions
- Support post-marketing requirements, as well as plans to optimize product positioning & reimbursement
- Assist growing R&D organizations and vendors create/fine-tune their value proposition and business plan
- Sales strategy, planning, and support including account plans and customer relationship management/mapping
- Executive support as CEO, Chief Officer of Operations/ Commercial/ Alliance Management
- Molecule licensing/acquisition opportunities along with associated due diligence

INNOVADERM RESEARCH **2021 - Present**
Mid-size, full-service, niche dermatology CRO + Phase I unit supporting pharma, biotech, and medical device sponsors.

CHIEF OPERATIONS OFFICER (2021 – PRESENT)
Responsible for all revenue-generating services on a global scale.

- Executive Committee member driving the near and long-term corporate success strategy
- Maintained persistent growth of the overall operational revenue at a rate of 25% annually
- Surpassed 2022 revenue target by 13%, and surpassed 2022 gross margin target by 2 points
- Direct responsibility for ~320 individuals across three continents (80% of the company) for the functions of Clinical Operations, Project Management, Start-Up, Biometrics, Regulatory Affairs, Medical Writing, & Drug Safety
- Revamped USA employee candidate assessment & retention model to combat high turnover (interview process, job grade levels, salary ranges, bonus, retirement, health benefits, etc.)
- Stabilized and united corporate culture subsequent to significant leadership change
- Initiated adaptive monitoring, with risk-based approach, and remote source data verification
- Established full functional capabilities in Europe (including Regulatory), plus increased leadership roles in India
- Restructured operational depts + defined high-relevance KPIs to enable high-quality and profitable execution
- Augmented financial acumen of Project Management team, with accuracy in monthly revenue projections
- Prioritized patient recruitment team leadership resulting in 95% patient recruitment timeline adherence
- Analyzed suite of clinical systems, followed by changes to software company-wide
- Collaborated with Business Development to maintain high win rate of 40%
- Integrated Change Order data with Finance to enable awareness + early revenue recognition
- Launched Continuous Improvement department to focus corporate attention on the areas of greatest need
- Created Early Phase department with high-science/low intensity processes, tools, and pricing algorithms
- Initiated electronic source data documents for the phase I unit, + promotion through external investigators
- Passed 2 FDA audits of the phase I unit with no significant findings, and no 483

LABCORP DRUG DEVELOPMENT **2001 - 2011, then again from 2013 – 2020**
One of the largest full-service global CROs (annual revenue > US$5B).

VICE PRESIDENT, ENTERPRISE ALLIANCE MANAGEMENT (2016 – 2020)
Accountable for ~US$2B pharma company alliance providing pre-clinical, clinical, lab, technology, plus FSP model.

- Reset partnership relationship resulting in 25% improvement in objective alliance scores
- Renegotiated alliance contract more than tripling net orders for 2016-2019, relative to the previous 3 years

- Writing the annual Strategic Account Plan to optimize value for the sponsor and revenue/profit for Covance
- Building plans to increase interaction and revenue through innovation in areas of low activity
- Streamlining the procurement process through an early engagement model
- Establishing and orchestrating internal and external senior account level relationships, as well as maintaining positive and effective sponsor relationships even when difficult discussions were needed
- Managing senior level quarterly governance meetings with key sponsor stakeholders
- Developing communication plans to generate a steady cadence of multi-media messaging (videos, blogs, newsletters, etc.) from the alliance executive to all bilateral stakeholders
- Revamping the ePortal to have greater relevance as an information source on success stories and innovation
- Setting alliance level goals and ensuring that each service line implements targets in full alignment
- Revising Key Performance Indicators to have a tighter focus on the outcomes of most relevance to the sponsor
- Ensuring high-quality performance on key trials/projects so as to remove barriers to repeat business

EXECUTIVE DIRECTOR, LATE PHASE STRATEGY & PLANNING (2013 –2016)
Accountable for Late Phase (peri/post-approval + real world evidence) operations and commercial strategy.

- Networking with pharmacy chains, specialty therapeutic groups, and integrated health delivery networks to create alternatives to traditional trial forecasting and execution
- Structuring a searchable database of international regulations governing submissions of phase IV trials, observational studies and expanded access programs
- Participating on the governance team with a major international pharma organization
- Strategizing and implementing business development targeting by client type, product pipeline, and geography
- Produced strategy to 'bundle' the affiliate research plans of our alliance partners so as to create a book of business whose size is aligned to Covance operational models, and thereby reduce the need for large numbers of local service providers regionally
- Wrote the business plan to grow the peri/post-approval and RWE business at Covance internationally Leading the process of updating SOPs for observational studies, as well as the subsequent training plan
- Developed a surveillance system of post-marketing commitments issued by major world regulators so as to prioritize business development targeting
- Built a classification and tracking system for Life Cycle Management proposals so as to ease retrieval of relevant templates and facilitate reporting
- Tailored the pricing algorithms to 3 levels of rigour aligned with Life Cycle Management studies and programs
- Worked on the implementation team for a low-cost EDC platform
- Created a presentation outlining the FDA's new focus on Patient Centred Outcomes

PAREXEL International **2011 – 2012**
One of the big six full-service global CROs with ~US$2.5B in annual revenue.

VICE PRESIDENT, STRATEGIC ACCOUNT LEADER
Accountable for global P&L, operations and client satisfaction in strategic partnerships (US$100M).

- Accountable for CRO service delivery to specific alliance partners, oversaw the matrix of ~350 business development and cross-functional operational staff working on all phases of clinical research globally
- Provided Executive Leadership for Strategic Accounts:
  - Developed the annual Strategic Account Plan
  - Built the account team with skilled and experienced individuals based on the sponsor's unique needs
  - Tailored infrastructure with focus on technology (i.e. CTMS, EDC, IVRS, portals) and system integrations
- Oversaw Business Development + P&L Responsibilities:
  - Ensured that revenue and profitability were maximized across the spectrum of internal business units
  - Centralized the BD approach/structure for consistency in proposals & rapid award of work
  - Created visibility into long-term clinical development plans via the early involvement model and compound teams, and then projected future revenue from it
- Directed Global Operations:
  - Supported global clinical trial operations by liaising with much focus on the unique situation in Japan
  - Ensured resourcing was prioritized as well as 'ring-fenced' teams to leverage lessons learned and efficiencies from previous trials
  - Managed quality governance to address a high volume of regulatory audits

LABCORP (CLINIMETRICS/OMNICARE/THEOREM; then CHILTERN; now part of LABCORP) **2001 –2011**

VICE PRESIDENT, LATE PHASE RESEARCH (GLOBAL) & COUNTRY MANAGER, CANADA (2010 –2011)
Executive Committee member, accountable for Late Phase business (US$20M) plus Canada Country Manager (US$10M).

- As site head in Canada, maintained dotted line oversight of department heads and their teams (37 staff)
- Oversaw the Late Phase Business Unit matrix of ~250 commercial & operational staff globally

- Developed and implemented the annual Late Phase Business Unit strategic plan and budget
- Surpassed 2010 profitability target by 6 points and maximized revenue despite slow market
  - 66% top-line profit margin
  - 2010 late phase sales matched 2009 despite all other units falling short
- Developed streamlined operational model for late phase using tight endpoints, standardized site contracting, remote site management, call centres, staff evolution plans, data querying, and propensity scoring
- Led global late phase project review teleconferences ensuring optimal performance and quality
- Oversaw resourcing (APAC, NA, EU), and led corporate training sessions the streamlined operational model
- Developed the Late Phase marketing plan including web site, printed materials, industry symposia, publications, press releases, competitive intelligence, and strategic partnerships
- Approved proposals to prospective clients, customizing budgets, and participating in bid defence meetings

SENIOR DIRECTOR, CANADIAN OPERATIONS: COUNTRY MANAGER, CANADA (2008 – 2010)
Executive Committee member, oversaw the Canadian organization, including P&L, plus a team of 37 professionals.

- Line Manager to department heads of Business Development, Project Management, Clinical Operations, Biometrics, Medical Writing, as well as Facilities Management
- As country manager of Canada, achieved Canadian profitability gains:
  - 2% in 2008 relative to 2007
  - 4% in 2009 relative to 2008, despite the economic downturn
- Revised the mission statement (& culture) to themes of customer service, quality, teamwork and technology
- Set, reviewed, and approved local department plans and budgets as a subset of the international corporate goals
- Customized the approach to target and win work from companies utilizing adaptive design
- Assigned client accounts to sales team, trained on sales strategies, and provided feedback on targets
- Cooperated with non-competing service providers (i.e. bioanalytical and safety laboratories, toxicologists, and phase I units), resulting in cross-referral of business

DIRECTOR, BUSINESS DEVELOPMENT (2006 – 2008)
Responsible for contracting with new clients as well as maximizing repeat business.

- Improved the financial performance of the Canadian organization:
  - 41% increase in sales in 2007 relative to 2006
  - 17% increase in revenue in 2007 relative to 2006 + another 16% in 2008 relative to 2007 which is directly attributable to the sales jump in 2007
- Targeted Canadian-based biotechnology clients to diversify and localize revenue stream, maximize RFPs, increase win-rate, and create self-reliance of the Canadian branch of the business
- Chaired the knowledge transfer process from BD to Operations when new projects were awarded
- Led quality partnership initiatives with key clients so as to promote repeat and long-term business
- Built and implemented the Canadian marketing plan by selecting publications for advertisements as well as wrote and designed the content of the promotional materials

ASSOCIATE DIRECTOR / DIRECTOR, PROJECT MANAGEMENT (2003 – 2006)
Oversaw all aspects of the Canadian Project Management Department.

- Built & oversaw the Project Management department consisting of 8 Project Managers and Project Assistants
- Developed SOPs, procedural adherence, compliance to GCP, and client relations
- Hired strong talent to ensure optimal resourcing with minimal turnover, with maximum profitability and quality
- Coached the project teams on optimizing the profitability of individual projects by setting and adhering to an ideal project timeline, by understanding the scope of work, by optimizing resources, and by managing the client
- Represented the executive team on client audits; collaborated with QA on audit responses
- Led a cross-functional team with the mandate to optimize study start-up activities across many service areas for trials utilizing electronic (internet-based) case report forms
- Project managed multiple trials investigating transplantation, oncology, HIV/AIDS, rheumatoid arthritis, stress urinary incontinence, hematology and neonatology

PROJECT MANAGER (2001 – 2002)
Responsible for the management of multiple clinical trials spanning phases I-IV over a wide array of therapeutic areas.

- Orchestrated in-house sponsor placement of multiple CRO staff ensuring a long-term revenue stream
- Wrote the clinical protocol for an ovarian cancer Investigator-initiated study
- Developed an advisory board of key opinion leaders to critique and finalize a clinical development plan
- Ran trials in various therapeutic areas: oncology (breast, ovarian, small cell lung, colorectal, advanced solid tumours), cardiovascular, CNS (bipolar depression), neurology, HIV/AIDS, osteoarthritis and pain management

BYK / ALTANA (became NYCOMED; now part of TAKEDA) **1997 – 2001**

PROJECT LEADER

Responsible for implementing phase II/III studies in asthma and COPD, as well as mentoring junior staff.

- Seconded to Germany for asthma protocol development investigating inhaled steroid
- Oversaw the largest single country contribution to patient recruitment in the asthma pivotal trial

ASTRA (now called ASTRAZENECA) **1992 – 1997**

CLINICAL TRIAL SCIENTIST (1994 – 1997)

Responsible for overseeing phase IIIb/IV studies in asthma and rhinitis.

- Cross-functional experience in Protocol Development, CRF Design, Project Management, Clinical Monitoring, Database lock, and Clinical Study Report Writing
- Sponsored by head office to go to Sweden to develop an asthma protocol

MEDICAL INFORMATION REPRESENTATIVE (1992 – 1994)

Responsible for interacting with pharmacists, physicians and patients regarding all company products.

- Built a database of product-specific information to support staff when responding to Medical Information calls

EDUCATION & PROFESSIONAL DEVELOPMENT

Honours Bachelor of Science (General Biology), 1991 - **Medalist in thesis course**
Certificat de français pratique (Certified French/English Bilingual), 1990
University of Western Ontario, London, Ontario

- Certificate of Achievement - Alliance Management - May 2017
- Drug Development Fundamentals: Overview of Drug Discovery & Preclinical Research - Mar 2016
- Propensity Scoring - May 2013
- Late Phase Drug Development World Europe / Americas 2010 – March/December 2010
- Differentiation-Based Leadership – June 2009
- HIPAA Training – June 2008
- SOX Training – June 2008
- Excelling as a Highly Effective Team Leader – October 2007
- Health Outcomes Research. Do We Really Need it? – February 2007
- Introduction to Oracle Clinical Remote Data Capture – June 2006
- New EU Pharmaceutical Legislation – July 2004
- Ontario Personal Health Information Protection Act – June 2004
- Common Technical Document – November 2002
- Pharmacogenomics – June 2002
- Accreditation in Gastroenterology Postgraduate Program – May 2000
- Certification as an APMR [Accredited Pharmaceutical Manufacturers Representative] – May 1999
- How to Survive a FDA Audit – November 1998
- Certified Clinical Research Associate – August 1997
- Pharmacoeconomics – September 1996
- Pharmacokinetic Concepts in Drug Development – May 1996
- Statistics for Medical Writers and Editors – May 1995

EDITORIALS & PRESENTATIONS

- Presentation on Sponsor-CRO Relationships at the Clinical Research Association of Canada, Feb 2014
- Presentation on Late Phase Research at the 14th Clinical Trial Forum, Jacksonville FL, May 2011
- Multiple authors including Selkirk D, The ERA of Proactive Safety (pg 21), *PharmaVOICE,* Feb 2011
- Selkirk D, Late Riser, *International Clinical Trials*, (pg 38), Aug 2010
- Multiple authors including Selkirk D, Postlaunch: Phase IV Activities (pg 41), and Postlaunch: Marketing Research (pg 42), *PharmaVOICE*, March 2010
- Selkirk D, EDC and Clinical Trials in 2008, *CRO, CMO & Clinical Trials Canada Outsourcing Guide 2008*, (pg 57), 2008

LANGUAGES

- Bilingual in both English and French; written and spoken
- Functional knowledge of German