

Résumé - Steven K Baker

PROFILE:

A successful, results orientated consultant with experience in many aspects of international business development, product management and clinical & regulatory procedures. Energetic and goal orientated with a passion for bringing innovative technologies to market.

PROFESSIONAL ACHIEVEMENTS

- Worked with SMEs for over 16 years; delivering product & clinical development and future commercialization Strategies including regulatory insight in both the professional & OTC markets for new innovative light based technologies.
- Specialist in low level light/Laser/LED therapy, class II (special controls) medical devices.
- Competent and experienced in clinical & regulatory affairs, authored, submitted and executed FDA approvals, Santé Health and Medical CE. Experienced in Shonin and KFSA.
- Designed, managed and executed phase I-III trials collaborating with Key opinion leaders in the fields of Low level light therapy, NMSC, Dermatology, diabetic neuropathy and Herpes viridae.
- Developed and executed B2B marketing strategies, communications & International training programs to maximize sales.

PROFESSIONAL EXPERIENCE:

2014 – Present

i-SMART Consulting US

Offers help to medical and non-medical device manufacturers looking for assistance in all aspects of product & clinical development including regulatory guidance, clinical trial design and execution, marketing & commercialization.

2009 – 2014

Product Development Manager

Pacer Therapeutics Ltd. UK

SME, medical device company specializing in the development, production and commercialization of both over the counter (OTC) and professional medical light based devices.

Key Achievements

- First OTC device to receive FDA clearance for a wound healing application (treatment of Herpes labialis).
- Developed and managed B2B opportunities with global and national OTC players and distributors
- Company turned over \$1.5m in year one of business
- Developed a strong clinical and regulatory pipeline for new indications
- Competent in regulatory approvals delivering FDA, Santé Health, Medical CE.

2000 – 2009

Business Development Manager

Photo Therapeutics Ltd. UK

Medical Device Company. Manufacturer and global distributor of light emitting diode technology to the medical and aesthetic markets ISO13485: 2003 registered. 8 FDA clearances

Key Achievements

- Design and delivery of global training programme for distributors and end users
- Responsible for management communications across product portfolio
- Authored and Ghost wrote numerous trade pieces on emerging light-based technologies
- Design, implementation and management of pilot and phase 1-3 clinical trials
- Key member of regulatory team delivering 7 FDA clearances, Santé Health, medical CE, Shonin & SFDA
- Management of European, Asian and African distributors
- Double digit growth in managed territories 2006-08

1998 – 2000

**Sales Office Manager
Scientific & Chemical Supplies Ltd**

Supplier of laboratory chemicals and equipment to industrial and educational markets throughout the UK and Europe

Key Achievements

- Daily supervision and operational management of sixteen staff
- Operational management of service sector, 80% growth in second year
- Instrumental in the implementation and management of strategic sourcing initiatives
- Territory manager, grew business by 35%

1993 – 1998

**Biomedical Scientist Grade II
Microbiology Dept, City Hospital NHS Trust**

Major teaching hospital, Regional Antimicrobial Chemotherapy laboratory

Key Achievements

- Daily supervision & operational management of all technical areas including staff development and appraisal
- Management of all “out of hours” services. Reduced operating costs by 42% without reduction in service.
- Training of degree students to State Registration, project supervisor
- Developed in-house training manuals for all grades of staff

1988 – 1993

**Biomedical Scientist Grade I
Microbiology Dept, Selly Oak Hospital NHS Trust**

Key Achievements

- Instrumental in the implementation of a novel fully automated blood culture machine
- Wrote in house training manual – adopted by manufacturer

QUALIFICATIONS / AWARDS / EDUCATION:

- Master’s degree in Business Administration - Merit “*Impact of differing growth strategies in the Pharmaceutical over the Counter (Home-use) device market.*” (2011)
- Barton award for Innovation University of Derby (2010)
- Statistics for Clinical Trials & Introduction to Randomized Controlled Clinical Trials. University of York (2007)
- Diploma in Management Studies (MBA Program). Research paper “*Fitness to Practice, the Effect of Competency Testing on Biomedical Scientists.*”(1998)
- Fellowship of the Institute of Biomedical Science (Bacteriology option) (1992)
- Higher National Diploma in Medical Laboratory Sciences with Bacteriology as a specialist option. (1989)
- 3 A Levels (Biology, Chemistry, Food and Nutrition), 9 O levels.

PUBLICATIONS :

Use of Sentinel blood culture system for analysis of specimens from potentially infected prosthetic joints.
J Clin Pathol 1994 May; 47(5):475-6

OTHER INTERESTS:

2015-16. Member of LA Bicycle Coalition, working on education, advocacy and outreach to make LA a safer cycling city. www.LA-BIKE.ORG

2013-14. Academic volunteer at Squashsmarts an “out-of-school time” program offering academic and athletic mentoring for 5th-12th graders. Awarded “Volunteer of the year 2013-14”.
www.squashsmarts.org.

PERSONAL DETAILS:

Marital Status: Married
Permanent US resident (Green Card Holder) United Kingdom passport
Driving License: United Kingdom, United States of America – Full - Clean