CEO Europe Success Story

From bench-top drug candidate synthesis to the clinic in 240 days

I was invited to serve in the contracted capacity of Vice-President of Regulatory Affairs and Quality Operations for the "virtual" pharmaceutical development firm, AlgoRx, Inc (Fremont, CA, Secaucus, NJ).AlgoRx had completed Series A: $10MM, and Series B: $25 MM funding

In this role, I built a cross-functional team, hired, and managed Regulatory, R&D, and Quality employees on both East and West US coasts. We performed our first studies in the UK, which continued to continental Europe and eventually to the US. I identified and oversaw domestic and internationally situated out-sourced partners for clinical supplies R&D and manufacture, analytical development, and product release, warehousing and distribution – all of which were accomplished under stringent compliance with the expectations of Current Good Manufacturing Practices (cGMP). I trained clinical personal in protocol execution, reconciled and audited studies and supplies as a part of closure of pre-clinical and clinical studies, and led pre-clinical through Phase 2 regulatory filings to the point of AlgoRx's acquisition.

I continued in this consultative capacity through the acquisition, and hired in my replacements. Under the combined firm's new name, Anesiva, the firm received FDA approval for its first NDA, a drug-device combination product, marketed as ZingoTM (originally known as Oxford University's PowderJect® Lidocaine needle-free injection) in August, 2007. Anesiva's AdleaTM (ultra-purified capsaicin for injection) went into Phase 3 trials (knee replacement, bunionectomy indications). I am named on 5 of the patents (US and EU) for AdleaTM.

Noteworthy in the context of AdleaTM is the comparatively brief time (8 months) which transpired from first successful API purification, to first-in-man clinical studies done in the UK. From February to September I accomplished the following:

1. Vendor due diligence and selection and API scale up purification including certified reference standards and impurities standards.

Written by
Timothy A. Anderson
iCEO #19891

Find us on the Web:
www.ceo-europe.com

+33 (0) 970 448 419

2. Vendor due diligence and selection for formulation development
3. Vendor due diligence and selection for analytical method development (US), and product assay verification in the UK.
4. Vendor due diligence and selection of bioanalytical assay method development, international clinical sample plasma shipment and storage.
5. Vendor due diligence and selection for domestic and UK-based clinical supplies labeling, warehousing, and distribution.
6. Vendor due diligence and selection of UK-based regulatory filing service for preparation of CTX.
7. API and formulation stability studies, accelerated and RT
8. Formulary in-use bench stability studies.
9. Successful scale up sterile formulation for clinical supplies and release qualification accomplished under cGMP.
10. Training of UK-based pharmacy technicians in cGMP handling of clinical supplies and final formulary bench protocol execution prior to patient dosage administration in the surgical theater.

I am named on 5 patent applications which proceeded from this effort.

First-in-man clinical trials for the knee replacement indication were scheduled to occur at Charing Cross Hospital, London, UK in October that same year. First-in-man studies were both successful, and were accomplished on time and without delay.

Timothy A. Anderson is the founder of a life-sciences consulting firm. He is a former FDA Review Chemist with a successful 10-year regulatory, and quality ops/cGMP compliance advisory track record.

Written by
Timothy A. Anderson
iCEO #19891