CURRICULUM VITAE

(name, contact info)

PROFILE

A global regulatory professional with twenty-two years clinical drug development experience, seventeen of which within global regulatory affairs. Broad experience across various therapeutic areas including CNS, anti-infective, ophthalmology, GUGI, respiratory and oncology. Proven scientific, regulatory and managerial expertise in driving both early development teams (resulting in successful CTA and IND submissions) and full development programs (overseeing the preparation of and successful submission of NDAs, MAAs, and NDSs). A proven ability to lead and manage teams through complex global regulatory submissions and interactions with numerous global health authorities (including FDA, EMA, regional country authorities and Health Canada)

Professional Experience

May 2008- Current **(Company name)**
Senior Director, Regulatory Affairs

- Plan global regulatory strategy and prepare regulatory submissions of multiple health authority (HA) applications, such as, INDs, CTAs, NDAs, MAAs, related supplements, and responses to questions from health authorities. On a day to day basis provide guidance and oversight to project teams, collaborating closely with nonclinical and CMC colleagues, to help assure that all submissions are timely and of high quality, so as to minimize HA issues/questions that might impede a projects progress.
- Interact directly with health authorities, including FDA, to facilitate assessment of regulatory submissions. Organize and manage meetings with Health Authority personnel to obtain commitments and agreements enabling rapid and compliant development of new drug programs.
- Member of promotional material review committees (PMRC) ensuring compliance with applicable regulatory requirements concerning drug advertising and promotion.
- Provide regulatory oversight and guidance to project teams on compliance matters, FDA and other competent authority requirements, clinical study design issues and on timing, logistics and operational recommendations for product development.
- Prepare risk assessment profiles for regulated aspects of new drug development, and communicates risk assessment to senior management.
- Review and submit reports of serious and unexpected adverse events; final clinical and nonclinical study reports, and other development-related documents.
- Monitor the US and international regulatory environments, and provide senior management and project teams with assessments of the impact of new and changing regulations on the company's research and development programs.
- Senior leader within the regulatory department with management oversight responsibilities for 2 direct reports covering compliance activities and regulatory oversight of projects

June 2007- May 2008 **Director**
(Company name)
Worldwide Regulatory Strategy
Worldwide Regulatory Affairs and Quality Assurance

Jan 2002-June 2007 **Associate Director**
(Company name)
Worldwide Regulatory Strategy
WRAQA

Global Regulatory Lead for (provide examples) approved products (provide programs)

Regulatory Lead in Therapeutic Area: (provide examples)

- Provided regulatory leadership to these project teams. Ensured robust, well-aligned regulatory strategies existed between development and commercial partners and associated implementation plans are in place for each project.
- A key participant in project-specific, internal strategic meetings covering various levels of governance and key markets.
- Eexperienced with multiple registrations worldwide and as such have experience filing NDAs, MAAs, NDS and JNDAs.

July 2001- Jan 2002 **Senior Regulatory Executive**
(Company name)
Regulatory Policy and Intelligence

- Worked within the newly formed Regulatory Policy & Intelligence Group and subsequently the Regulatory Development Group within Worldwide RA, during this time assisted in the roll out of the REACH project. This important initiative embedded good regulatory business practice within the wider regulatory organization.
- A trainer and advocate for REACH at site in the US, which involved training of Global Therapeutic Area Leaders and their staff at the site. This was also extended to other Pfizer development sites. Worked with the Site Regulatory Portfolio leaders to communicate on the 'Label Drives Development' process to key stakeholders who reside outside of regulatory organization.
- Chair of the Clinical Trial Directive Action Group until relocating to the US July 2002. Coordinating and inputting to the Pfizer position on early draft guidance's and ensuring communication of these positions to Trade Associations and communicating progress as appropriate throughout the organization.
- Collaborated with market assessment group to rationalize product profiling and develop a framework for effective decision-making.
- Worked with Head of Regulatory Development to partner with colleagues across company to position company as a proactive, responsive and participative partner in regulatory interactions and in the development of regulatory policies and principles worldwide

Oct 1998- July 2001 **Senior Regulatory Executive**
(Company name)
Regulatory Registration and Strategy
Metabolic Endocrine Group

Nov 1996-Oct 1998 **Regulatory Executive**
(Company name)
Regulatory Registration and Strategy
Metabolic Endocrine Group

- EU Regulatory lead for Cardura XL responsible in guiding the team in the filing of Cardura XL within the EU
    - As a member of the World Wide Development Team, was active in the preparation and implementation of a complicated filing strategy, which involved several Mutual Recognition Procedures and multiple national filings.
    - Provided regulatory guidance to clinical development in Japan (J-Clin) in the preparation of the JNDA working closely with colleagues in. Acted as point of contact for the clinical team in each of these areas, facilitating the discussions, ensuring that J-Clin received the support necessary from the Western team members to build their submission.

Jan 1994- Nov 1996 **Senior Clinical Research Associate**
(Company name)
Early Clinical Research Group

Supported a number of exploratory candidates from first in human to Phase 2a including co-ordinating many of the Phase 1 clinical PK/PD studies for Viagra. In doing so developed my broad clinical trial expertise and grew my understanding of the clinical development process and have a strong understanding of the implementation and requirements of Good Clinical Practice

July 1992- Jan 1994 **Clinical Research Associate**
(Company name)
Medical Department

AWARDS:

EDUCATION AND QUALIFICATIONS

Publications: available on request