PERSONAL DETAILS

Name:	Darryn Bampton MMSc, BSc, PGDip (Reg Affairs)
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Nationality:	Australian and British citizenship

CAREER PROFILE

I am a competent and resourceful Regulatory Affairs and project management professional with 16 years experience in the prescription medicine industry (including 13 years of broad based regulatory affairs experience). I have undertaken regulatory and development activities for European, US, Australian and New Zealand markets. I have worked with biopharmaceuticals (monoclonal antibodies, oligosaccharides, an autologous T-cell therapy), small molecule new chemical entities, and generics, in numerous therapeutic areas. I have guided regulatory projects from initial early development to licensing and managed all aspects of licence maintenance including variations, renewals, labelling updates. I have worked on project teams for compounds in early stage development (non-clinical to first-in-human), in regulatory, clinical and project manager roles, and have the ability to drive projects through to completion in a positive and focused manner. I have extensive experience in liaising with regulatory authorities, including preparation and attendance at regulatory meetings, and am very comfortable with this role.

I have extensive management experience, have prepared department budgets, and been involved with CRO selection. I have excellent oral and written communication skills and am able to distil information succinctly. I am a capable and enthusiastic professional, with excellent interpersonal skills, a rational, calm and positive disposition, and demonstrated management skills.

EMPLOYMENT HISTORY

March 2012 to Present – Bampton Regulatory Services Pty Ltd

Director

Services

- Provision of strategic regulatory affairs advice to facilitate efficient drug development and licensing.
- Provision of regulatory support throughout the licensing process.
- Preparation of agency briefing documents and provision of regulatory support at agency meetings across all stages of a therapies life-cycle.
- Preparation of regulatory documentation, including IND, CTD, Investigators' Brochures, IMPD, CTA, CTX, and SCOTT applications.
- Ghost writing Module 2 overviews and summaries, including summary tables.
- Preparation of drug development project management tools, including Target Product Profiles, drug development plans, project timelines.
- Preparation and management of post-licensing regulatory activities.
- Expertise in EU, US, and AUS/NZ regulatory affairs.

April 2009 to February 2012 – Progen Pharmaceuticals Ltd, Australia

Director of Regulatory Affairs and Clinical Development

Key Achievements

- Preparation and management of regulatory and development tools for a new oncology candidate, including regulatory strategy, drug development plans, Target Product Profile, and Microsoft Project.
- Leadership roles on cross-functional teams.
- Project management of Phase I First-in-human clinical trial, including protocol design, identification of trial sites, and CRO selection.
- Preparation for and attendance at an FDA pre-IND meeting.
- Preparation of an IND.
- Preparation for an End-of-Phase II (EOP2) meeting with Taiwanese Centre for Drug Evaluation for an oncology product.
- Line management of the regulatory and clinical groups (3 staff).
- Preparation of department budgets.

September 2002 to April 2009 – Origin Pharmaceutical Services/Constella Group/SRA Global Clinical Development

July 2006 to April 2009: Senior Regulatory Affairs Manager
Constella Group Pty Ltd (subsequently SRA GCD), Melbourne, Australia

Feb 2005 to July 2006: Regulatory Affairs Group Manager
Origin Pharmaceutical Services Ltd (subsequently Constella Group Ltd), Oxon, UK

Oct 2002 to Jan 2005: Regulatory Affairs Manager
Origin Pharmaceutical Services Ltd, Oxfordshire, UK

Key Achievements

- Group Manager duties included line management of 7 regulatory professionals with a broad range of experience (0 to 15 years regulatory expertise). This included management of staff that were working remotely.
- High level regulatory support, including provision of strategic development and regulatory advice: review of regulatory *prior art* (Summary Basis of Approval, European Public Assessment Reports), review of existing regulatory guidance, interpretation of EU regulatory Directives and Regulations considering legal precedence, performance of literature reviews and gap analyses, and input into the preparation of development plans.
- Preparation for and attendance at regulatory agency meetings: EMEA (protocol assistance, MAA pre-submission, orphan designation pre-submission and oral explanation meetings), EU national agencies (EOP2 meetings, scientific advice for pre-clinical packages), FDA (preparation of an EOP2 meeting, preparation and attendance at a special post-submission defence meeting for a product granted priority review) and Australian TGA (EOP2 meeting).
- Submission and regulatory support of a successful Mutual Recognition Procedure in 6 European Countries.

- Managing project teams, involving members located across the globe. Two specific examples are:
    - Regulatory project management of a European centralised procedure for an orphan oncology drug; this included the provision of mentoring for the client's regulatory team based in Denmark, preparation and submission of the MAA using client and CRO staff, and project management for the subsequent NDA submission to the US, including management of US CRO activities.
    - Project management for a pre-Phase I investigational oncology product. The team included UK based CRO and CMO staff, a US based toxicologist, and an Australian based client.
- Preparation of orphan drug designation applications for the US and Europe for a number of oncology products and a paediatric GI indication. This included drafting of the application package, preparation for and attendance at EMEA pre-submission meetings and an oral explanation meeting.
- Business development activities: identification of potential clients; building on relationships with current clients.
- Preparation of clinical trial authorisation applications in various European markets for small molecules and biotechnology derived products; individual studies involved up to 5 EU states.
- Preparation of investigational medicinal product dossiers.
- Extensive experience in preparation of Quality documentation in Common Technical Document format for standard oral dosage forms and parenterals.
- Ghost writing of clinical and non-clinical overviews from literature.
- Coordination and liaison with clinical, marketing and manufacturing departments/subcontractors.
- Management of post-approval activities, such as variations and renewals.
- Preparation and revision of Summary of Product Characteristics, US labelling, Patient Information Leaflets, packaging, and Target Product Profiles.
- Regulatory activities while working in the Australian office were largely EU and US focussed.

December 1995 to September 2002 - Merck Generic Group of Companies

April 2002 – September 2002: Senior Regulatory Affairs Scientist
Generics [UK] Ltd, Hertfordshire, UK

September 2000 – April 2002: Regulatory Affairs Associate (Secondment)
Pacific Pharmaceuticals Limited, Auckland, NZ

March 1999 – September 2000: Regulatory Affairs Scientist
Generics [UK] Ltd, Hertfordshire, UK

June 1998 – March 1999: Stability Analyst
Generics [UK] Ltd, Hertfordshire, United Kingdom

December 1995 – June 1998: Raw Materials/Finished Products Analyst
Alphapharm Pty Ltd, Brisbane, Australia

Key Achievements

- Preparation of national and mutual recognition Marketing Authorisation Applications (MAA) and responses to regulatory authority post-submission questions.
- Preparation of licence variations for both national and mutual recognition procedures.
- Liaison with development sites to ensure generation of suitable data for MAAs.
- Preparation of Part I and Part II sections of MAAs, including liaison with development sites, and interpretation and distillation of scientific data.
- Review of Chemistry and Pharmaceutical dossiers to determine suitability of in-licensed products.
- Resolution of quality assurance issues from a regulatory perspective.
- Provision of regulatory support to drug development sites.
- Provision of technical knowledge to solve product queries.

TERTIARY EDUCATION

Master of Medical Sciences (Drug Development)
University of New South Wales
2008 – 2011 (with High Distinction)

TOPRA Postgraduate Diploma in Regulatory Affairs
University of Wales
2002 – 2006

Bachelor of Science
Majors in Chemistry and Biochemistry
University of Queensland
1992 – 1995

INTERESTS

Interests include reading, music, cricket and travel.

REFEREES

Supplied on request