AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

Industry Workshop

Preclinical, clinical and business development considerations for expediting drug development and partnering within the US and Europe.

Speakers: Dr Jim Chubb, Dr Paul Cossum and Geoff Kitson

City: Brisbane
Date: Monday 27 July 2009
Venue: Hilton Brisbane Hotel, 190 Elizabeth St, Brisbane
Time: 4.00 to 6.00pm

City: Melbourne
Date: Wednesday 29 July 2009
Venue: AusBiotech, Level 1, 322 Glenferrie Rd, Malvern,
Time: 4.00 to 6.00pm

Cost: AusBiotech member **$44.00** Student member **$33.00** Non member **$66.00**

Dr James Chubb is broadly experienced in operational management, strategy and financing of biopharmaceutical companies, as well as possessing extensive pharmaceutical product-development experience. As a senior executive at GSK with more than 12 years' experience, Dr Chubb was responsible for directing the filing of more than 15 NDAs and ANDs for anti-bacterial and anti-fungal drugs, beta agonist bronchodilators and inhaled steroids for asthma, topical steroids for dermatological indications and serotonin antagonists for cancer-induced nausea and vomiting. As President and Chief Executive of Triplex Pharmaceuticals and its successor, Aronex Pharmaceuticals, for 8 years, Dr Chubb raised over $65 million in financing, and established several corporate partnerships. He built a strong management team and over saw advancement of three cancer drugs and an anti fungal into clinical trials. In 1999, Dr Chubb founded ProPharma International Partners, a consulting and advisory service company to biotechnology companies. ProPharma has grown over the past 10 years and has locations in the San Francisco Bay area London, and Tokyo, Dr Chubb received his Ph.D. in Pharmacology from the University of Arizona, College of Medicine, and completed a cardiovascular research fellowship at Michigan State University.

Dr Paul Cossum has more than 20 years' experience in the US biotechnology business. He has been a successful scientist and, in recent years, a successful executive who took university IP and built a company with drug discovery and development capacity. Areas of management responsibilities have ranged from groups of laboratory bioanalytical, metabolism, pharmacology and toxicology scientists, through to overall responsibility for R&D and then to being a CEO of a biotechnology startup company where he was responsible for raising $40 million. He began his career as a scientist in the Pharmacological Sciences Department at Genentech Inc. There he worked on the metabolism and toxicity of recombinant human proteins, as well as peptides, with new therapeutics entering clinical trials. Over the next two decades he assumed increasingly broader roles and responsibilities in drug development. Much of his experience has focused on the interface between discovery and development, although he has also been responsible for preclinical sections of (NDAs). Therapeutic areas of knowledge include inflammation, oncology, anti-infectives, cardiovascular, neurology and endocrinology. He has experience with small molecules, recombinant proteins, peptides, monoclonal antibodies and oligonucleotides. Paul provides consulting advice for startup and mid-size biotechnology companies on business plans, financing, product development planning and execution (IND-enabling pharmacology, toxicology, CMC and bioanalytical studies), CRO interfacing and offers interim executive management when needed. He earned bachelors, masters and PhD degrees from the University of Tasmania, Australia.

Geoff Kitson has gained a broad-based international perspective on drug development, from phase I to phase IV, experience of pre-clinical work, and regulatory requirements, since joining the pharmaceutical industry in the late 80s. He has been involved in the preparation of INDs, CTXs/CTAs, and the preparation of CTDs for MAAs and the preparation of other regulatory documents. Geoff has experience in the development of individual clinical studies, clinical trial programmes, running multinational clinical trials and developing clinical strategies. In the last few years, he has taken products into 'first in man' studies, subsequently progressing these products through to Phase II/III trials. In addition, he has set up a Phase III study that is creating a lot of interest in the respiratory field, supported licensing negotiations and prepared regulatory submissions for licensure. Geoff obtained his medical degree from the University of Nottingham and initially trained and worked in anaesthesiology and intensive care before joining the pharmaceutical industry with Syntex Pharmaceuticals. In various roles at Syntex he worked in a number of therapeutic areas, primarily pain, but also including female health care and cardiology. He was instrumental in the approval of ketorolac in the UK and maintaining the approval throughout Europe. He has worked in the USA, with global responsibilities for clinical trials, including planning a 16,000 patient "SAMM" study. Previous positions also include UK Medical Director at Yamanouchi Pharma, Head of Clinical Development at Chiroscience and Director of Exploratory Development Worldwide at Medeva. Before joining ProPharma, Geoff served as a consultant to startup companies offering services in clinical trial development and possible clinical strategies and identifying therapeutic areas for products.