NOVOTECH
The Asia Pacific CRO

BioDesk. Medical and Regulatory Consulting

BioDesk brochure

As the Asia-Pacific CRO with a global solution, Novotech has a unique capability through its in-house and integrated global product development and regulatory affairs consultancy, BioDesk. Novotech's BioDesk is an expert team offering CMC/manufacturing, toxicology, clinical and regulatory affairs consulting services for readying products to enter clinical trials or marketing approval.

The BioDesk team consists of experienced CMC, toxicology, medical writing, regulatory affairs specialists and consultant clinicians based in Australia and the USA. BioDesk works closely with clients to design and implement manufacturing and nonclinical plans, mindful of commercial timelines and budgets. BioDesk further adds value by ensuring that a global regulatory standard is inherent within client development programs.

BIODESK CORE SERVICES INCLUDE:

- Developing clinical and product development plans – always starting with the end in mind.
- Getting client's products GMP-compliant and ready for the clinic or approval.
- Designing and co-ordinating client's GLP-compliant toxicology studies in support of human studies and marketing approval.
- Co-ordinating meetings with international regulators and assisting with the preparation of optimal questions for the regulators in order to elicit meaningful responses.
- Writing all types of applications: pre-IND, IND, CTX, Orphan Drug Designations (ODDs) Paediatric Investigational Plans (PIPs), through to Marketing Authorisation Applications (MAAs) and everything in between.
- Vendor sourcing and management - particularly for virtual and small companies requiring a few more hands.
- Designing and writing protocols, investigator brochures and all modules in the Common Technical Dossier required for a Marketing Authorisation Application (MAA).

Further information about BioDesk services can be found at:
https://novotech-cro.com/Novotech/regulatory-and-clinical-consulting-biotechnology-companies

TEAM EXPERIENCE SNAPSHOT

With an average of over 10 years' per consultant, BioDesk offers its clients one of the most experienced and cohesive groups of regulatory, CMC and toxicology experts.

SENIOR and PRINCIPAL CONSULTANTS:

Tracey Brown is a Principal Consultant with over 25 years' experience in preclinical drug development, having worked as a Toxicology Study Director for 10 years and a Project Co-ordinator for over 10 years, responsible for the designing, implementing and interpretation of the toxicology packages required for a variety of clinical indications. Tracey has particular expertise in inhaled products developed while working in a large international pharmaceutical company. Tracey is a member of the British Toxicology Society (BTS) and the US Society of Toxicology (SOT) as well as being a UK/EU Registered Toxicologist.

Dr Hiram Chipperfield is a Senior Consultant with over 10 years of regulatory affairs experience. He has a scientific background with a PhD in cell biology followed by academic and commercial post-doctoral research. Prior to joining NOVOTECH, Hiram held roles in a regulatory affairs consulting firm and a global diagnostics company. With experience in products from diagnostics to cell therapies, he has managed projects ranging from preclinical development, first-in-human clinical trials, product registration, through to post-market reimbursement applications.

Fedora Daye is a Senior Consultant in the US office. She has a BSc (Biology/Chemistry) and a MPH (Public Health) and has held a range of positions in research, consultancy and marketing in the health sector. Since moving into Regulatory Affairs (RA) in 1998, she has held senior positions at Goldbelt Raven, Ioma Corporation and most recently as the Director RA at an International Partnership for Microbicides. Fedora has extensive experience in program management and strategic advisory both internationally and locally with the US (FDA) regulatory authorities.

Dr Simone Flight, a Senior Consultant within BioDesk, has worked for over eight years' in early drug development and more than 10 years' in the pharmaceutical industry including seven years' as a regulatory affairs consultant, consulting on international projects from early proof of concept, facilitating marketing authorisation approvals and coordinating post marketing activities. Simone has also worked for three years' in RA and compliance within a multinational pharmaceutical company.

Louise Moore, is the Director of BioDesk and has been with NOVOTECH for over eight years'. Louise has more than 20 years' experience in regulatory affairs and medical writing including nine years' working for multinational pharma companies based in the UK and five years' in a small Australian Biotech, all involving liaison with US, European and Australian regulatory authorities.

Dr Rosemarie Pereira is a Consultant with over fifteen years' of clinical research experience on early and late phase clinical studies in the therapeutic areas of autoimmune, dermatology, ENT, genetic disorders, immunology, infectious diseases, neurology, oncology, ophthalmology, paediatrics including paediatric allergy, reproductive, nutrition, respiratory

and hepatology. Rosemarie started her career as a research scientist in HIV immunology at the institute of Medical and Veterinary Science in Adelaide followed by a post-doctoral fellowship at the Pasteur Institute in Paris working with Nobel laureate Professor Francoise Barre-Sinoussi. Following her 4 year career in HIV research, she continued research on the immunopathogenesis of Herpes Simplex Virus in the peripheral nervous system. She worked at ICON Clinical research as a senior CRA before joining Novotech (formerly CNS) where she now works as a medical writer.

CONSULTANTS:

Kelly Burns is Consultant with over three years' experience on early phase clinical studies in the therapeutic areas of infectious disease, respiratory disease, haematology and immunological disorders. Kelly started her career as a research scientist in reproductive biology in Newcastle Upon Tyne, UK and worked in skin pathology and histology before joining NOVOTECH where she now works as a medical writer.

Dr Catherine Tabrett is a Consultant with a PhD in Agricultural Chemistry (1999) and a BScAgr(Hons1) (1995), both from the University of Sydney. Catherine has worked in academic research in Australia and the UK for over a decade and in national and international companies in Clinical Research Associate and Medical Writing roles, across a large range of therapeutic areas. More recently she has worked as a freelance Scientific/Medical Editor, Chemistry Teacher and Laboratory Demonstrator at tertiary institutions. At NOVOTECH, Catherine is focused on medical writing for core documents, such as Protocols, Investigator Brochures and Clinical Study Reports.

Babaji Yadav is a Consultant with over six years of academic experience in pre-clinical oncology drug development and three years of industry experience (biotech) in early phase drug development. Babaji has a strong background in pharmaceutical sciences with a PhD in Pharmacology and Toxicology from University of Otago, New Zealand. Previously he has worked as a Research Project Manager to oversee IND enabling toxicological studies for lead oncology drugs and, prior to joining NOVOTECH, was a Clinical Project Manager. Babaji is a UK Registered Toxicologist and at NOVOTECH he is focussed on providing technical toxicology advice and product development strategies to facilitate entry of client's compounds into clinical trials.

To contact us or find out more, click **here**

CVs

PERSONAL DETAILS

Name: Tracey Brown BSc(Hons), MSc

Academic Qualifications:

Qualification	Date	Institution
Master of Science Biomedical Science	1996	Anglia Polytechnic University (now known as Ruskin University)
BS Principals of Toxicology Pathology	1993	Robens Institute University of Surrey
Postgraduate Training in Inhalation Toxicology Grade A	1993	University of East London
Bachelor of Science Applied Biology second class honours (1st division)	1991	Polytechnic of East London (now known as University of East London)

Current Professional Societies and examinations:

Institution	Qualification	Examination
BTS	Registered member	-
SOT	Full member	-
Royal Society of Biology and BTS	UK Registered Toxicologist	By Review
Eurotox	EU Registered Toxicologist	

EMPLOYMENT RECORD

Current Company Position Title: Principal Consultant
Date Appointed to Position: 1 July 2019

Previous Employment History:

Position Title	Company	Date Started	Date Ended
Senior Consultant	Clinical Network Services (CNS) Pty Ltd	2015	June 2019
Regulatory Toxicology Consultant	DF Pre-clinical Services Pty Ltd	2011	2012
Manager Non-clinical Safety Projects	GlaxoSmithKline UK	2001	2010
Toxicologist/Principal Toxicologist General and Reproductive Toxicology Department	Glaxo Welcome	1991	2001
Laboratory Technician	Glaxo Group Research	1986	1991

EXAMPLES OF EXPERIENCE
Previous Employment Experience:

Regulatory Toxicology Consultant - DF Pre-clinical Services Pty Ltd
Responsibilities:

- Act as Regulatory Toxicology Consultant assistant.
- Review non-clinical toxicology packages to support the conduct of clinical trials and to support marketing applications in Australia.
- Performed literature reviews related to a development programme or issue.
- Advise on non-clinical regulatory toxicology requirements.

Manager, Non-clinical Safety Projects - GlaxoSmithKline UK
Responsibilities:

- Represent Safety Assessment Division on international project teams, designing preclinical packages of work as well as executing non-clinical studies to support clinical trials and submissions.
- Effective project management.
- Effective communication and project co-ordination within the project team and within own department to enable project deadlines and budget targets are met.
- Effective communication of project issues and options for resolution to senior stakeholders and project team.
- Design and manage toxicology programs that successfully support the conduct of phase I-III clinical trials and market applications in US and Europe.
- Design and dose selection of a range of toxicology studies eg, dose-range finding/maximum repeat dose studies, acute single dose studies, repeat dose studies, reproductive toxicity studies, carcinogenicity studies, combination toxicology, as well as juvenile toxicity studies.
- Review study reports of projects responsible for.
- Prepare and update Investigational brochures.
- Prepare US Pre-IND (non-clinical) and IND submissions
- Literature reviews for regulatory submissions
- Preparation of Paediatric Investigational Plans (non-clinical focus)
- Provide advice and training to less experienced project co-ordinators on non-clinical regulatory toxicology requirements.
- Represent the company at regulatory agency meetings including US FDA and European agencies.
- Prepare scientific advice documentation.
- Answer regulatory questions in a timely and effective manner.
- Perform due diligence on potential assets.

Toxicologist/Principal Toxicologist - Glaxo Welcome
Responsibilities:

- Act as Toxicology Study Director and Toxicology Study Monitor for contracted out studies.
- Liaise with CROs in UK, Europe and Canada for effective study conduct and resolution of study or project issues.
- Act as study director/monitor in inhaled toxicology studies using various formulations including powders, nebulisers and Metered Dose Inhalers.

- Act as study director for oral, IV and SC studies from acute to chronic studies in rodent and non-rodent species.
- Perform toxicology study report review.
- Write toxicology protocols and study reports, including compilation of data tables.
- Train junior staff in various study director-related duties, report writing, inhalation dosing and aerosol generation.

Laboratory Technician - Glaxo Group Research
Responsibilities:

- Support the day-to-day running of toxicology studies, preparing paperwork, assisting with animal procedures and data entry of study data to GLP standard.
- Determine drug requirements for a study and perform the aerosolization of dry powder, nebulisation and metered dose inhalation products.
- Sample collection for inhalation studies to confirm exposure concentration and particle size distribution.
- Collection of lab data and interpretation of study data.
- Preparing simple protocols and reports.

Publication Record

Theses

1. **Brown,TJ** (1996). Evaluation of in vivo liposome-mediated hCFTR transfection and expression in several animal species. MSc thesis.
2. **Brown,TJ** (1991) Studies to Investigate the Feasibility of dosing pregnant rabbits with metered dose aerosol formulations using an automated inhalation dosing system. BSC thesis.

Publications

1. 1. Dow G, **Brown T**, Reid M, Smith B, Toovey S. Tafenoquine is not neurotoxic following supertherapeutic dosing in rats. Travel Medicine and Infectious Disease, 2017, 17:28-34.

PERSONAL DETAILS
Name: Kelly Burns, BSc (Hons)

Academic Qualifications:

Qualification	Date	Institution
BSc Medical Science with First Class Honours in Physiological Science	2012	University of Newcastle-upon-Tyne
Certificate IV Finance	2000	Melbourne Institute of Technology

EMPLOYMENT RECORD
Current Company Position Title: Consultant
Date Appointed to Position: July 2019

Previous Employment History:

Position Title	Company	Date Started	Date Ended
Associate Consultant	NOVOTECH	Aug 2017	Jun 2019
Project Administrator	NOVOTECH	Apr 2016	Aug 2017
Office Administrator	NOVOTECH	Sep 2013	Feb 2014
Histology Scientist	Sullivan Nicolaides Pathology	Feb 2013	Sep 2013
Critical Incident Coordinator	PPC Worldwide	Jul 2012	Feb 2013
Research Scientist	Newcastle University Institute of Cellular Medicine	Mar 2011	Jul 2012
Office Manager	Scottish Ski Holidays	Nov 2004	Sep 2009
Loans Officer	Bank of Queensland	Jul 2000	Nov 2004

EXAMPLES OF EXPERIENCE
Previous Employment Experience:

Project Administrator - NOVOTECH
Responsibilities:

- Draft ethics and regulatory applications
- Online submission of CTN applications
- Collection, tracking and filing of all documents generated throughout a clinical study
- Reconciliation of Investigator Site Files and Trial Master Files
- Assist in producing clinical and regulatory documents including reports, project plans, manuscripts and patient information documentation

Office Administrator - NOVOTECH
Responsibilities:

- Draft work instructions and company policies
- Database management / maintenance
- Scheduling and travel arrangements

Histology Scientist – Sullivan Nicolaides Pathology
Responsibilities:

- Dissection of patient specimens
- Reconciliation of patient information and specimen with suspected pathology
- Describe and report macro properties of a specimen
- Selectively stain and orientate specimens for further micro examination by a pathologist

Publication Record

1. Lysine deacetylase inhibition promotes relaxation of arterial tone and C-terminal acetylation of HSPB6 (Hsp20) in vascular smooth muscle cells – Physiol Rep. 2013 Nov;1(6):e00127. Doi: 10.1002/phy2.126. Epub 2013 Nov 7

PERSONAL DETAILS

Name: Dr Hiram Chipperfield, PhD

Academic Qualifications:

Qualification	Date	Institution
Doctor of Philosophy – Adult Neural Stem Cells	2003	University of Queensland
Research Honours (Biochemistry)	1998	University of Queensland
Bachelor of Science (Genetics and Biochemistry)	1997	University of Adelaide

EMPLOYMENT RECORD

Current Company Position Title: Senior Consultant
Date Appointed to Position: August 2018

Previous Employment History:

Position Title	Company	Date Started	Date Ended
RA and Market Access Manager	Abbott (formerly Alere) Brisbane, Australia	2015	2018
Regulatory Affairs Manager	Alere Brisbane, Australia	2012	2015
Regulatory Affairs Project Manager and Consultant	ERA Consulting Brisbane, Australia London, UK	2008	2012
Research Scientist	ES Cell International Singapore	2006	2008
Post-Doctoral Research Fellow	MCB, Harvard University Boston, USA	2003	2006

EXAMPLES OF EXPERIENCE

Previous Employment Experience:

Regulatory and Market Access Manager - Abbott (formerly Alere)
Responsibilities:

- Negotiated the registration of the first rapid HIV test for point of care use in Australia
- Managed more than 50 IVD registrations during the transition to the current Australian regulatory framework
- Chair of IVD Australia regulatory committee and represented industry at TGA Reg-Tech meetings
- Managed 3 MSAC applications for Medicare reimbursement. Managed advocacy and stakeholder engagement
- Technical management of private labelled products
- Internal auditor for ISO 13485 and ISO 9001 certified quality systems
- Supported clinical trials of diagnostics

- Regulatory responsibilities: pre- and post-market medical device compliance, compliant distribution, electrical compliance, advertising/marketing review, privacy, and import permits

Regulatory Affairs Project Manager and Consultant – ERA Consulting
Responsibilities:

- Preparation and compilation of Module 3 (CMC/Quality) of a successful European Marketing Authorisation Application (MAA) of a complex biological medicinal product
- Project management of a recombinant therapeutic development program encompassing pivotal toxicology studies, GMP manufacture of clinical trial supplies and first in man clinical trial
- Development of a regulatory strategy for a novel cell therapy business model
- CMC/Quality due diligence, gap analyses, and regulatory strategy development activities
- Preparation of a range of regulatory documents including Investigator's Brochures (IB), orphan drug applications, CTD modules, clinical trial applications (CTA) and Certificates of Suitability (CEP)
- Project management and consulting. Product development and regulatory projects with a focus on biotech and cell therapy products

Publication Record

1. Teo AK, Ali Y, Wong KY, **Chipperfield H**, Sadasivam A, Poobalan Y, Tan EK, Wang ST, Abraham S, Tsuneyoshi N, Stanton LW, Dunn NR. (2012) Activin and BMP4 synergistically promote formation of definitive endoderm in human embryonic stem cells. *Stem Cells.* Apr;30(4):631-42
2. Hurley P and **Chipperfield H** (2011) Commentary: EMA gives opinion on biomarkers for Alzheimer's disease. *MedNous* 5(6):9
3. **Chipperfield H** and Jackson-Matthews (2010) The impact of recent 'Biologicals' legislation on clinical trials in Australia. *Journal for Clinical Studies* July: 20-23
4. Cai J, Xie D, Fan Z, **Chipperfield H**, Marden J, Wong WH, Zhong S. (2010) Modeling co-expression across species for complex traits: insights to the difference of human and mouse embryonic stem cells. *PLoS Comput Biol.* Mar 12;6(3)
5. Hong F, Fang F, He X, Cao X, **Chipperfield H**, Xie D, Wong WH, Ng HH, Zhong S. (2009) Dissecting early differentially expressed genes in a mixture of differentiating embryonic stem cells. *PLoS Comput Biol.* Dec;5(12
6. **Chipperfield H** and Dunn NR (2009) Method of differentiating stem cells United States Patent Application Application number: 12/865,454
7. Phillips BW, Hentze H, Rust WL, Chen QP, **Chipperfield H**, Tan EK, Abraham S, Sadasivam A, Soong PL, Wang ST, Lim R, Sun W, Colman A, Dunn NR. (2007) Directed differentiation of human embryonic stem cells into the pancreatic endocrine lineage. *Stem Cells Dev.* Aug;16(4):561-78.
8. Zhou Q, **Chipperfield H**, Melton DA, Wong WH. (2007) A gene regulatory network in mouse embryonic stem cells. *Proc Natl Acad Sci USA.* 104(42):16438-43
9. Wang S, Cowan CA, **Chipperfield H**, Powers RD. (2005) Gene expression in the preimplantation embryo: in-vitro developmental changes. *Reprod Biomed Online.* May;10(5):607-16.
10. **Chipperfield H**, Cool SM, Bedi K, Nurcombe V. (2005) Adult NOVOTECH explants as a source of neural progenitors. *Brain Res Brain Res Protoc.* 14(3):146-53

11. Hogg RC, **Chipperfield H**, Whyte KA, Stafford MR, Hansen MA, Cool SM, Nurcombe V, Adams DJ. (2004) Functional maturation of isolated neural progenitor cells from the adult rat hippocampus. *Eur J Neurosci.* May;19(9):2410-20.
12. **Chipperfield H**, Bedi KS, Cool SM, Nurcombe V. (2002) Heparan sulfates isolated from adult neural progenitor cells can direct phenotypic maturation*. Int J Dev Biol.* 46(4):661-70.
13. Nurcombe V, Smart CE, **Chipperfield H**, Cool SM, Boilly B, Hondermarck H. (2000) The proliferative and migratory activities of breast cancer cells can be differentially regulated by heparan sulfates. *J Biol Chem*. Sep 29;275(39)

PERSONAL DETAILS
Name: Fedora Daye

Academic Qualifications:

Qualification	Date	Institution
Masters of Public Health	1988	University of North Carolina at Chapel Hill, Chapel Hill, NC
Bachelor of Science	1982	North Carolina Central University, Durham, NC

EMPLOYMENT RECORD
Current Company Position Title: Senior Consultant
Date Appointed to Position: 31st January 2017

Previous Employment History:

Position Title	Company	Date Started	Date Ended
Director Regulatory Affairs	International Partnership for Microbicides	July 2015	August 2016
Senior Regulatory Affairs and Quality Assurance Scientist	GoldbeltRaven, LLC	May 2007	July 2015
Director Regulatory Affairs	Iomai Vaccines	July 2003	April 2007
Regulatory Affairs Manager	Dynport Vaccines	April 2002	July 2003
Manager, Quality Systems and Regulatory Compliance	Digene Corporation	April 2001	April 2002
Regulatory Affairs Contractor	Aerotek	April 2000	April 2001
Director Regulatory Affairs	Acon Laboratories	January 1999	April 2000

EXAMPLES OF EXPERIENCE
Previous Employment Experience:

Director Regulatory Affairs - International Partnership for Microbicides (IPM)
Responsibilities:

- Managed eCTD submission projects (INDs, NDA, and other correspondence to regulatory agencies)
- Liaison to FDA, EMA, and other regulatory agencies
- Devised regulatory strategies, lead risk mitigation strategies, and developed collaborative relationships with developmental partners.
- Assessed the state of controls, compliance, and quality to determine the impact of GMP processes and deviations.
- Review, analyze, and translate regulatory requirements into a workable deliverable for project team meetings, executive management decisions, etc.
- Supervise, interact with and/or coordinate with contract regulatory staff and external service providers to ensure adequacy of project team support and deliverables

- Review regulatory documents and packets for submissions to national regulatory authorities (NRAs) and/or scientific or executive management boards
- Serve as lead writer for high priority submissions such as meeting briefing materials and coordinate with service providers to ensure document publishing and timely submission to NRAs
- Lead internal preparation for key regulatory meetings and manage meeting logistics, eg, rehearsals, slide presentation, and preparation of sponsor minutes.
- Facilitate product registration and approvals
- Act as liaison with appropriate regulatory authorities and provide as-needed support (regulatory input/editing/review) for various proposals, reports, etc. for various Resource Development activities

Senior Regulatory Affairs and Quality Assurance Scientist - GoldbeltRaven, LLC
Responsibilities:

- Produced, reviewed, and edited FDA briefing packages (Pre-IDE, Pre-IND, Pre-NDA, Technical Files, Design History Files), and product labeling, to ensure compliance with federal regulations and product requirements.
- Managed and implemented electronic submissions to the FDA (INDs, NDAs, Annual Reports).
- Primary Regulatory Affairs Representative for writing Request for Information, Proposals for new products. Member of four “Selection and Evaluation Boards” to evaluate various proposals
- Implemented SPL procedures to updated FDA approved to market pharmaceuticals applications.
- Implemented TPP procedures across 3 departments that managed device, biologics, and pharmaceuticals applications.
- Conducted risks assessments to identify and evaluate risks associated with the development of medical devices, therapeutics, vaccines, and program/project management.
- Provided analytical and technical program support through implementing FDA regulations to oversee product development, manufacturing and sustainment of medical devices, therapeutics, and vaccines to provide medical countermeasures for the US Army.
- Expertise in FDA Regulations – specifically developed clinical study documentation for clinical investigations of IVDs in the area of biological warfare agents and Infectious Diseases for 510(k)s, and PMAs, and NDAs for the identification and/or treatments for CBRN threats and biologics (vaccines) for biological warfare agents.
- Served as primary liaison to the FDA and other government organizations (Centers for Disease Control, Health and Human Services); ensuring the complete development of program documentation (i.e. PESHE, LCMP, briefing materials, regulatory submissions) to meet DoD/HHS requirements.

PERSONAL DETAILS

Name: Dr Simone Flight B.Sc. (Hons), Ph.D., RAC.

Academic Qualifications:

Qualification	Date	Institution
Doctor of Philosophy (Plant Physiology)	2003	Massey University New Zealand
Research Honours (Biochemistry) *Grade: First Class*	1996	Massey University New Zealand
Bachelor of Science (Biochemistry)	1995	University of Queensland

Current Professional Societies and examinations:

Institution	Qualification	Examination
RAPS (Regulatory Affairs Professionals Society)	Member and Regulatory Affairs Certified (General Scope)	2012
ARCS (Association of Regulatory and Clinical Scientists)	Member	-

EMPLOYMENT RECORD

Current Company Position Title: Senior Consultant
Date Appointed to Position: March 2014

Previous Employment History:

Position Title	Company	Date Started	Date Ended
Senior Quality and Compliance Associate	LEO Pharma Pty Ltd	2013	2014
Senior Regulatory Affairs Associate (QA responsible)	LEO Pharma Pty Ltd	2011	2013
Regulatory Affairs Consultant	ERA Consulting	2007	2011
Post-Doctoral Research Fellow	University of Queensland	2003	2007
Research Officer	Massey University (NZ)	1997	1999

EXAMPLES OF EXPERIENCE

Previous Employment Experience:

Senior Quality and Compliance Associate - LEO Pharma Pty Ltd

Responsibilities:

- Pharmacovigilance Safety Contact Person for pre- and post-marketed products
- Established and maintained the Quality Management System including: Documentation Control, Quality Defects, Deviation and Investigation Management, Local Self-Inspection, Vendor/Service Supplier Audits, Quality and Technical Agreements, Risk Management, Change Control, Annual Product Review and Management Review

- Generated and monitored quality performance metrics and resolved quality issues promptly
- Performed additional tasks as listed for previous position

Senior Regulatory Affairs Associate (QA responsible) - LEO Pharma Pty Ltd
Responsibilities:

- Provision of information and advice to internal departments on regulatory strategy and requirements for regulatory documentation
- Managed new product applications submitted to the TGA and Medsafe including generating NeeS submissions
- Generated regulatory strategies for new products and line extensions
- Coordination of regulatory activities in Australia and NZ for partnered (out licensed) products
- Authoring and coordinating the generation of labelling, packaging, Product Information and Consumer Medicine Information for Australia and New Zealand
- Managed the QA aspects of approving products for distribution in Australia and New Zealand
- Reviewed promotional and advertising materials for compliance with Australian and New Zealand Codes of Practice for Medicines
- Trained staff on the scientific aspects of pharmaceutical products and company databases including preparing and reviewing materials
- Pharmacovigilance Safety Contact Person

Regulatory Affairs Consultant - ERA Consulting
Responsibilities:

- Managed projects and provided consulting in scientific and regulatory affairs for biotechnology medicinal products including;
    - Writing and reviewing documents for clinical trial, marketing authorisation and post marketing dossiers
    - Scientific and regulatory strategy consultant for biologics in the USA, Europe, Japan, India, S. Korea and Australia

Publication Record

1. Psuedonaja Textilis Factor Xa-like Protease and anti-bleeding. Masci PP, Johnson LA, Birrell G, **Flight S**, de Jersey J, Lavin MF. Toxicon. In Press.
2. Identification and characterisation of Kunitz-type plasma kallikrein inhibitors unique to Oxyuranus sp. snake venoms. Earl ST, Richards R, Johnson LA, **Flight S**, Anderson S, Liao A, de Jersey J, Masci PP, Lavin MF. Biochimie. 2012 Feb;94(2):365-73.
3. Altered clot kinetics in patients with non-alcoholic fatty liver disease. Hickman IJ, Sullivan CM, **Flight S**, Campbell C, Crawford DH, Masci PP, O'Moore-Sullivan TM, Prins JB, Macdonald GA. Ann Hepatol. 2009 Oct-Dec;8(4):331-8.
4. Textilinin-1, an alternative anti-bleeding agent to aprotinin: Importance of plasmin inhibition in controlling blood loss. **Flight S**, Johnson LA, Du QS, Warner RL, Trabi M, Gaffney PJ, Lavin MF, de Jersey J, Masci PP. Br J Haematol. 2009 Apr;145(2):207-11.

5. Cloning and characterisation of natriuretic peptides from the venom glands of Australian elapids. St Pierre L, **Flight S**, Masci PP, Hanchard KJ, Lewis RJ, Alewood PF, de Jersey J, Lavin MF. Biochimie. 2006 Dec;88(12):1923-31.
6. Resistance of porcine blood clots to lysis relates to poor activation of porcine plasminogen by tissue plasminogen activator. **Flight S**, Masci PP, Lavin MF, Gaffney PJ. Blood Coagul Fibrinolysis. 2006 Jul;17(5):417-20.
7. Comparison of textilinin-1 with aprotinin as serine protease inhibitors and as antifibrinolytic agents. **Flight S**, Johnson L, Trabi M, Gaffney P, Lavin M, de Jersey J, Masci P. Pathophysiol Haemost Thromb. 2005;34(4-5):188-93.
8. Comparison of active venom components between Eastern brown snakes collected from South Australia and Queensland. **Flight S**, Mirtschin P, Masci PP. Ecotoxicology. 2006 Mar;15(2):133-41.
9. Cloning and functional expression of venom prothrombin activator protease from Pseudonaja textilis with whole blood procoagulant activity. Filippovich I, Sorokina N, St Pierre L, **Flight S**, de Jersey J, Perry N, Masci PP, Lavin MF. Br J Haematol. 2005 Oct;131(2):237-46.

PERSONAL DETAILS

Name: Mrs Louise Moore BSc (Hons)

Academic Qualifications:

Qualification	Date	Institution
BSc (Hons) Pharmacology and Physiology	1995	Southampton University (UK)

Current Professional Societies:

Institution	Qualification	Examination
The Organisation for Professionals in Regulatory Affairs (TOPRA)	Industry member	-

EMPLOYMENT RECORD

Current Company Position Title: Director, BioDesk
Date Appointed to Position: 1 February 2019

Previous Employment History:

Position Title	Company	Date Started	Date Ended
Director BioDesk Australia	Clinical Network Services	10/2017	01/2019
Associate Director BioDesk and Regulatory Affairs	Clinical Network Services	08/ 2014	10/2017
Medical Writer and Regulatory Affairs Manager	Clinical Network Services	10/2012	07/2014
Medical Writer	Clinical Network Services	10/2009	09/2012
Regulatory Project Manager	AGEN Biomedical Ltd (Australia)	11/2003	09/2009
Associate Director	GMG BioBusiness Ltd (UK)	04/2000	11/2003
Principle Regulatory Affairs Executive	Hoechst Marion Roussel Ltd (UK)	11/1996	03/2000
Regulatory Affairs Executive	SmithKline Beecham Consumer Healthcare (UK)	08/1995	11/1996

EXAMPLES OF EXPERIENCE

Technical Experience:

- Preparation of clinical section of a complex common technical document (CTD) for a marketing application in Australia.
- Responsible for the Project Management of various multi-functional teams in the preparation of clinical development plans and clinical trial protocols.
- Development and writing of numerous clinical trial protocols (Phase I and Phase II), and subsequent preparation of the resulting Clinical Study Reports.
- Preparation of drug development plans.

- Preparation of Briefing Documents and organization of a number of Regulatory Agency meetings, including TGA (Australia), EMA (Europe), MHRA (UK), IMB (Ireland) and MPA (Sweden)
- Regulatory Project Management for global development of a monoclonal antibody for in-vivo diagnostic imaging through Phase I and II development, including:
  - Preparation and review of the Investigational New Drug (IND) application and Clinical Trial Application (CTA) for the US and Canada. Subsequent maintenance of these applications through amendments, notifications and annual reports.
  - Preparation and review of clinical documents, including of a number of clinical protocols.
  - Regulatory input into the product development strategy, including liaison with FDA regarding proposed clinical development plans.
  - Preparation and review of a number of Clinical Study Reports.
- Compilation and submission of a number of Clinical Trial Applications in Europe.
- Compilation and submission of a number of Marketing Authorisation Applications (MAA), including key input into Clinical and Non-Clinical Expert Reports.
- Liaison with Regulatory Authorities in US, Canada and throughout Europe.
- Preparation of Orphan Drug Applications for submission to the European Medicines Agency (EMA).
- Strategic Regulatory input into various product development programs.

Speaking Engagements:

- Chair of GMG BioBusiness Seminar “Biotechnology Products: From Transcription to Prescription”. June 2002.

PERSONAL DETAILS

Name: Dr Rosemarie Pereira PhD

Academic Qualifications:

Date	Qualification	Institution
2002	Graduate Diploma in Education	University of Adelaide
1986	Doctor of Philosophy (Immunology)	Australian National University
1981	Bachelor of Science First Class Honours (Medical Microbiology)	University of Malaya

Awards/Achievements:

Year	Award/Achievement
2001	Start-up grant from the Sealy Foundation, University of Texas Medical Branch: USD 250,000
1996-1998	NHMRC grant**:** Molecular anatomy of the host response to a neurotropic viral infection: herpes simplex: AUD 225,000
1989	French Government Fellowship
Dec 1981-Dec 1985	ANU PhD Scholarship
Jun 1981	University Book Prize (University of Malaya)

EMPLOYMENT RECORD

Current Company Position Title: Consultant (Medical Writer)/CNS-Novotech
Date Appointed to Position: 11 November 2019

Previous Employment History:

Start Date	End Date	Position Title	Company
29 Sep 2015	07 Nov 2019	Senior Clinical Research Associate	Clinical Network Services
8 Apr 2013	30 May 2014	Senior Clinical Research Associate	ICON Clinical Research
1 Jul 2007	31 Oct 2012	Private Clinical Research Management Consultant/Director	Synapse Research Connexions (own company)
7 Jan 2007	30 Jun 2007	Senior Clinical Research Associate	Centre for Pharmaceutical Research, University of South Australia
15 Mar 2004	22 Dec 2006	Research and Vaccine Manager	Numico Research Australia Pty Ltd
Jan 2003	Mar 2004	High School Teacher	Scotch College (private) and Dept of Education and Children's Services

Jan 2001	Dec 2001	Assistant Professor and Scientist	Department of Paediatrics and Sealy Centre for Vaccine Development, University of Texas Medical Branch, Galveston, Texas, USA
Aug 2000	Jan 2001	Visiting Fellow (Herpes Research)	Division of Infectious Diseases, Department of Paediatrics, Children's Hospital Medical Centre, Cincinnati, Ohio, USA
Aug 1988	Nov 1989	Post-Doctoral Fellow (Retrovirus Biology Laboratory)	Pasteur Institute, Paris, France
May 1986 Jan 1991	Aug 1988 Jul 2000	Research Officer (Commonwealth AIDS Research Grant; NHMRC Grant – Herpes Research)	Institute of Medical and Veterinary Science, Adelaide, South Australia

EXAMPLES OF EXPERIENCE
Current Employment Experience:

Consultant (Medical Writer) – CNS-Novotech
Responsibilities:

- Production of Clinical Study Report (CSR) at completion of each study in accordance with ICH E3 guidelines (with current experience in drugs for potential treatment of atopic dermatitis, macular atrophy and vision loss associated with Stargardt's Disease Type 1, post-surgery recovery from total knee arthroplasty, non-alcoholic steatohepatitis and autism spectrum disorder).
- Review and interpret statistical outputs from study statistician for inclusion in CSR.
- Support in the creation and delivery of high-quality documentation for clients, including study protocols (current experience in idiopathic pulmonary fibrosis/interstitial lung disease).
- Generate and summarize relevant information from meetings and disseminates this to the relevant stakeholders.
- Assist in the development and maintenance of Standard Operating Procedures (SOP) and other relevant training materials.
- Ensure that all client material is treated and maintained in full respect of client confidentiality.

Previous Employment Experience:

Senior Clinical Research Associate – CNS
Responsibilities:

- Perform Study Feasibility across the ANZ region

- Perform Site Selection Visits and provide recommendations for site selection
- Complete Regulatory and Ethics Committee applications
- Draft and QC Site essential documents
- Write, review and QC Participant Information Sheet and Consent Form (PICF) and country specific PICF Checklist
- Compile, review and QC applications in order to facilitate timely Ethics and Regulatory approvals
- Collate and QC Site Activation Packages
- Complete and document Project training
- Prepare Site Initiation training material
- Perform Site Initiation Visits (SIV)
- Participate in and if required, present at Investigator Meetings.
- Contribute to user acceptance testing (UAT) of electronic data capture (EDC) databases and EDC completion guideline review
- Contribute to project risk assessment process, propose and apply to assigned Site(s) and plan and implement related risk mitigation
- Contribute to set up and maintenance of project tracking systems
- Assist in Clinical Trial Research Agreement (CTRA) negotiation
- Review and input into Project documents including protocol review
- Perform site management tasks as follows:
    - Conduct regular monitoring visits according to the Monitoring Plan
    - Collect and QC essential documents for Trial Master File (TMF) including tracking of Trial Master File essential documents and reconciliation to corresponding Investigator Site Files (ISF)
    - Ensuring ISF and TMF maintenance to ‘audit ready’ expectation
    - Ensure Investigational Product (IP) request, shipping, receipt, accountability and destruction
    - Develop and implement recruitment strategy across the Project to facilitate enrolment
    - Ensure Site staff are informed of any new or updated Study information
    - Maintain regular contact with Project Team and Site staff
    - Drive issue resolution, appropriately escalating and keeping interested parties updated
    - Ensure appropriate reporting of Serious Adverse Events
    - Oversee periodic safety reporting to Ethics
    - Present the views of the Investigator to the PM or client
    - Perform site closure visits and support junior CRAs in all close out activity
    - Facilitate notification of Site / Project closure to the applicable Ethics / Regulatory authorities
    - Perform final reconciliation of the ISF to TMF, final disposition of IP and Site payments per CTRA
    - Ensure resolution of all site issues
- Attend and contribute to Project meetings
- Support the PM in the driving completion of contracted services to the time scheduled in the Project Management Plan (PMP)
- QC safety listing ahead of provision to the Safety Management Committee (SMC) required data
- Accompany CRAs on monitoring visits
- Function at a Lead CRA level, when required

- Conversant with the dynamics of Early phase drug development
- Understand the responsibilities of CNS as a service provider
- Attend and contribute to training sessions and meetings
- Contribute to process review / improvement via training sessions and meetings
- Provide cover for distinct PM tasks as required
- Developed clinical operations expertise in all phases of clinical trials – Phase 1 (including First in Human), Phase 1a and 1b, Phase 2, Phase 2a and 2b, Phase 3
- Developed clinical operations expertise in the following therapeutic areas: Autoimmune (Rheumatoid Arthritis, Psoriatic Arthritis, Ulcerative Colitis); Dermatology (Atopic Dermatitis, Psoriatic Arthritis); ENT (Chronic Sinusitis); Genetic Disorders (Mucopolysaccharidosis (MPS)IIIA); Immunology (Paediatric Allergy); Infectious Diseases (Meningitis B, Respiratory Syncytial Virus (RSV), Rotavirus, Human Deficiency Virus (HIV)antibiotic resistant Staphylococcus Aureus in Chronic Sinusitis); Musculoskeletal (tourniquet induced sarcopenia in total knee arthroplasty); Neurology (Epilepsy, MPS IIIA); Oncology (Metastatic non-small cell Lung Cancer Human Papilloma Virus associated cancers); Ophthalmology (Geographic Atrophy Primary Open Angle Glaucoma); Reproductive (Contraception); Respiratory (Bronchiectasis); Transplant (Renal); Vaccine (Meningitis B, Respiratory Syncytial Virus); Nutrition (addressing malnutrition with colostrum); Pediatric (Meningitis B, RSV, Rotavirus, pediatric allergy, MPSIIIA)

Senior Clinical Research Associate – ICON Clinical Research
Responsibilities: As above

Private Clinical Research Management Consultant/Director – Synapse Research Connexions
Responsibilities:

- Recruit Australian sites (in Adelaide, Melbourne, Sydney, Brisbane and the Gold Coast) to participate in paediatric allergy prevention study by establishing contact with paediatric allergists
- Prepare submissions to Human Ethics Committees at relevant institutions and deal with all correspondence with Ethics Committees
- Submit Clinical Trial Notifications of Intent to supply an unapproved substance to the Australian Therapeutics Goods Administration for each of the study sites following ethics approval
- Initiate and coordinate investigator meetings including teleconferences
- Work with investigators to finalise protocol for Australia including recruitment strategy
- Facilitate budget negotiations
- Prepare import license applications to AQIS
- Liaise with import authorities to facilitate clearance of imported study product
- Source and facilitate warehousing and distribution of study product to study sites
- Train study staff at all sites
- Assist sponsor with generation of study documentation (including Australia-specific protocol)
- Initiation of the first study site was conducted in June 2007, with the last site of 5 being initiated in November 2007. Upon study commencement I trained study nurses at all sites in study conduct and GCP and continued to provide advice and re-training as often as required
- Monitor at each study site once a month

- Report to Numico (later Danone) on a regular basis including written reports as well as monthly teleconferences
- Closeout
- Archiving

Senior Clinical Research Associate – Centre for Pharmaceutical Research, University of South Australia
Responsibilities:

- Monitor Phase 1 pharmaceutical studies, specifically on various delivery methods of a contraceptive drug in 50 healthy female and 50 healthy male volunteers
- Represent Numico Research Netherlands (Danone Research as of 2007) as an advisor for establishment of a Phase III HIV nutritional intervention study
- Project manage a multi-centre Phase III allergy prevention study in infants using specialised infant formula developed by Numico – duties included selection of study sites (Adelaide, Melbourne, Sydney, Brisbane, Gold Coast and Perth), negotiating study recruitment strategy and budget with investigators, establishment of study including preparation of Ethics submissions and correspondence with Ethics committees, conducting pre-study feasibility checks, organising import documentation, initiation and monitoring, assessing feasibility of conducting this study in Indonesia.

Research and Vaccine Manager – Numico Research Australia Pty Ltd (NRA)
Responsibilities:

- Direct research activities including vaccine design and production
- Line manage research personnel
- Manage biosafety and regulatory aspects of the research programme including preparing applications to Animal and Human Ethics Committees, Australian Quarantine and Inspection Service (AQIS) and Australian Pesticides and Veterinary Medicines Authority (APVMA)
- Establish national and international collaborations (collaboration with the University of Georgia, USA also involved review of a grant proposal to the NIH incorporating aspects of our collaborative studies)
- Obtain and manage academic and/or industrial grant funding for research projects where appropriate. I am, therefore, familiar with the procedures of several granting bodies, e.g., DRDC, Gardiner Foundation, National Food Industry Strategy (Food Innovation Grants)
- Address intellectual property and confidentiality issues
- Assume the role of project manager for all of the company's key research initiatives
- Manage the research department including budget, writing of project proposals, project reports and publications, reviewing and approving all technical reports and standard operating procedures involving the research department, sourcing and employing new research personnel as required.
- Phase II trial to test efficacy of a single ingredient in a clinical nutritional supplement for HIV patients. Responsibilities:
    - Concept development
    - Assist with preparation of Product Information Brochure
    - Assist with protocol development
- International Phase III trial to test a clinical nutritional supplement in HIV patients – Numico Project Coordinator for Australian Sites. Responsibilities:

    - Assist with preparation of Product Information Brochure
    - Assist with protocol development
    - Recruit participating sites in Australia
    - Assist with start-up activities including import license application to AQIS and acting in an advisory capacity to Numico/Danone
    - Represent Numico's/Danone's interests in trial activities
    - Assist in sourcing and establishing links between Numico and contract researchers
- Clinical Project Manager for the study "A randomised, double blind, placebo-controlled study to determine the protective efficacy of orally administered infant formula containing bovine antibodies to human rotavirus" conducted in Indonesia.
  Responsibilities:
    - Establish contact with key opinion leader in Indonesia
    - Recruit trial sites to the study
    - Protocol design and development
    - Design of all trial documentation
    - Coordinate production and packaging of study formula in conjunction with Nutricia Indonesia, in addition to designing study product labels in line with GCP requirements
    - Coordinate and monitor advisory document translation into Indonesian
    - Select sites and principal trial staff
    - Initiate and train all trial staff (approximately 100 personnel)
    - Supervise and monitor laboratory activities including set-up of testing for Rotavirus by ELISA and monitor collection, processing, storage and testing of clinical trial samples.
    - Monitoring and generation of associated reports
    - Close-out and generation of associated reports
    - Coordinate data entry and checking
    - Coordinate data analysis
    - Prepare clinical study report using Numico Netherlands template

Assistant Professor and Scientist - Department of Paediatrics and Sealy Centre for Vaccine Development, University of Texas Medical Branch, Galveston, Texas, USA
Responsibilities:

- Establish own Herpes immunology research group and research program
- Assist with the set-up of laboratories in a new facility
- Manage laboratory budget (250,000 USD)
- Interview and employ research support staff
- Teach medical students
- Continue previous research on the pathogenesis and immunobiology of Herpes Simplex Virus (HSV) infection of the peripheral nervous system including preparing manuscripts for publication.
- Referee articles and books for the Journal of Virology and Doody Publishing respectively
- Assist with grant preparation and internal review of grant proposals to the NIH.

Visiting Fellow Herpes Research – Division of Infectious Diseases, Department of Paediatrics, Children's Hospital Medical Centre, Cincinnati, Ohio, USA with Professor Larry Stanberry
Responsibilities:

- Continue collaborative research on induction of MHC-I in response to HSV infection, in the guinea pig model, a herpes animal model more closely resembling human disease, which was well established in Prof Stanberry's laboratory

National Health and Medical Research Council (NH&MRC) Research Officer – Herpes Research laboratory, Institute of Medical and Veterinary Science, Adelaide, Australia
Responsibilities:

- Develop research programme
- Daily supervision of technical staff, research assistants and students (graduate and post-graduate)
- Assist in grant proposal preparations
- Prepare presentations for local and international audiences
- Write manuscripts for publication.
- Develop assays required for research project including: in situ hybridisation and Northern analysis for detection and quantification respectively of MHC class 1 messenger RNA; Immune rosetting assays; Flow cytometry; Immunoelectron microscopy for detection of MHC class I antigen on cell surfaces
- Develop proficiency in small animal handling including flank inoculation as per the mouse zosteriform model developed by Dr Simmons
- Develop proficiency in removal and fixation/culture and sectioning of mouse dorsal root ganglia, brain, lymphoid organs and skin, quantifying virus in tissues by plaque assay
- Develop method to separate neurons and glia by sequential density gradient and rate zonal centrifugation in Percoll gradients
- Develop proficiency in scanning immunogold backscatter electron microscopy, transmission electron microscopy
- Become accomplished in a range of molecular biological techniques including cloning, restriction analysis, plasmid preparation, and preparation of pure DNA and RNA from tissues, generation of recombinant viruses, Northern and Southern analysis and PCR
- Acquire experience in the culture and handling of a wide variety of cell lines of both human and animal origin.

Post-Doctoral Fellow – Retrovirus Biology Laboratory, Pasteur Institute, Paris, France
Responsibilities:

- Direct a research programme on the susceptibility of thymic precursor cells to HIV
- Set-up all immunohistochemical and *in situ* hybridisation techniques, flow cytometry and thymic cell subtype isolations from foetal thymuses (obtained from aborted foetuses from HIV seropositive women)
- Carry out HIV culture and concentration in a PC3 facility
- Supervise a technician and various students, both at junior and PhD levels

Research Officer Commonwealth AIDS Research Grant – Institute of Medical and Veterinary Science, Adelaide, South Australia
Responsibilities:

- Develop safety regulations for working with HIV in a containment laboratory
- Make contact with international HIV laboratories to obtain basic materials such as cell lines to culture HIV

- Establish techniques for culture, isolation and detection of HIV, including reverse transcriptase assays, immunofluorescence, electron microscopy and Northern analysis
- Train junior staff i.e. technical assistants and research assistants.

Publication Record:
Peer reviewed publication:

1. **Pereira R**, King N, Blanden R (1986) Comparison of functional properties of thymic and splenic dendritic cells Cellular Immunol 102: 152-67
2. Mullbacher A, Woodhams C E, Tomaska LD, **Pereira R** and Ashman R B (1985) Mouse serum as a medium supplement for murine immune responses in vitro. J Immunol Methods 76: 17-26
3. **Pereira R**, Pang T and Bosco J (1983) Production of monoclonal anti-platelet antibodies by the hybridoma technique Singapore Medical J 24(1):31-32
4. **Pereira R**, Pang T and Bosco J (1981) Detection of anti-platelet antibodies in patients with idiopathic thrombocytopenic purpura (ITP) by immunofluorescence. Singapore Med J 22(4): 203-6
5. Shing C; Peake J; Suzuki K; Okutsu M; Pereira R; Stevenson L; Jenkins D; Coombes J (2007) Effects of Bovine Colostrum Supplementation on Immune Variables of Highly-Trained Cyclists. J App Physiol 102:1113-22
6. **Pereira R** and Simmons A (2001) Cutting Edge: A natural killer complex linked locus governs acute versus latent herpes simplex virus infection of neurons. **J Immunol** 166:5869-73
7. Abendroth A, Simmons A, **Pereira R** (2000) Expression of a MHC class I gene in HSV infected neurons in vivo using a MHC recombinant viral vector **J Gen Virol** 81:2375-83
8. Van Den Heuvel C, Blumbergs P, Finnie J, Manavis, Lewis S, Jones N, Reilly P and **Pereira R** (2000) Upregulation of amyloid precursor protein mRNA in an experimental model of paediatric head injury. **J Clin Neuroscience** 7(2): 140-145
9. Van Den Heuvel C, Finnie J, Blumbergs P, Manavis, Jones N, Reilly P and **Pereira R** (2000) Upregulation of neuronal amyloid precursor protein (APP) and APP mRNA following magnesium sulphate (MgSO4) therapy in traumatic brain injury. J Neurotrauma 17(11): 1041-53
10. **Pereira R**, Simon M, Simmons A (2000) Granzyme A, a non-cytolytic component of CD8+ T cell granules, restricts the spread of herpes simplex virus in the peripheral nervous systems of experimentally infected mice **J Virol** 74: 1029-1032
11. Van Den Heuvel C, Blumbergs P, Finnie J, Manavis, Jones N, Reilly P and **Pereira R** (1999) Upregulation of amyloid precursor protein mRNA in response to traumatic brain injury. **Exp. Neurol.** 159(2): 441-50
12. **Pereira R** and Simmons A (1999) Cell surface expression of H-2 antigens on primary sensory neurons in response to acute but not latent herpes simplex virus infection in vivo **J Virol** 73: 6484-6489
13. Wilkinson R, Leaver, C, Simmons A, **Pereira R** (1999) Restricted replication of herpes simplex virus in satellite glial cell cultures clonally derived from adult mice **J Neurovirology**. 5: 384-391
14. **Pereira RA**, Tscharke DC, Simmons A. (1994). Up-regulation of class I MHC gene expression in primary sensory neurons, satellite cells and Schwann cells of mice in response to acute but not latent HSV infection in vivo. **J Exp Med**. 180: 841-850
15. Valentin H, Nugeyre M-T, Vuillier F, Boumsell L, Schmid M, Barre-Sinoussi F, **Pereira RA**. (1994). Two subpopulations of human triple-negative thymic cells are

susceptible to infection by human immunodeficiency virus type 1 in vitro. J Virol. 68: 3041-50.

Conference Presentations:

1. 25th International Herpesvirus Workshop, Portland, Oregon, USA (July 2000): Oral presentation and poster entitled “Induction of neuronal Class I MHC expression by replication impaired strains of HSV-1”; Oral presentation and poster entitled “Rhs-1: A novel genetic locus proximal to Ly55 and CMV-1, influences the magnitude of acute and latent herpes simplex virus infection of the nervous system”; Poster entitled “Granzyme A is an essential downstream effector molecule for perforin dependent clearance of herpes simplex virus from sensory nerve ganglia”
2. 24th International Herpesvirus Workshop, Boston, USA (July 1999): Oral presentation and poster entitled “Rhs-1: A genetic locus which controls the severity of herpes simplex virus infection”
3. 23rd International Herpesvirus Workshop, York, U.K (July 1998): Oral presentation and poster entitled “Granzyme A, a non-cytolytic component of CD8+ -cell granules, influences the severity of herpes simplex in the nervous system”; Oral presentation and poster entitled “Mice in which the delta T-cell receptor chain is disrupted fail to clear herpes simplex virus from the nervous system”; Poster entitled “Cultured satellite cells are non-permissive for HSV replication”
4. 22nd International Herpesvirus Workshop, University of San Diego, La Jolla, California, USA (July 1997): Oral presentation and poster entitled “Cell-surface expression of H-2 antigens on primary sensory neurons in response to acute but not latent Herpes Simplex Virus infection in vivo”
5. Australian Society for Immunology conference at the Gold Coast, Queensland (1995): Poster entitled “Virally induced expression of MHC Ib molecules on glial cells in vivo”
6. 19th International Herpesvirus Workshop, University of British Columbia, Vancouver, Canada (1994): Poster entitled “Class I MHC gene expression in the peripheral nervous systems of HSV infected mice: Up-regulation during productive phases of infection and establishment of latency”
7. Australian Society for Immunology conference in Sydney (1993): Poster entitled “Upregulation of MHC Class I genes in the peripheral nervous systems of HSV infected mice.”
8. 18th International Herpesvirus Workshop, University of Pittsburgh Medical Center, USA (1993): Poster entitled “Enhanced transcription of MHC class I genes in the peripheral nervous systems of HSV infected mice: Implications for the fate of virally infected neurons”
9. V International Conference on AIDS, Montreal, Canada (1989): oral presentation entitled “Susceptibility of immature CD3-4-8- thymocytes to HIV infection”
10. AIDS conference in Hobart, Tasmania- oral presentation

Other:

1. Thesis (PhD) Studies on Lymphoid Dendritic Cells; ANU, 1986
2. Thesis (Hons) Detection of anti-platelet antibodies in patients with Idiopathic Thrombocytopenic Purpura, University of Malaya, 1981

PERSONAL DETAILS
Name: Dr Catherine Tabrett BScAgr (Hons1) PhD

Academic Qualifications:

Qualification	Date	Institution
PhD in Agricultural Chemistry Australian Postgraduate Award	1999	University of Sydney
Bachelor of Science in Agriculture with First Class Honours • Dean's List of Excellence in Academic Performance • Joyce Winfred Rouse Prize in Agricultural Chemistry • Simon Leake Sydney Environmental and Soils Laboratory Prize Pig Research and Development Corporation Undergraduate Summer Scholarship	1995	University of Sydney

EMPLOYMENT RECORD
Current Company Position Title: Consultant (Medical Writer)
Date Appointed to Position: 21 January 2019

Previous Employment History:

Position Title	Company	Date Started	Date Ended
Scientific/Medical Editor	Freelance/The Expert Editor	April 2016	January 2019
Chemistry Teacher	UNSW Global Pty Ltd	May 2016	December 2018
Clinical Monitoring Associate II	PAREXEL International	December 2011	October 2015
Medical Writer/Clinical Research Associate	Datapharm Australia Pty Ltd	October 2010	November 2011
Senior Research Officer and Conjoint Lecturer UNSW	Lowy Cancer Research Centre, The University of NSW	January 2005	October 2010
Research Officer and Conjoint Lecturer UNSW	Centre for Vascular Research, The University of NSW	January 2004	December 2004
Research Officer and Conjoint Lecturer UNSW	Diabetes Transplant Unit, Prince of Wales Hospital	July 2002	January 2004
Postdoctoral Research Assistant	Department of Molecular and Cellular Pathology, University of Dundee, Ninewells Hospital and Medical School	January 2000	December 2001
Laboratory Demonstrator	University of Sydney	January 1995	December 1999

EXAMPLES OF EXPERIENCE
Previous Employment Experience:

Clinical Monitoring Associate II - PAREXEL International
Awards:

- Recipient of the PAREXEL Reward and Recognition Program – for outstanding customer service and teamwork

Responsibilities:

- Ensure compliance with protocol, timelines, recruitment procedures and data recording by maintaining regular contact with investigators and trial staff across Australia and New Zealand
- Assess protocol violations and patient withdrawals
- Provide CRF data to data management for data entry
- Provide regular updates of trial progress to sponsor including SAEs and safety issues
- Manage all phases of remote site management activities from study start up to database close

Medical Writer – Datapharm Australia Pty Ltd
Responsibilities:

- Provide medical writing services across Phases I to IV - including the production of:
  - Full Study Reports
  - Case Histories
  - Interim Reports
  - Protocols
  - Investigator Brochures
  - Patient Information Sheets
  - Patient consent forms
  - Peer Review Publications
  - HREC Applications
  - Regulatory Documents
- QC documents
- Critically review published literature

Clinical Research Associate – Datapharm Australia Pty Ltd
Responsibilities:

- Ensure compliance with protocol, timelines, recruitment procedures and data recording by maintaining regular contact with investigators and trial staff
- Onsite monitoring of trial progress, checking of documentation and trial files
- Monitor adverse events, assess protocol violations and patient withdrawals
- Provide CRF data to data management for data entry
- Provide regular updates of trial progress to sponsor including SAEs and safety issues

Publication Record:

Journals

1. Matthias, L.J., Azimi, I., **Tabrett, C.A.**, Hogg, P.J. (2010) 'Reduced Monomeric CD4 is the Preferred Receptor for HIV' Journal of Biological Chemistry 285:40493-40499
2. **Tabrett, C.A.**, Harrison, C.F., Schmidt, B., Bellingham, S.A., Hardy, T., Sanejouands, Y., Hill, A.F., and Hogg, P.J. (2010) 'Changing the Solvent Accessibility of the Prion Protein Disulfide Bond Markedly Influences its Trafficking and Effect on Cell Function', Biochemical Journal, 428:169 – 182.
3. **Tabrett, C.A.,** and Coughtrie, M.W.H., (2003) 'Phenol Sulfotransferase 1A1 Activity in Human Liver: Kinetic properties, Interindividual Variation and Re-evaluation of the Suitability of 4-Nitrophenol as a Probe Substrate' Biochemical Pharmacology, 66:2089-97.
4. **Tabrett, C.A.**, and Copeland, L., (2002) 'Enzymes of malate metabolism in *Mesorhizobium ciceri* CC 1192' Canadian Journal of Microbiology, 48:279-284.
5. **Tabrett, C.A.,** and Copeland, L., (2000) 'Biochemical Controls of Citrate Synthase in Chickpea Bacteroids', Archives of Microbiology, 173:42-48.

Book Chapters

6. Les Copeland, Lu Feng and **Tabrett, C.A.,** (1999) Polyhydroxybutyrate in Nitrogen-Fixing Symbioses, Current Plant Science and Biotechnology in Agriculture Nitrogen Fixation: From Molecules to Crop Productivity, Vol 38

Conferences

7. **Tabrett, C.A.,** Harrison, C.F., Schmidt, B., Bellingham, S.A., Hardy, T., Sanejouands, Y., Hill, A.F., and Hogg, P.J., (2010) 'Changing the Solvent Accessibility of the Prion Disulfide Bond Markedly Influences its Trafficking and Effect on Cell Function' OzBio 2010
8. **Tabrett, C.A.,** Harrison, C., Sharples R., Schmidt, N., Han, S., Hill, A., and Hogg, P., (2008) 'Increasing Access to the Prion Protein Disulphide Decreases Protein Stability' ComBio 2008
9. Hardy, T., **Tabrett, C.A.,** Hill, A., Schmidt, B., and Hogg, P.J., (2007) 'Disulfide Bond Switching in the Prion Protein', ComBIo 2007
10. **Tabrett, C.A.**, Hardy, T., Hill, A., Schmidt, B., and Hogg, P.J., (2007) 'Disulfide Bond Switching in the Prion Protein', Prion 2007, Edinburgh
11. Mathias, L., **Tabrett, C.A.,** and Hogg, P.J., (2007) 'The CD4 Allosteric Disulfide Regulates HIV Entry', The Boden Conference on Disulfide Bonds and their Role in Protein Folding and Function, Oral Presentation
12. **Tabrett, C.A.,** Hardy, T., Hill, A., Schmidt, B., and Hogg, P.J., (2007) 'Disulfide Bond Switching in the Prion Protein', The Boden Conference on Disulfide Bonds and their Role in protein Folding and Function, Oral Presentation
13. Mathias, L., **Tabrett, C.A.,** and Hogg, P.J., (2007) 'The CD4 Allosteric Disulfide Regulates HIV Entry', International Aids Society, Sydney
14. **Tabrett, C.A.,** Sanejouand, Y., Hill, A., Schmidt, b., and Hogg, P.J. (2005) 'Cleavage of the Prion Disulphide-Bond: in Search of a Molecular Mechanism', Prion 2005 Between Fundamentals and Society's Needs, STRCT-15, p344
15. Mathias, L., **Tabrett, C.A.,** and Hogg, P.J., (2005) 'Control of CD4 Function by Disulphide-Bond Switching', The Protein World 30th FEBS Congress and 9th IUBMB Conference, Budapest, Hungary
16. Mathias, L., **Tabrett, C.A.**, and Hogg, P.J., (2004) 'Disulphide-Bond switching in CD4 Regulates HIV Entry', Australian Health and Medical Research (AHMR) Congress, Darling Harbour, Sydney – Oral Presentation

17. **Tabrett, C.A.**, Mathias, L., and Hogg, P.J., (2004) 'Disulphide-Bond Switching in CD4 Regulates HIV Entry', Proceedings of the Australian Society for Biochemistry and Molecular Biology and Australian Society of Plant Physiologists, Pos-Mon-11
18. **Tabrett, C.A.**, Tuch, B., (2003) 'Insulin secretion in Foetal Pancreatic Beta Cells', proceedings of the Australian Society for Biochemistry and molecular Biology and Australian Society of Plant Physiologists, Pos-Mon-47
19. **Tabrett, C.A.**, and Coughtrie, M.W.H. (2001) 'Kinetic Characterisation of Human Sulfotransferase 1A1', Drug Metabolism Reviews, 33:135
20. Copeland, L., Feng, L., and **Tabrett, C.A.**, (2000) 'Polyhydroxybutyrate in Nitrogen Fixing Symbioses', In: Nitrogen Fixation: From Molecules to Crop Productivity, Ed: Pedrosa, Hungria, Yates and Newton, Kluwer Academic Press, pp 377-378.
21. **Tabrett, C.A.**, and Copeland, L., (1999) "Citrate Synthase as a Control Point of carbon metabolism in Chickpea Bacteroids', The Proceedings of the 12th Australian Nitrogen Fixation Conference, Wagga Wagga, pp61
22. Copeland, L., Feng, L., and **Tabrett, C.A.**, (1999) 'Polyhydroxybutyrate in Nitrogen-Fixing Symbioses', The Proceedings of the 12th Australian Nitrogen Fixation Conference, Wagga Wagga, pp55
23. **Tabrett, C.A.**, and Copeland, L., (1998) 'Metabolic Regulation of Citrate Synthase in a Microaerobic Environment', Proceedings of the Australian Society for Biochemistry and Molecular Biology and Australian Society of Plant Physiologists, Vol 30, POS-MON-52
24. **Tabrett, C.A.**, and Copeland, L., (1997) 'Inhibition of Citrate Synthase from Chickpea Nodulating Bacteria', Proceedings of the 11th International Congress on Nitrogen Fixation, Institut Pasteur, Paris, France, Vol 31, pp474
25. **Tabrett, C.A.**, and Copeland, L., (1997) 'Regulation of Citrate Synthase from Chickpea Nodulating Bacteria', Proceedings of the Australian Society for Biochemistry and Molecular Biology and Australian Society of Plant Physiologists, Vol 29, POS-B1-16
26. **Tabrett, C.A.**, and Copeland, L., (1996) 'Fine Control of Citrate Synthase from *Rhizobium* sp *Cicer* CC 1192', Proceedings of the Australian Society for Biochemistry and Molecular Biology and Australian Society of Plant Physiologists, Vol 28, POS-139-01

PERSONAL DETAILS
Name: Babasaheb Yadav M.Pharm PhD

Academic Qualifications:

Qualification	Date	Institution
Doctor of Philosophy (Ph.D)	2008-2011	University of Otago, Department of Pharmacology and Toxicology, Dunedin, New Zealand
Master of Pharmacy (M. Pharm)	2003-2005	Bharati Vidyapeeth University, Department of Pharmacognosy/Natural products, Pune, India
Bachelor of Pharmacy (B. Pharm)	1999-2003	University of Pune, Poona college of Pharmacy, Pune, India

Current Professional Societies and examinations:

Institution	Qualification	Examination
BTS	UK Registered Toxicologist	By Review

EMPLOYMENT RECORD
Current Company Position Title: Consultant
Date Appointed to Position: 23rd July 2018

Previous Employment History:

Position Title	Company	Date Started	Date Ended
Associate Clinical Project manager	IQVIA, Sydney, Australia	July 2017	July 2018
Project manager	Kazia therapeutics (formerly Novogen ltd) Sydney, Australia	Sept 2015	May 2017
Post-doctoral research fellow	Children's Cancer Institute Leukaemia Biology Program Sydney, Australia	April 2012	August 2015
Lecturer	Alard College of Pharmacy affiliated to University of Pune, Pune, India.	Feb 2007	Sept 2008
Lecturer	Vishal Institute of Pharmaceutical education and research affiliated to University of Pune, Pune, India.	August 2006	Feb 2007
Research Trainee	Sanofi-Aventis Ltd	August 2005	August 2006

	Analytical Development Department, Goa, India		

EXAMPLES OF EXPERIENCE
Previous Employment Experience:

Associate Clinical Project manager - IQVIA, Sydney, Australia
Responsibilities:

- Project manage phase 1 and 2 clinical development of immuno-oncology drugs for biotech companies across the globe
- Negotiate budget and contract with the sponsor
- Review, or develop as needed, all key documents/deliverables in the trial, e.g. regulatory and Ethics submissions, eCRF, Data Management Plan, Clinical Operational Plan, Integrated Project Management Plan, Safety Plan, Pharmacy Manual, Randomisation Plan, Statistical Analysis Plan and Clinical Study Report.
- Ensuring frequent and effective communication with all study sites, consultants and other vendors in Australia and overseas if necessary.
- Manage investigational product distribution.
- Proactively manage the timely resolution of any identified problems with study sites, CRAs, consultants, other vendors and internal team.
- Support sponsors in set-up, implementation, and execution of the assigned clinical study
- Prepare and present project information at internal and external meetings
- Support feasibility and site identification activity
- Support medical writing activity (PK/PD and Biomarker section of the clinical protocol)
- Produce and distribute status, tracking and financial reports for internal and external team members and senior management
- Coordinate with other support staff within and across the global project management unit to identify and consolidate support processes
- Serve as the primary contact for internal project team and for external stakeholders
- Undertake responsibilities for financial reporting on the project including tracking, revenue recognition and invoicing
- Train and mentor junior project support staff

Project manager - Kazia therapeutics, Sydney, Australia
Responsibilities:

- Assisted in reviewing and quality controlling IND application for Cantrixil, one of the lead molecules for ovarian cancer. Cantrixil IND application was successful in June 2016
- Assisted clinical/regulatory director in reviewing phase I clinical trial protocol for Cantrixil. The phase I clinical trial of Cantrixil commenced in Dec 2016
- Assisted in managing and quality controlling HREC application for phase 1 study of Cantrixil
- Assisted clinical research director in setting up a phase II glioblastoma study
- Successfully planned and completed IND enabling non-clinical toxicological studies for another oncology lead molecule (orphan drug)
- Liaised with internal and external cross functional teams (chemists, biologists, clinicians, chief medical officer, chief business development officer and CROs) to remain abreast of the project development and ensure project success**.** Worked with contract research and manufacturing organisations (CROs and CMOs) across the globe (USA, China, India & UK)
- Prepared and presented toxicological/drug safety data to internal (scientific advisory board) and external stakeholders.

- Demonstrated critical thinking and creative problem solving skills to ensure timely and successful implementation of projects
- Participated in writing the pharmacology and toxicological section of the investigator's brochure (IB) and IND application for regulatory submissions
- Participated in writing FDA annual reports for orphan drugs under development
- Managed and collected all pre-clinical research data from contract research organisations and prepared ICH compliant reports for IND application
- Set up and maintained budgets in liaison with the project director

Publication Record

1. **Babasaheb D Yadav** et al. (2016) Heterogeneity in mechanisms of emergent resistance in paediatric T-cell acute lymphoblastic leukemia. **Oncotarget**, 7 (37):58728-42
2. **Babasaheb D Yadav** et al. (2014) A Pre-Clinical Model of Resistance to Induction Therapy in Paediatric Acute Lymphoblastic Leukemia. **Blood Cancer J**, 4: e232
3. **Yadav B D** et al. (2012) RL66, a second-generation curcumin analog has potent in vivo and in vitro anticancer activity in ER-negative breast cancer models. **Int J Oncol**. Nov, 41(5):1723-32
4. **Yadav B D** et al. (2012) RL71, a second-generation curcumin analog, induces apoptosis and downregulates Akt in ER-negative breast cancer cells. **Int J Oncol**. 2012 Sep;41(3):1119-27
5. **Yadav B D** et al. (2010) Synthesis and cytotoxic potential of heterocyclic cyclohexanone analogues of curcumin. **Bioorganic & Medicinal Chemistry** 18(18): 6701-7
6. **Yadav B D**, Khaled Greish (2011) Selective inhibition of HO-1 as a therapeutic target for novel anticancer treatment. Journal of **Nanomedicine & Nanotechnology**, S4, 1-8
7. Dzeyk, J, **Yadav B D**, Rosengren RJ, (2011) Experimental Therapeutics for the Treatment of Triple Negative Breast Cancer. **In: Breast Cancer** – Curr

Conference presentations

1. 2015 Lowy Cancer Symposium: Drug discovery and personalised medicine, Sydney
2. 2012 Lorne Cancer Conference, Lorne, Victoria, Australia
3. Taurin S, **Yadav B D**, Nimick M, Rosengren RJ. Poster presented at the American association of cancer research (*AACR*) 103rd Annual meeting held at Chicago. 2012
4. **Yadav B D**, et al. Poster presented at the 2011 European Multidisciplinary Cancer Congress held at Stockholm, Sweden. September 23-27, 2011
5. **Yadav B D**, et al. Poster presented at 3rd QMB Cell Signalling meeting held at Queenstown, New Zealand. August 28-29, 2011
6. **Yadav B D**, et al. Poster presented at QMB Cancer Satellite meeting held at Queenstown, New Zealand. September 2-3, 2010
7. **Yadav B D**, et al. Poster presented at AACR (American association of cancer research) 101st Annual meeting held at Washington DC. April 17-21, 2010

Awards/Achievements

1. Shout Out Award for delivering on an important milestone for IB data cleaning, 2017, IQVIA ltd.
2. Best poster presentation at 3rd QMB Cell Signalling meeting held at Queenstown, New Zealand, 28-29th August 2011
3. Best poster presentation at PhD colloquium session organized by Otago School of Medical Sciences at Otago, New Zealand, 2011
4. Travel grant from Maurice and Phyllis Paykel Trust, New Zealand to attend The 2011 European Multidisciplinary Cancer Congress held at Stockholm, Sweden in September 2011
5. Received Professional Development Award from Genesis Oncology Trust, New Zealand to attend the 2011 European Multidisciplinary Cancer Congress held at Stockholm, Sweden in September 2011
6. Received travel grant from division of health sciences, University of Otago to attend 101st American association of cancer research (AACR) conference held at Washington DC in April 2010
7. Received scholarship from University of Otago for PhD studies
8. Received award for Excellence in Teaching from Alard College of Pharmacy, India
9. Achieved Distinction with 5th rank in M. Pharm examination conducted by Bharti Vidyapeeth University, India in July 2005
10. Received prize for oral presentation in an International Herbal Conference held at Bhopal, India in Jan 2004
11. Received fellowship from the University Grant commission (UGC), Government of India for Masters in Pharmacy studies