

## Life Sciences

### Our team

McCullough Robertson is a leading life sciences legal practice.

### We understand your business

While most of our lawyers have science qualifications, our experience goes beyond a mere understanding of the life sciences. For example:

- our lawyers have undertaken training in current Good Clinical Practice (cGCP) under training programs accredited by the Association of Clinical Research Professionals (ACRP)
- our lawyers have spent time on secondment with listed life sciences companies during key phases of multi-site clinical trials to better understand the issues sponsors face during the clinical trial process, and
- our lawyers regularly act for a diversity of clients including ASX listed life sciences companies, universities and research institutions, clinical trial sites, foreign corporations and private companies across a wide range of fields within the life sciences.

Our group advises on all aspects of bio-business, including corporate advisory, commercial contracts, collaborative research, manufacturing, intellectual property protection and commercialisation, venture capital, capital raising and clinical, ethical and regulatory issues.

### Corporate capabilities

McCullough Robertson has a team of more than 50 corporate lawyers with strong experience advising clients in the life sciences industry. Our corporate advisory practice is one of Queensland's largest and most experienced. Its capabilities include:

- capital raising (both regulated and unregulated)
- mergers and acquisitions (both regulated and unregulated)
- strategic advice (particularly in relation to regulated mergers and acquisitions and shareholder disputes)
- restructuring
- employee share schemes and associated shareholders' approvals
- regulatory and compliance issues
- corporate governance
- directors duties and liabilities, and
- corporate due diligence.

Signature corporate transactions in the life sciences industry include:

- IPOs of Peplin Limited, Alchemia Limited, Tissue Therapies Limited, Narhex Life Science Limited and Genera Biosystems Limited
- rights issues for ChemGenex Pharmaceuticals Ltd, Tissue Therapies Limited, Peplin Limited and Viralytics Limited, as well as associated placements and share purchase plans
- Pfizer Inc's \$230 million collaboration and licensing agreement with pSivida, including \$10 million equity subscription
- Shire Biochem Inc's licensing and equity agreement with Avexa Ltd
- demerger of Verva Pharmaceuticals from ChemGenex Pharmaceuticals Ltd
- \$21 million takeover of BresaGen Ltd by Hospira, Inc, and
- Medi-Stream Pty Ltd's (Delvtech) \$2.5 million venture capital investment by Innovation Capital.

## Clinical trials

McCullough Robertson has extensive experience in the legal aspects of clinical trials.

The conduct, documentation and regulations (both legal and ethical) applicable to clinical trials are complex and dynamic. Having a legal team on your side that understands this process can give you a competitive advantage and help reduce your risk profile.

McCullough Robertson advises Sites, CROs and Sponsors (both national and international) on issues associated with the conduct of clinical trials in Australia, the negotiation of clinical trial agreements and regulatory and ethical issues.

Signature transactions in the clinical trial field include:

- assisting two US Sponsors to establish and negotiate clinical trial documentation for a phase 3 multi-centre study and a phase 2 cancer study
- advising one of the largest Queensland-based research institutes on establishing suitable clinical trial documentation for the management of its relationships with sponsors and investigators
- compliance review of informed consent forms for phase 2 clinical trials for a listed biotechnology company, and
- secondment with a listed biotechnology company during a key phase of multi-centre clinical trials.

McCullough Robertson was the first law firm to become a member of the Queensland Clinical Trials Network (QCTN).

## Medical devices

Queensland has a strong medical devices community. McCullough Robertson acts for a number of medical device companies in Queensland and interstate.

Regulation of medical devices in Australia is particularly dynamic. Some of our signature transactions in the medical devices field include:

- advising the manufacturer of an in-vitro diagnostic device on registration and classification of the device under the *Therapeutic Goods Act 1989* (Cth)
- advising Occupational and Medical Innovations on its North American distribution agreement with Cardinal Health
- advising Impedimed on its acquisition of Aorora Technologies Pty Ltd, and
- advising Delvtech on its manufacturing and distribution agreements.

## AgBio

McCullough Robertson has strong ties with the food and agricultural industry and our Life Sciences Group is a key part of the firm's Food and Agribusiness Group.

Over the years we have advised agricultural biotechnology companies, livestock, animal health and veterinary supply companies on numerous legal issues, including in respect of plant breeder's rights, propagation and growing contracts, agricultural inventions and technology, agbio collaborations and mergers and acquisitions.

Our team was involved in the following agbio deals:

- advising Farmacule Bioindustries Pty Ltd on its collaboration with QUT, QutBlueBox and Syngenta Biotechnology, Inc. involving complex cross licensing of sugarcane technology for the production of biofuels which led to the establishment of the Syngenta Centre for Sugarcane Biofuel Development at QUT
- merger of Catapult (New Zealand) and Genetic Solutions (including ownership interests of Nanyang Innovation Fund, CSIRO, Meat & Wool NZ, Ag Research and founders) to create a global leader in sheep and cattle technologies
- acting for Catapult Genetics during its subsequent acquisition by Pfizer Animal Health
- assisting Plavacc during its expansion in Australia and entry into the competitive US market
- advising a leading producer on grower contracts and in-licensing of plant breeder's rights
- advising a leading cattle company on artificial insemination and embryo transfer contracts for a cattle breeding program, and
- advising ProVet in its \$13 million takeover of Westralian Holdings.

## Commercial contracts

Contracts and agreements are a key part of securing and protecting your interests and managing risk.

Whether it be a research agreement, clinical trial agreement, manufacturing contract or licence, it is important to have a lawyer who can provide technically excellent advice and assist in negotiating your position without unnecessarily hindering the progress of a transaction.

Our demonstrated experience includes advising:

- ChemGenex on the assignment of Stragen's omacetaxine mepesuccinate IP suite and the negotiation of a new manufacturing agreement between those parties for a patented GMP manufacturing process
- Australian Genome Research Facility on a range of intellectual property and licensing matters
- Alchemia Limited on its licence deal with American Pharmaceutical Partners (and subsequent exit), its R&D collaboration with Euroscreen and many others
- Peplin Limited on its licence deal with Allergan (and subsequent exit), its R&D collaboration with the NIH and its clinical trial program
- ChemGenex Pharmaceuticals Ltd on a wide variety of life science and corporate matters
- advising IMBcom Pty Ltd on areas ranging from research and development and intellectual property licensing through to spinout and venture capital issues
- numerous clients on regulatory issues in their commercial dealings including, Peplin Limited, ChemGenex Pharmaceuticals Ltd, the IMBcom and others
- Tissue Therapies Limited's collaborative research and development agreements and other intellectual property issues
- Bureau of Sugar Experiment Stations on intellectual property protection, CRC participation and corporatisation, and
- Vaccine Solutions Pty Ltd, the CRC for Vaccine Technology and the CRC for Diagnostics on research and development and intellectual property issues.

## Our leading life sciences team

The size and depth of experience of our team across a wide range of disciplines and transactions places us in an excellent position to deliver quality legal services to life science businesses.

The key members of our life sciences team are profiled on the next page of this brochure.



**Malcolm McBratney**

Partner  
**Telephone** 07 3233 8878  
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Malcolm is the head of our Intellectual Property group. With an honours degree in law and an MBA in technology management, Malcolm has extensive experience in technology acquisitions and joint ventures, internet and e-commerce, and intellectual property management and commercialisation. He also has extensive expertise in biotechnology, strategic alliances, media and broadcasting.



**Katrina Chambers**

Senior Associate  
**Telephone** 07 3233 8940  
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Katrina holds degrees in both Science and Law and is a registered Trade Marks Attorney. She specialises in intellectual property and advises on intellectual property protection and commercialisation. Katrina has completed a research scholarship with the University of Queensland's Department of Physiology and Pharmacology and is a member of the Queensland Law Society's Intellectual Property Committee.



**Brett Heading**

Partner  
**Telephone** 07 3233 8956  
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Specialising in capital raising and mergers and acquisitions, Brett has managed over 200 capital raisings over his career, including many ASX listings and has a particular interest in technology issues. Brett is a director of several companies and a member of the Takeovers Panel and Board of Taxation.



**James Cameron**

Senior Associate  
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James is the vice-chairperson of the Queensland branch of Ausbiotech and a member of the QCTN. He has advised life science businesses on regulatory issues under Australia's clinical trial regime and the *Therapeutic Goods Act 1989*. He has over six years experience practising as a lawyer in the life sciences field. James has undertaken training in good clinical practice and holds Bachelors of Science and Law from the University of Queensland.



**Reece Walker**

Partner  
**Telephone** 07 3233 8654  
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Reece has experience in a broad range of corporate and commercial matters including mergers and acquisitions, divestitures, restructures, joint ventures as well as public and private security offerings.



**Emma Weedon**

Senior Associate  
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Emma has experience in intellectual property licensing and protection, research and development arrangements and trade marks. She holds a Bachelor of Laws and a Bachelor of Science and has advised various biotechnology companies and research organisations on intellectual property issues.



**David Downie**

Partner  
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David has a background in computer science, giving him an understanding of the technical issues affecting the IT and communications industries. He has also in-house experience at the Commonwealth Bank of Australia, giving him an understanding of the commercial issues facing large consumers of information technology.



**Belinda Breakspear**

Lawyer  
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Belinda manages our clients' trade mark portfolios and has experience in franchising, research and development arrangements and intellectual property licensing. Belinda also has experience in residential and commercial property law. Belinda holds an honours degree in Law and International Business.



**Dr Amanda McBratney**

Consultant  
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Dr Amanda McBratney is a specialist patent and biotechnology lawyer with an LLM in international intellectual property from the University of London. Amanda's doctoral thesis was on aspects of patent law, and her work in the area was cited by the High Court in a 2004 decision. Amanda previously taught postgraduate intellectual property in biotechnology and other intellectual property commercialisation courses.



**Jill Penridge**

Graduate  
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In addition to her general background in intellectual property, Jill also has experience in commercial and contract law. Jill's main focus is dealing with commercial contractual issues particularly in relation to the information technology and communications industries. She has experience in trade marks and franchising.