



# Code of Conduct

January 2019

\*The essential principle of this Code is that on becoming a Member of AusBiotech, companies and individuals would agree, as part of their Membership Application to adopt the Code of Conduct in their working practices.

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## **1. About the Code of Conduct**

### *Purpose*

The purpose of the AusBiotech Code of Conduct is to provide a set of guidelines and principles for Members of AusBiotech that ensure responsible practices and appropriate standards for the biotechnology industry.

This Code of Conduct supports an industry membership aiming to:

1. Realise the potential of biotechnology to improve the quality of human life, enhance sustainable agriculture and secure improvement in the environment;
2. Recognise the need for health, safety, and environmental protection when undertaking the research, development, manufacture and distribution of our products and services;
3. Acknowledge the power of biotechnology and its development and use with full respect for human dignity and human and animal rights;
4. Communicate and share information about biotechnology and its derived products and services in a balanced manner, stating both benefits and risks and engaging with stakeholder views;

### *Scope*

The Code of Conduct is applicable to all areas covered under AusBiotech's definition of biotechnology.

AusBiotech utilises the following definition of biotechnology.

"The application of all natural sciences and engineering to the direct or indirect use of living organisms or parts of organisms, in their natural or modified forms, in an innovative manner in the production of goods and services (including, for example, therapeutics, foodstuffs, medical devices, diagnostics) and/or to improve existing industrial processes in the general areas of human health, food production, industrial bio-processing, and other public good and environmental settings."

## 2. AusBiotech's responsibility to members



### **AusBiotech's mission**

AusBiotech's mission is to foster a growing, strong and profitable biotechnology and life science industry in Australia through representation, advocacy and the provision of services and benefits to its members to help the industry realise its nationally important economic potential.

### **AusBiotech's vision**

AusBiotech's vision is to be the leading Australian industry body representing and advocating for organisations doing business in and with the global life sciences economy.

### **Objectives**

1. Strengthen AusBiotech's reputation as the voice of biotechnology in Australia.
2. Enjoy growing support from members through knowledge of what our members want and the ability to deliver on their expectations.
3. Be recognised as Australia's primary facilitator of investment partnerships and effective government relationships in biotechnology/life sciences.
4. Ensure the biotechnology industry is increasingly perceived by government as a key and growing economic and social driver.
5. Lead the development of industry policy in Australia.
6. Be a sustainable and financially-sound organisation.
7. Position AusBiotech for long-term growth, recognising the importance of its people.

### 3. Member commitments to the industry

The Code of Conduct outlines guidelines and principles for appropriate and expected standards for ethical conduct, professional conduct, quality standards, communication needs and community expectations.

AusBiotech acknowledges the specific requirements of the sectors of Human Health, Agriculture, Medical Devices and Regenerative Medicine.

#### *Ethical conduct*

The Code of Conduct expects AusBiotech members and affiliates to:

Adhere to regulatory and statutory laws governing biotechnology in Australia<sup>1</sup>, and to:

- Not engage in practices restricted by law or professional agreement;
- Foster the need for uniform, national and stringent regulation to assist in the development of this technology towards the benefit of society and the environment with appropriate regulation of biotechnology solidly based on values such as autonomy, privacy, beneficence, social justice and intellectual freedom; and
- Avoid conduct that will damage Australia's standing internationally, and observe all relevant obligations and standards of other countries where the industry is involved in biotechnology research, development or export.
- Support strict regulatory risk management plans and guidelines to ensure compliance with all relevant conditions<sup>2</sup>;

Ensure that conduct in medical research and commercialisation is held to high standards by:

- Encourage all research involving humans is conducted under relevant guidelines and ethical practices, with review and approval to ensure standards of safety, dignity and compliance;
- Respect the codes of ethics of the healthcare professionals who diagnose and treat disease, and who prescribe, dispense, and use biotechnology products or make use of biotechnology services whether in research, development or patient care;
- Treat animals in a respectful manner and, when at all possible, limiting their use in research with any disproportionate suffering to animals involved in biotechnology research and/or other parts of industry work avoided to ensure the highest standards of well-being are maintained
- Ensure commercialisation pathways appropriate demonstration of safety and efficacy, adherence with patient informed consent requirements and compliance with defined regulatory standards permitting such commercialisation
- Commit that commercialisation of potential therapies in a country, region or geographic jurisdiction that do not have well defined regulatory standards or an appropriately authorised regulatory framework to ensure the quality, safety and effectiveness of such therapies should never be misused to compromise the safety and well-being of patients.

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<sup>1</sup> In medicine, including therapeutics, devices and regenerative medicine, relevant authorities include Therapeutics Goods Administration (TGA), the US Food and Drug Administration (FDA), European Medicines Agency (EMA), Japanese Ministry of Health and Welfare (MHW), Korea's Ministry of Food and Drug Safety (MFDS) and others to best ensure patient safety and produce efficacy;

<sup>2</sup> In agriculture, risk management plans are established by the Gene Technology Regulator

Ensure that conduct in agricultural development is held to a high standard by:

- Promote the development of agricultural products to enhance sustainable agriculture and provide environmental benefits, ensuring that products do not adversely impact genetic diversity and the uniqueness of Australia's environment;
- Promote the efficient and sustainable agriculture and support new biotechnological developments, which offer additional opportunities for farmers to protect or improve their crops and to use natural resources more effectively;
- Foster and encourage quality investigations to ensure that plants, animals and other organisms produced do not present unacceptable risks when grown or utilised in the environment;
- Foster and encourage quality processes to ensure that all proposed work involving genetic modification in animals is referred to, and approved by, the relevant regulatory and ethical committees and that all information and monitoring will be reported to the relevant authorities as necessary and appropriate
- Support the development of Genetically Modified (GM) agriculture assessed on a case-by-case basis by properly constituted federal regulatory agencies<sup>3</sup>.

Ensure that the product(s) developed and commercialised have high standards of safety, efficacy and quality, including:

- Ensuring that the provision of medicines and devices conform to the highest standards of safety, efficacy, and quality
- Encourage quality processes that ensure devices are supported by comprehensive technical and informational services in accordance with current accepted medical and scientific knowledge and experience
- Ensure that all transport of biological materials comply with relevant international, national and state guidelines for safety in transport and that all exportation and importation of products or materials will comply with national standards of the Australian Quarantine and Inspection Service (AQIS) and Australian Customs Service (ACS);
- Support improvements in the quality of food and agricultural products, in order to enhance the world's food supply and thereby human and animal nutrition
  - a. Foster the principle that food products meet the highest standards and benefit for consumers;
  - b. Support the development of bioremediation and cleaner industrial and municipal processes through biotechnology and work to ensure that none of these processes pose unacceptable risks to human health or the environment;

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<sup>3</sup> Relevant authorities include the Office of the Gene Technology Regulator (OGTR), Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medical Authority (APVMA), Therapeutics Good Administration (TGA) and the Australian Quarantine Inspection Services (AQIS);

### *Professional behaviours*

The Code of Conduct expects AusBiotech members and affiliates to act in the best interest of the Australian biotechnology sector, and with integrity and honesty

- Use professionalism in dealing with healthcare professionals, public health officials, AusBiotech staff, committee members, volunteers, and any other representatives of AusBiotech, and the general public;
- Avoid behaviour, and avoid advocating or encouraging behaviour, that may be construed as harassment or discrimination, including, but not limited to:
  - verbal, physical, or visual conduct based on sex, sexual orientation, gender expression or identity, transgender status, race, age, national origin, disability.
  - inappropriate use of nudity and/or sexual images in public spaces (including presentation slides);
  - deliberate intimidation, stalking or following;
  - harassing, photography or recording;
  - sustained disruption of sessions, talks or other events;
  - inappropriate physical contact, and any unwelcome sexual attention.
- A Member shall at all times in the course of their professional activities consider a person's individual merit and standing over and above characteristics of age, race, religious belief, sexual preference, cultural or ethnic background, and shall encourage this behaviour in colleagues;
- Avoid unwarranted statements that reflect upon the character or integrity of other Members or knowingly do or cause any activity that reflects badly upon AusBiotech or the industry without verifiable cause;
- Inform their employer or client if circumstances arise in which their judgment or advice may be called into question due to a conflict of interest or for any reason of business connections, personal relationships, interests, or affiliation; and

### *Information: Ensuring confidentiality and privacy alongside appropriate communication and transparency*

The Code of Conduct expects AusBiotech members and affiliates to:

- Support the protection of the confidentiality of medical information, which includes genetic information and opposing the disclosure of such information without informed consent, which could lead to intolerance or stigmatisation
- Ensure that informed consent includes potential risks and benefits of potential therapies based on rigorous scientific and clinical standards
- Adhere to strict informed consent procedures, implementing quality processes to ensure that the informed consent is obtained of all individuals participating in biotechnology research programs, taking genetic tests or undergoing medical treatment. When individuals are unable to give their consent, it is obtained from their legal representatives according to current legislative requirements;
- Encourage the accessibility of counselling for genetic testing;

Support the provision of transparent product information to promote informed consumer choice

- Foster dialogue that is inclusive, comprehensive, well informed, and structured to facilitate meaningful dialogue and help the public and stakeholders to understand complex technologies
- Foster medicines support through comprehensive technical and informational services in accordance with current accepted medical and scientific knowledge and experience;
- Acknowledge that foods produced using gene technology, and sold in Australia, will be labelled where the food contains novel DNA or protein or has altered characteristics and encouraging compliance with authorities on these compliance and testing requirements for food labelling
- Only publish or issue information, claims, or graphical representations that are an accurate record of soundly based observation, experimentation, or are otherwise clearly identified as an opinion

Ensure employees are equipped to discharge their responsibilities for transparency and accuracy in communication

- Commit to transparency of operations and open communications with employees and the public on relevant biotechnology issues;
- Develop training and information programs for their employees to ensure they have access to the most up to date and accurate information;

#### *Community obligations and expectations*

Members are to recognise their responsibility to the community and the environment, including:

- Support the conservation of biological diversity;
- Oppose the use of biotechnology to develop or produce any biological or other weapons;
- Oppose the use of cloning technologies to reproduce human beings;
- Protect the community and environment from exposure to actual or potential hazards;
- Support and encourage biotechnology role to enhance a productive, environmentally sustainable and socially responsible value-chain today and in the future.

### *Conduct at AusBiotech Events*

The Code of Conduct expects AusBiotech members and affiliates to be particularly mindful of standards of professional behaviour at AusBiotech events.

- AusBiotech is dedicated to providing a harassment-free event experience for everyone (regardless of gender, gender identity and expression, sexual orientation, disability, physical appearance, body size, race, age or religion). We do not tolerate harassment (as defined above) of event participants in any form. Event participants, including sponsors and exhibitors, violating these principles may be sanctioned or expelled from an event (without a refund) at the discretion of AusBiotech management.
- If you have a complaint or concern about harassment, discrimination, bullying or any other conduct that violates the AusBiotech Code of Conduct, we encourage you to report this to an event staff member or security personnel immediately. If you witness this happening to someone else, please report that, too. You may request that your report remain completely confidential.

## **4. AusBiotech Code of Conduct implementation**

*In administering or implementing this Code:*

- Members may advertise their Membership of AusBiotech when promoting their services, through the use of the phrase 'Member of AusBiotech';
- Members will ensure that staff and colleagues are made aware of this Code of Conduct and other standards, guidelines and laws relevant to the safe and ethical conduct of biotechnology activities;
- Members will develop training and information programs for their employees to ensure they have access to the most up to date information about this Code;
- Members are to avoid unwarranted statements that reflect upon the character or integrity of other Members or knowingly do or cause any activity that reflects badly upon AusBiotech or the industry without verifiable cause;
- Members are requested to comply with the spirit of this Code of Conduct;
- Member companies also recognise AusBiotech's responsibility to consider deviations by its Members from the Code of Conduct and to recommend appropriate responses after a reasonable due process.

Since biotechnology is innovative and rapidly developing, the Code of Conduct will be continually updated to address new issues and new insights that arise in the future.

*\*Note - AusBiotech represents core focus sector areas. In general, the principles outlined in this Code of Conduct apply to all four areas of Human Health, Agricultural Biotech, Medical Devices and Regenerative Medicine. Over time, additional sector requirements may be included, to accommodate specific focus needs.*