

Takeda's Position on Biotechnology

Key message

As a global, R&D-driven biopharmaceutical company, we discover and deliver life-transforming treatments to patients. We strive for the highest standards of integrity in our research activities and act responsibly when utilizing emerging technologies.

Background

The continuous evolution of scientific and medical technology provides researchers with unprecedented opportunities to develop medicines and vaccines for previously untreatable diseases. As Takeda responsibly translates science into highly innovative, life-changing medicines and vaccines, we understand our responsibility to meet the highest standards of ethical behavior. Integrity in our research and development activities is central to our philosophy as a company. We act responsibly when utilizing emerging technologies.

This paper outlines Takeda's view and approach towards some of these novel technologies, including cloning, stem cells, genetically modified organisms (GMO), and gene therapy.

Takeda's position

Guiding principles

Research conducted by Takeda, or at its direction, is designed to advance scientific knowledge and support the development of medicines as we focus on diseases with high unmet needs. Cloning techniques are essential for the discovery and development of targeted therapies. These techniques are used routinely in the discovery and development of new products and therapies. Stem cell research and related technologies allow scientists to understand a new medicine's potential efficacy and safety in functional human cells years before it enters the clinic. These cells and GMOs help accelerate the discovery and development of safer, more effective, medicines. Researchers are exploring gene therapies as potential treatment for patients suffering from cancer and genetic diseases.

R&D Integrity

Takeda's position regarding the use of several specific novel technologies covers internal research programs and the research it supports through grants and collaborations.

Research is conducted responsibly and ethically

All research activities are conducted in accordance with applicable laws and regulations, accepted international guidelines, and sound ethical principles as outlined below. As a values-based company, we are committed to the highest standards of ethical behavior in our global enterprise of biopharmaceutical research, development, manufacturing, distribution and other activities. These ethical standards serve as the foundation of Takeda policies and procedures.

No human reproductive cloning

Takeda does not support research that involves human reproductive cloning.

Stem Cell Technologies

- Takeda conducts research with and supports external research programs that use animal stem cells, human induced pluripotent stem cells, umbilical cord blood stem cells in the allogenic setting, and adult human stem cells. These cell sources are widely used and well-established resources in several areas of pharmaceutical research and development. All research conducted or funded by Takeda is done in compliance with all federal, state and local regulations – including those set forth by the International Society for Stem Cell Research, the National Institutes of Health and the National Academy of Sciences.
- Takeda does not manufacture or market any products derived from human embryonic stem cells.

Genetically Modified Organisms, Gene Therapy

- Takeda supports the ethical production and use of genetically-modified organisms (GMO).
- Takeda is exploring somatic gene therapy (including genome editing therapy) as a potential treatment for oncology and/or genetic diseases with unmet medical needs.
- Takeda does not conduct or fund research programs that are designed to enable germline transmission.

Closing

As biotechnology advances, so must our understanding of bioethical considerations. Takeda listens to and considers views regarding evolving ethical and social concerns with the application of new advances in the research, development, manufacture, and distribution of our medicines and vaccines. We actively participate in forums that encourage science-based policies and regulations that serve the public interest. To that end, Takeda is committed to working with government and regulatory bodies to support appropriate legislation and regulations that address societal concerns related to biotechnology.

Additionally, recognizing the fast pace of innovation in science and medicine and emerging ethical challenges, Takeda has established the Takeda Ethics Advisory Council (TEAC). The TEAC is comprised of a diverse group of professionals that include prominent external ethics experts and selected Takeda leaders. The primary



responsibility of the TEAC is to analyze and provide advice on ethics topics so Takeda can develop robust and principled positions on these issues into the future. TEAC's predecessor organization, the Bioethical Advisory Group, provided input for the current position.

September 2021