Our position on
Managing and Using Genetically Modified Materials

What is the issue?

As a healthcare company aiming to unite science, talent and technology to get ahead of disease together, we are at the forefront of the development and application of new scientific techniques to discover and develop new medicines and vaccines. This includes the safe and responsible use of genetically modified materials (GMM). These may include microbiological entities such as bacteria, fungi, viruses, viroids, animal or plant cells in culture, which are developed and used in contained environments.

There are a number of benefits associated with the use of GMM in the research, development and manufacture of medicines and vaccines. For example, the use of GMM technology has enabled us to:

- develop a Hepatitis B vaccine without using human blood products, eliminating the inherent risk of infection from contaminated source material
- reduce the pathogenicity of micro-organisms used when developing and producing vaccines or when developing new GMM vectors, making them safer to handle, and allowing us to use containment controls with a reduced energy requirement
- reduce the use of animals when producing monoclonal antibodies
- construct micro-organisms that have a reduced capacity to survive outside of the manufacturing process compared to naturally produced micro-organisms.

Nonetheless, we recognise that the use of GMM technology may cause concern. This paper sets out what we believe to be an effective and responsible approach to assess and manage potential risks associated with the use of GMM.

What is GSK's view?

- **All work with GMM within GSK is assessed and controlled applying best practice across all our facilities.** We adopt a responsible approach to the use of GMM. Our global EHS standards set out our expectation and through their implementation, we comply with applicable laws and regulations, and GSK requirements.
- **GSK is committed to ensuring that we control the risks to our employees and the environment when we use GMM technology to develop and manufacture products.** We have procedures that ensure the hazards and risks associated with the development and manufacture of our new products are thoroughly assessed and controlled.
    - Any work with GMM is subject to a risk assessment to identify appropriate controls including safe conditions of use, storage, disposal and emergency management procedures to minimise contact between GMM, humans and the environment.
    - We manage the use of GMM through bodies such as site Institutional Biosafety Committees (IBC) or Genetic Modification Safety Committees (GMSC) in line with national and local regulations.
- **GSK is committed to the control of environmental, health and safety risks throughout our manufacturing supply chains, including third-party manufacturers.** This principle is central to

product stewardship, which means taking responsibility for a product throughout its whole life cycle, i.e., during its development, manufacture, use and disposal. We expect our business partners to meet similar standards for EHS and quality to those required from our own factories and we audit contract manufacturers to ensure appropriate standards are maintained. We communicate information and guidance for employees, customers, contract manufacturing partners and onward users on the safe processing, usage, transportation and disposal of any GMM or products derived from GMM.

- **GSK requires that GMM are inactive in waste streams to ensure safety to human health and the environment.** We evaluate the risks associated with the GMM that we use and employ processes that are effective in inactivating waste streams to ensure protection to human health, safety and the environment.
- **GSK is committed to openness and transparency about how we manage risks associated with use of GMM and continue to engage with stakeholders to enable us to understand and keep in touch with their views.**