

HUMAN GROWTH HORMONE BIOASSAY

This is a cell line which can be used to assay human growth hormone. Currently manufacturers of human growth hormone use an animal model for quality control which costs several million dollars per year. For a fraction of that cost, this cell line offers: simpler ease of use, and greater sensitivity and specificity.

Market Need and Opportunity

Manufacturers of human growth hormone (hGH) currently use a hypophysectomised rat model (removal of pituitary gland) to assay the potency and efficacy of hGH in their quality control procedures. This model is expensive and extremely labour intensive. Furthermore ethical and public relations considerations dictate that pharmaceutical companies should, wherever possible, phase out animal testing. The use of this cell line would provide obvious benefits in terms of cost, ease of use and specificity to the manufacturers.

The total global human growth hormone market currently stands at over US\$2.2 billion dollars and the leading manufacturers of recombinant hGH include Novartis (Sandostatin LAR), Pfizer (Genotropin), Eli Lilly (Humatrope), Novo Nordisk (Norditropin), Genentech (Nutropin), Serono (Saizen, Serostim) and Ipsen (Somatuline) among others.

IMBcom's Position

Technology

The technology relates to a human growth hormone receptor (hGHR) expressing cell line (mouse proB) developed by Professor Waters at the University of Queensland's Institute for Molecular Bioscience. The cell line has been independently shown, by Lucky Goldstar Life Science (LGLS), to provide much greater sensitivity and specificity than the hypophysectomized rat assay currently used. The LGLS studies also showed that the hGHR cell line was superior in terms of specificity and selectivity to a cell line they (LGLS) had developed in house.

Intellectual Property

In collaboration with AlphaPharma Pty Limited a validation report has been produced which includes standard operating procedures and performance characteristics, all of which were developed under good laboratory practice frameworks.