



## **Eden Biodesign Announces Second Successful MHRA Audit of Its State-of-the-Art cGMP Manufacturing Facility**

**Liverpool, UK and Research Triangle Park, NC, May 12, 2009** – Eden Biodesign, a globally-integrated provider of biopharmaceutical and vaccine process development, cGMP manufacturing and consultancy services, today announced that it has completed a very successful second audit by the UK Medicines and Healthcare Products Regulatory Agency (MHRA), European Medicines Agency (EMA) to manufacture Investigational Medicinal Products (IMPs) at its state-of-the art facility in Liverpool, UK.

The three-day MHRA inspection took place in March 2009 and demonstrates that the Company's processes, facilities and excellent quality systems continue to meet international Good Manufacturing Practices (cGMP) standards. The result of the inspection was an outstanding success, with no critical or major deficiencies found by the inspector.

"I am delighted that our world class cGMP production facilities have passed their second audit," said Dr. Crawford Brown, co-founder and CEO of Eden Biodesign. "The inspection recognizes that we have a highly trained and knowledgeable team and appropriate and well-developed quality systems in place at Eden Biodesign. We have a growing track record with a global client



base, and we deliver a full-service offering for the production of new medicines across all major biopharmaceutical production platforms.”

Eden Biodesign has recently prepared a Drug Master File (DMF) for submission to the U.S. Food and Drug Administration (FDA). The Type V DMF details confidential information about the production and testing facilities at Eden Biodesign’s UK Facility. Eden Biodesign plans to submit the DMF to the FDA in June 2009. Clients of Eden Biodesign will be able to cross reference the Eden Biodesign DMF in their Investigational New Drug Application (IND) or Biological Licence Application (BLA) submissions to the FDA.



## **About Eden Biodesign**

Eden Biodesign is a globally-integrated biopharmaceutical company offering consultancy, biopharmaceutical design and cGMP manufacturing services to leading biotech and pharmaceutical clients around the world. With a reputation for successfully commercializing biopharmaceutical products and processes, the Company offers expertise and guidance in multiple sectors. Eden's world-class facilities and knowledge in process development, manufacturing, regulatory and technology transfer support ensures Eden Biodesign offers much more than a traditional CMO. Learn more at [www.EdenBiodesign.com](http://www.EdenBiodesign.com).

# # #

Media Contact:

John D. Wagner

Propel Marketing Group

919 796 9984

[Jdwagner@PropelMG.com](mailto:Jdwagner@PropelMG.com)

[www.PropelMG.com](http://www.PropelMG.com)