bio outsource™
cGMP compliant biotesting

Your Partner in Release Testing for Biologics and Vaccines

BioOutsource Ltd is a company created with the future in mind. Drawing on many years of experience the founders of BioOutsource have brought together a vision of partnering world class scientific expertise with the advantages of innovative Information Technology solutions embedded in a GMP compliant quality driven environment which eliminates many of the problems in testing products for release.

Service Offering

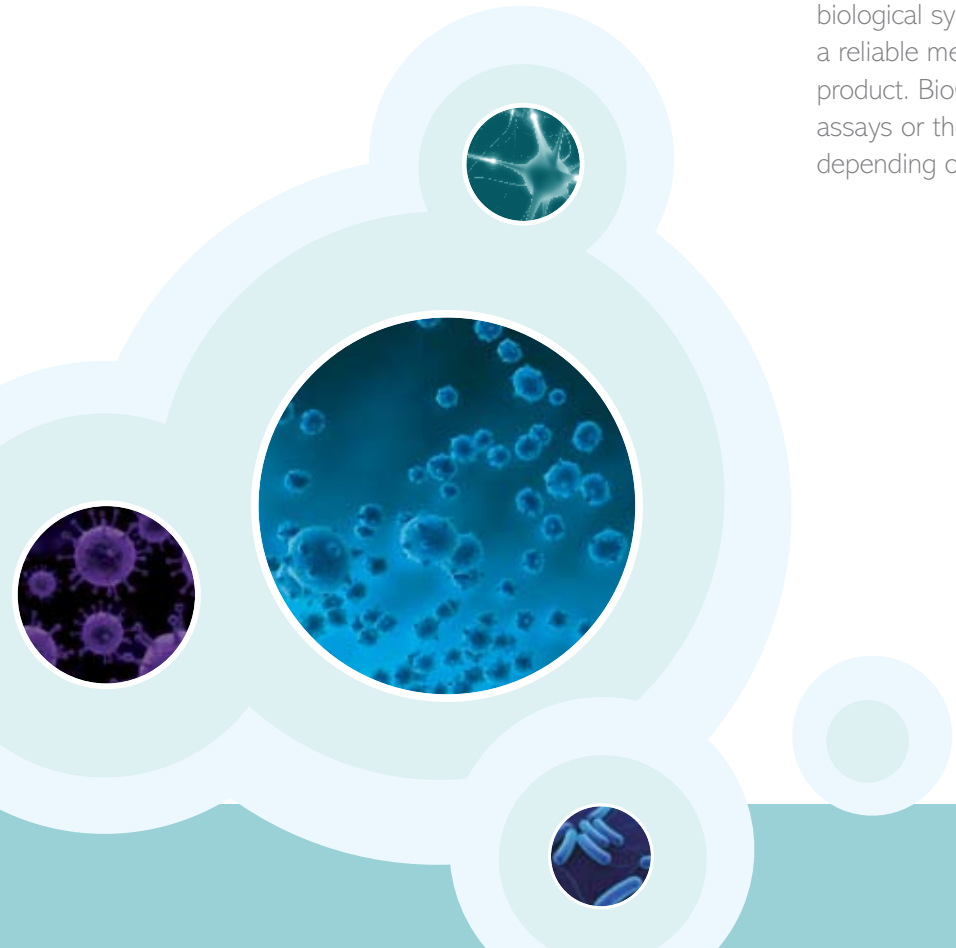
BioOutsource Scientists believe they can provide a unique combination of experience and talent which not only solves your immediate problems for testing but provides solutions which are future proofed for Regulatory Guidelines and Industry Challenges for the foreseeable future. We seek to become the partner of choice for release testing to GMP for cell based assays, molecular biology and protein analytical tests. As well as this we can offer cell based neutralisation assays to detect antidrug antibodies – an issue of critical importance.

In Vitro Services

Cell based assays are perhaps one of the most important and challenging techniques which are used in the batch release of products. These tests fall into two general categories: Safety Testing and BioPotency Testing.

BioOutsource provides the complete range of tests required for batch release of Viral Vaccines/ Gene Therapy Vectors and Biologics such as Monoclonals and Recombinant Proteins. All of these tests are performed to GMP with fully validated assays.

BioPotency has become one of our fastest growing services. The measurement of drug potency using a biological system such as cell based assays provides a reliable measure for batch release and stability of product. BioOutsource has a package for transfer of assays or the development and validation of new assays depending on client requirements.



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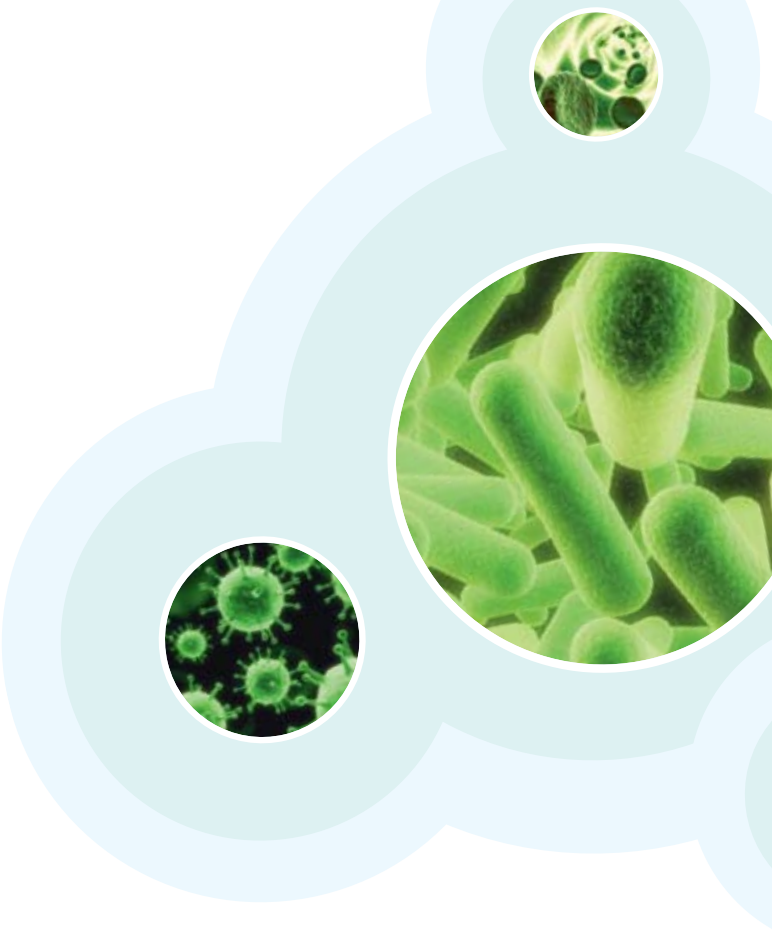

Molecular Biology Services

The advent of PCR has caused a dramatic change to the way many tests are performed for product safety. The BioOutsource Molecular Biology Team are led by experienced scientists who can provide both "off the shelf" assays as well as developing custom techniques to suit your specific needs.

The two main areas for Molecular Biology Services are Safety Testing of samples for the presence of adventitious viruses and testing for Residual DNA in final product. Safety testing falls mainly to PCR techniques to detect the presence of viruses such as Hepatitis or HIV in samples for clients or the PERT assay to detect the presence of Retroviruses. Residual DNA techniques again use PCR techniques, PICO Green or the Threshold Method (Molecular Devices).

Quality

BioOutsource successfully passed a routine GMP Compliance Inspection by the MHRA in March 2008. This provides the required regulatory acceptance of BioOutsource for GMP testing. GMP is at the heart of all procedures and quality systems created in BioOutsource. Our Quality group is led by Gillian Hill who has a number of years of experience in similar environments. The philosophy of the Quality group in BioOutsource is to integrate GMP and process excellence throughout all of our processes.

Information Technology

The BioWeb has been created to bring BioOutsource and our Clients closer together. All testing documentation is placed in a secure web based application which can be reviewed at any time by the clients. This level of transparency is unsurpassed in the industry and provides a means for a much closer, more positive relationship.

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