

Bioassay



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Bioassay is an independent contract laboratory that specialises in the routine performance of bioanalytical assays for the pharmaceutical industry. Development and validation of biological assays for the pharmaceutical industry. Bioassay provides qualified analytical services that are good manufacturing practices (GMP) and good laboratory practices (GLP) certified. Analytical services offer a strong framework for successful projects and routine bioanalysis. The company is experienced in the development, validation and execution of biological assays within quality control of pharmaceutical and chemical products. Potency assays for medicine. Bioassay executes and assesses potency assays through quality control of active pharmaceutical ingredients (APIs) and pharmaceuticals. The company has experience in developing and validating new assays to International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) standards. Bioassay also optimises existing assay formats and transference into routine applications. Antibody dependent cell mediated cytotoxicity. Bioassay has established potency assays of therapeutic antibodies running under GMP, which are rituximab, trastuzumab, adalimumab, infliximab, etanercept and antibody drug conjugates (ADC). The company also focuses on the development of assays regarding antibody dependent cell mediated cytotoxicity (ADCC) attributed to the mode of action of therapeutic antibodies, especially tumor cell targeting. ADCC assays are available for development and quality control. Hormones and growth factors for quality control. Bioassay's portfolio includes hormones and growth factors, as well as potency assays based on monoclonal antibodies.

European Pharmacopoeia (EP) and United States Pharmacopeia (USP) within the biopharmaceutical industry. These run under GMP in a daily quality control routine for stability testing and batch release of APIs and drugs. The company's portfolio includes erythropoietin, follicle stimulating (FSH) and luteinising hormones (LH), human chorionic gonadotropin (HCG), parathyroid hormone (PTH), filgrastim (G-CSF), human growth hormone (hGH) and interleukins. Biopharma efficacy models Bioassay has efficacy models to address the demand of characterisation of new drugs, especially in the biopharmaceutical field such as monoclonal antibodies, hormones and cytokines. These include FACS-based receptor binding assays, specific cell line development and neutralising antibody assays. The company has experience in the field of characterisation of biosimilars and modified biologics such as pegylated products. About Bioassay Located in Heidelberg, Germany, Bioassay started specialising in biological assays within pharmaceutical quality control in 2002. Bioassay focuses on four key areas, namely biopharma potency, efficacy, safety and chemicals / cosmetics safety. The company's in-vivo and in-vitro facilities use state-of-the-art-equipment. Clients can visit the laboratories located in the Heidelberg Technology Park in Germany.

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