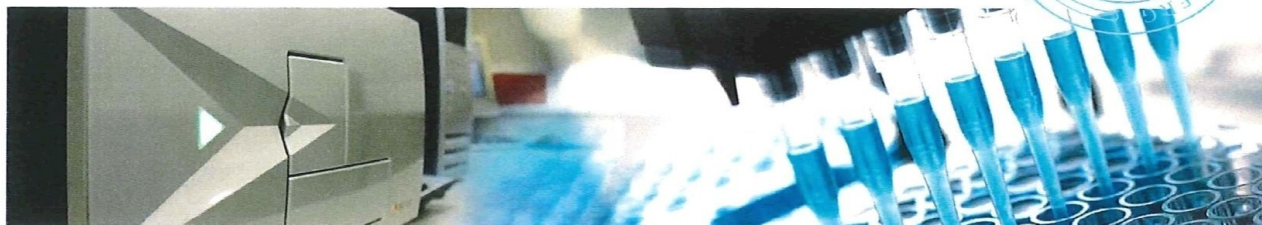


## CELL-BASED ASSAYS



For more than 25 years SYMBIOSIS develops and validates bioassays. Profit from our experience and our dedicated one-stop-shop services. Our multidisciplinary team of expert scientists support your needs starting from early cell-based assay development up to routine GMP/GLP testing.

Potency determination is required for batch release and regulatory submission for biopharmaceuticals. Whenever a biological response related to its mode of action or potency has to be monitored bioassays are the method-of-choice. Data evaluation is typically performed by using biostatistical methods.

### SERVICES

- Bioassay development and optimization
- Bioassay validation according to ICH guidelines
- Method transfer into our laboratories or to our clients
- Lot release/stability testing of drug substance/product
- Development of assays for detecting and measuring immune responses will be performed by using a distinct three-step strategy consisting of screening, confirmatory and neutralization assays as suggested in the recent EMA guideline on immunogenicity assessment.

### PRODUCTS

A comprehensive set of in-vitro bioassays for a variety of originator, biosimilar and biobetter molecules are available.

- Hormones, e.g. EPO, PTH, FSH
- Growth Factors, e.g. G-CSF, IL's
- Antibodies, e.g. Adalimumab

### Readout

- Absorbance
- Fluorescence
- Time-resolved fluorescence
- Luminescence

### Data Evaluation

- Parallel line
- Four and/or five-parameter fit
- EC<sub>50</sub> or CPE<sub>50</sub> determination

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+49 (0) 6221 5383-52

### ASSAYS

- Cell proliferation
- IL's, G-CSF, PTH
- Native and pegylated compounds

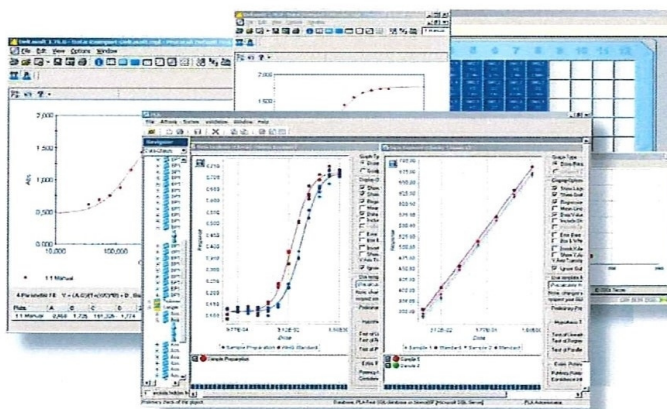
### Assays for immunogenicity testing

- Anti-drug antibody (ADA)
- Neutralizing antibody (NAb)

### Assays for monoclonal antibodies

- Apoptosis assays
- Binding assays
- Neutralization assays
- Competitive assays

Additionally SYMBIOSIS provides you with all key reagents and cell-related services such as cell banking and storage.



### SYMBIOSIS

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