

New Biological Entities Product Characterization Services

Features and Benefits

- **Speed:**
Faster assay development to shorten your timeline to IND submission
- **Flexibility:**
Tailored testing packages
- **Expertise:**
Extensive experience & full range of platform methodologies
- **Compliant:**
Fully cGMP compliant laboratories



NBE Product Characterization Services

The foundation for approval of new biological entities (NBE) is built on a robust analytical data package that proves the safety, purity, and potency of the product.

Our dedicated team will partner with you to provide pre-qualified assays, or develop custom assays for your specific needs.

Sartorius Stedim BioOutsource product characterization services combine physicochemical and biological analysis for in-depth characterization studies from a single contract partner with fully compliant cGMP facilities, as audited by the FDA & MHRA.

Our panel of off-the-shelf monoclonal antibody characterization assays are ready to be implemented for a range of targets. Our assays have been qualified with commercially available innovator mAbs.

Our Approach = Your Success

TNF α	HER2	IgE
CD20	EGRF	IL12/23
VEGF	PD-1	RANKL

This list is not exhaustive. If you don't see your target, don't worry - contact us today to discuss

Our Service Offering

Fab Binding

- ELISA Methods
- Flow Cytometry
- SPR Methods

Structural Analysis

- LC-MS Methods
- N-glycan Analysis
- Intact Mass
- Peptide Mapping

Fab Functional

- Various direct
- Blocking
- Neutralizing
- MOAs

Fc Binding

- C1q (ELISA & SPR)
- Fc γ Receptor SPR
- FcRn



Fc Functional

- ADCC
- ADCP
- CDC



One Single Contract Partner for a Total Solution

Cell Line Development

Cell Bank Manufacturing

Biosafety Testing


Analytical Testing

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Specifications subject to change without notice.

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