



The National Institute for
Bioprocessing Research
and Training

Contract Bioanalytical Services

World Leading Contract
Research Services



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About Us

The National Institute for Bioprocessing Research and Training (NIBRT) is a global centre of excellence for training and research in bioprocessing.

Our world leading NIBRT principal investigators and scientific advisors including Dr Jonathan Bones and Prof Pauline Rudd continue to drive advancements in the field of bioprocessing analytics through pioneering and innovative research.

Our highly regarded scientists are situated in the award winning NIBRT facility with access to state-of-the-art laboratory equipped with top-of-the-line instrumentation.





About NIBRT Contract Research

- We provide detailed characterisation of biologics in line with ICH Q6B and Q5E.
- For over 10 years NIBRT Contract Research has worked with Top 20 global Biopharma companies as well as SME's, virtual companies and law firms.

NIBRT Mission

Our mission is to provide you with a partner to outsource analytical services. We provide invaluable information on your biologics, assisting you in key decision making during candidate development and process change.

We support you in bringing high-quality, safe and efficacious drugs to market.

“ NIBRT came highly recommended from a contact in New York and we were not disappointed: Patrick Jennings and his team did a fantastic job for us on a very short turnaround. Within a couple of weeks they had optimised several testing processes for measuring the purity of an antibody for the purposes of litigation and provided helpful results that were strategically important to the case. No amount of effort was too much and Patrick and Caitriona provided daily updates, slide decks and telephone calls to keep the team apprised as to progress, Patrick even going so far as taking delivery of an HPLC column at his home address on a Saturday so that a valuable day's testing could be saved. We would recommend them universally and thoroughly enjoyed the experience of working with them. Ten out of ten for service, quality and professionalism. ”

Partner at a top-tier patent litigation boutique law firm in London



Contract Research Services

- > Structural characterisation, measurement of physicochemical properties and determination of process and product related impurities to satisfy ICH Q6B requirements.

Bespoke Analytical Development

- > Feasibility/pre-validation, verification and qualification
- > Troubleshooting of existing client methods
- > Replication of methods for IP litigation



We came across NIBRT Contract Research through our work with a leading expert in the Biotherapeutic characterisation field. From first contact, NIBRT Contract Research has been an outstanding facility to work with. The team at NIBRT Contract Research has been instrumental in pushing the boundaries of our testing needs. They are not only flexible, responsive and a pleasure to work with, they also go several steps further to help us problem solve and develop new ways to test our products and learn more about our systems. NIBRT Contract Research is a top class analytical facility and we will continue to work with them and recommend them to our colleagues going forward. We would use no one else.



North American Law firm specialising in intellectual property



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Why NIBRT?

- **We are a team of characterisation specialists with expertise in the characterisation of biological products such as monoclonal antibodies, fusion proteins, erythropoietin, interferon, enzymes and many more.**
- **We provide tailored detailed reports to ensure full clarity of data and results.**
- **Creation of bespoke projects, flexibility in scheduling, quick response times.**
- **Each service is overseen by a subject matter expert project manager and dedicated highly trained analyst(s) who offer support throughout the project lifetime.**



NIBRT Bioanalysis Services

Areas	Technique	Utility	Equipment
Cell Enrichment	Magnetic separation	Selective cell isolation, co-precipitation of cell phenotypes, effector lymphocyte activation	Thermo Scientific™ Kingfisher™ Flex
Cell Phenotyping	FACS	Cell cycle analysis, biomarker expression, intracellular staining, cell viability/apoptosis	BD FACSMelody™
Protein Determination	Western blot	Protein detection, protein concentration, protein-protein interactions, PTMs, epitope mapping	GE™ Healthcare image scanner III
	Spectroscopic (BCA/Bradford/Lowry/NanoDrop™)	Total protein quantitation	Thermo Scientific™ NanoDrop™ 2000
	Magnetic bead separation	Protein purification	Thermo Scientific™ Kingfisher™ Flex
Nucleic Acids	Magnetic bead separation, sqPCR, sqRT-PCR	host DNA purification and quantitation, gene expression analysis	Thermo Scientific™ NanoDrop™ 2000
Ligand Binding Assays	ELISA, FIA, Surface plasmon resonance, hybrid LBA/LC-MS	Drug/analyte quantitation, cytokine detection, potency measurement, active concentration, binding affinity/kinetics, epitope mapping	Perkin Elmer™ Victor X3 2030 Multilabel Plate Reader GE™ Healthcare Biacore™ T100 Agilent™1290 Infinity™II/ Agilent™ 6460 Triple Quadrupole

ICH Q6B Area: Structural Characterisation

Protein		
Analysis	Technique	Equipment/software
Amino acid sequence	Peptide mapping by LC-MS and bioinformatic analysis against provided protein sequence	Thermo Scientific™ Vanquish™-Q Exactive Plus™/ Byos™ (Protein Metrics)
N- C- terminal sequencing	Confirmation of N- and C- terminal amino acids by peptide mapping (detection of blocked N-terminus pyroglutamate/pyroglutamic acid)	Thermo Scientific™ Vanquish™-Q Exactive Plus™/ Byos™ (Protein Metrics)
	Top down intact mass for orthogonal confirmation	Thermo Scientific™ Vanquish™-Q Exactive Plus™/ Byos™ (Protein Metrics)
Amino acid composition	Derivatisation and quantitation with AccQ.Tag™ Ultra by UPLC-UV/FLR	Waters™ Acquity™-UV/FLR
Disulfide bonds	Comparison of reduced and non-reduced peptide mapping by LC-MS	Thermo Scientific™ Vanquish™-Q Exactive Plus™/ Byos™ (Protein Metrics)
Free thiols	Determination of free thiols using DNTB	Agilent™ Cary 60 UV Vis™
Glycosylation		
Analysis	Technique	Equipment/software
Site occupancy	Comparison of glycosylated and deglycosylated sample peptide maps by LC-MS	Thermo Scientific™ Vanquish™-Q Exactive Plus™/ Byos™ (Protein Metrics)
N-glycan analysis O-glycan analysis	Released glycans with labelling (2-AB, APTS) and analysis by UPLC-FLD and LC-MS or CE-LIF/ Linkage confirmation by exoglycosidase digestion	Waters™ Acquity™-FLD/ Thermo Scientific™ Vanquish™-Q Exactive Plus™/ Beckman Coulter™ PA800 plus™
Sialic acid quantitation	DMB labelling of hydrolysed sialic acid by UPLC-FLD	Waters™ Acquity™-FLD
α(2-3,2-6) sialic acid linkage relative quantitation	Derivatisation of sialic acids by DMT-MM and analysis by LC-MS	Waters™ Acquity™-FLD/ Thermo Scientific™ Vanquish™-Q Exactive Plus™/ Beckman Coulter™ PA800 plus™



NIBRT Contract Research has enabled Levicept to access a wide range of analytical services delivered through the provision of top specification analytical instrumentation. In addition to providing protein and glycan analytical services their ability to develop new methods to meet our specific needs enables us to quickly resolve our analytical queries in timely and cost effective manner. Working with NIBRT Contract Research has enable us to gain a greater understanding of our clinical candidate.



Dr Simon Westbrook
CEO Levicept

Levicept

ICH Q6B Area: Physicochemical properties

Analysis	Technique	Equipment/software
Intact protein molecular weight	Molecular weight determination by RP-LC-MS	Thermo Scientific™ Vanquish™-Q Exactive Plus™/ Byos™ (Protein Metrics)
	Native MS	Thermo Scientific™ Vanquish™-Q Exactive Plus™EMR/ Byos™ (Protein Metrics)
Isoform pattern	Profiling of isoforms by various techniques: cIEF peptide mapping and UPLC: IEX, HIC, RP, SEC	Beckman Coulter™ PA800 plus™ Waters™ Acquity™-UV
Determination of extinction coefficient	Amino acid analysis combined with UV 280nm dilution series	C Technologies SoloVPE- Agilent™ Cary 60 UV Vis™

ICH Q6B Area: Process and product related impurities

Analysis	Technique	Equipment/software
Aggregate analysis	Determination of aggregates and fragments by SEC, AUC and LC-MS	Waters™ Acquity™-UV Beckman XLI analytical ultracentrifuge Thermo Scientific™ Vanquish™-Q Exactive Plus™/ Byos™ (Protein Metrics)
Molecular variants	Profiling of isoforms by various techniques: cIEF peptide mapping and UPLC: IEX, HIC, RP, SEC	Beckman Coulter™ PA800 plus™ Waters™ Acquity™-UV
	Charge variant analysis by IEX-UPLC and CIEF	Waters™ Acquity™-UV Beckman Coulter™ PA800 plus™
	Oxidation by HIC and RP-UPLC	Waters™ Acquity™-UV
Host Cell Proteins (HCP)	Absolute quantitation of HCP by LC-MS and ELISA	Thermo Scientific™ Vanquish™-Q Exactive Plus™/ Byos™ (Protein Metrics)
Residual protein A	qPCR using ProteinSEQ™	Applied Biosystems™ 7500 RT-PCR
Host cell DNA	qPCR using resDNASEQ™	Applied Biosystems™ 7500 RT-PCR
PPG and PEG analysis	Detection of free PPG and PEG by UPLC-CAD	Thermo Scientific™ Vanquish™- Corona™ Veo™ Charged Aerosol Detector
Extractables and leachables	Detection and quantitation of extracted and leached compounds by ICP-MS, GC-MS and LC-MS	Thermo Scientific™ iCAP™ RQ ICP-MS Thermo Scientific™ Q Exactive™ GC Orbitrap™ GC-MS/MS Thermo Scientific™ Vanquish™-Q Exactive Plus™

Get in Touch



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