



Analytics for Biologics and Vaccines

Biologics and vaccine developers leverage our analytics expertise to advance their innovative treatments from discovery to application for clinical trials. We also transfer our data and methods to Contract Research Organizations (CROs) and Contract Manufacturing Organizations (CMOs), enabling them to offer new services while strengthening the Canadian biopharma ecosystem.

Constantly innovating to better characterize your molecules

The development and approval of new treatments like antibody therapeutics, immunotherapies and virus-like particle (VLP)-based vaccines requires innovative analytical methods. Our experts excel at designing non-standard assays and can help you fill gaps in lead identification, characterization, bioanalysis, and biomarkers.

We can work with you to define your target product profile (TPP) and develop a lead candidate. Our biophysical and physicochemical characterization expertise supports you as you prepare your Clinical Trial Application (CTA) in Canada or Investigational New Drug (IND) application in the USA. We can identify, evaluate and monitor your lead candidate's critical quality attributes (CQA), and provide you with documentation in line with regulatory requirements.

R&D expertise

Target discovery and selection

- › Proteomics
- › Glycoproteomics
- › Lipidomics
- › Metabolomics
- › Bioinformatics and computation biology
- › Data mining and machine learning
- › Development of non-standard assays and approaches
- › Characterization of intact mass and post-translational modifications
- › Cell-based and potency assays

Candidate design and lead selection

- › Selection of bi-specific candidates
- › Antibody-drug conjugate characterization

- › Multi-domain biologics analysis
- › Characterization of virus-like particles (VLPs) and bacterial-based vaccines
- › Higher order structure analysis
- › Epitope mapping
- › Glycosylation analysis
- › Stability and formulation assessment
- › Structure-function relationships to validate molecular modeling approaches
- › Developability and manufacturability assessments

Preclinical development

- › Bioanalysis including pharmacokinetic (PK) measurements
- › Process residuals measurement (endotoxins, proteins, DNA)
- › Host-cell protein identification
- › Targeted biomarker quantification



Candidate characterization for Clinical Trial Application (CTA or IND)

- › CTD Module 3 Quality: Drug Substance
 - 3.2.S.3 Support for Characterization: structure, other characteristics, impurities
 - 3.2.S.4 Support to establish Control of Drug Substance: analytical procedures, batch analyses, justification for specification
 - 3.2.S.5 Reference Standards or Materials for technology transfer and first GMP batches
 - 3.2.S.7 Trend data to support Stability programs
- › CTD Module 3 Quality: Drug Product

- 3.2.P.5 Support to establish Control of Drug Product: analytical procedures, batch analyses, justification for specification, impurities
- 3.2.P.6 Reference Standards or Materials for technology transfer and first GMP batches
- 3.2.P.8 Trend data to support Stability programs

Equipment

- › Analytical ultracentrifuge (AUC)
- › Differential scanning calorimetry (DSC)
- › Differential scanning fluorescence (DSF)
- › Isothermal titration calorimetry (ITC)
- › Electrophoresis

- › Fractionation and asymmetric flow field-flow fractionation (FFF)
- › Static (multi-angle) and dynamic light scattering (MALS and DLS)
- › Size-exclusion chromatography (SEC)
- › Isoelectric focusing (IEF)
- › Electrospray mass spectrometry (LC-MS and nano LC-MS)
- › Capillary electrophoresis mass spectrometry (CE-MS)
- › Gas chromatography mass spectrometry (GC-MS)
- › Matrix-assisted laser desorption and ionization mass spectrometry (MALDI-MS)
- › Liquid chromatography multiple reaction monitoring (LC-MRM)
- › Nuclear magnetic resonance (NMR) spectrometers: 500, 600, and 800 MHz
- › Circular dichroism (CD) spectroscopy
- › Electron Microscopy (EM)
- › Automated liquid handlers

Helping SMEs characterize their products

The NRC is successfully partnering with innovative Canadian biotechnology company Zymeworks to validate their *in silico* algorithms for designing bi-specific antibodies capable of binding two different therapeutic targets. NRC's characterization expertise supported Zymeworks as they secured strategic partnerships with multinational pharmaceutical companies Merck, Eli Lilly, Celgene, and GSK.



CONTACT

Susan Twine

Section Head, Analytics
Tel.: 613-949-7545
Susan.Twine@nrc-cnrc.gc.ca

Donald Paquette

Team Leader, Biophysical Assays and Characterization
Tel.: 514-496-6317
Donald.Paquette@cnrc-nrc.gc.ca

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