

PHARMA CORE

Translational Nanomedicines
Pharmacology / Toxicology &
Scale-up Manufacturing

FAST FACTS

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PharmaCore

is funded by the
Nanomedicines
Innovation Network
(NMIN)

NMIN

is a Networks for
Centres of
Excellence funded
by the Government
of Canada

NMIN

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NMIN
NANOMEDICINES INNOVATION NETWORK
RESEAU D'INNOVATION NANOMÉDECINES

MISSION:

To provide support for NMIN investigators and research partners to facilitate the preclinical and clinical development of novel nanomedicines through: formulation development; characterization; biological activity in cell models and animal models; as well as manufacturing designed to meet regulatory requirements to advance new therapeutics from bench to clinic

ADVANTAGES:

- Expertise in nanomedicines formulation, pre-clinical development, scale-up manufacturing, and commercialization
- Performed by Highly Qualified Personnel (HQP)
- Quality management oversight with standard operating procedures
- Services provided at arm's length
- Project management support for budgeting, grant applications, manuscripts
- Successful completion of more than 125 batches in GMP-compliant clean room facility since 1995
- Accredited by Standards Council of Canada for GLP studies (audits performed every 2 years)
- Compliant in CCAC, OECD, Health Canada and FDA requirements

SERVICES:

Pharmacology & Toxicology CORE SERVICES

- **In Vitro**—tissue culture and assay support (e.g. IN CELL®, INCUCYTE®, western blotting, FACs, cytotoxicity etc.)
- **In Vivo**—non-GLP preclinical (e.g. dose range finding and identification of maximum tolerable dose, pharmacokinetic/ pharmacodynamic, biodistribution, etc.)
- **In Vivo**—model development, efficacy studies (oncology xenograft, syngeneic, PDX, orthotopic or other), In Vivo Imaging (IVIS-fluorescence/bioluminescence), radiation (SARRP, Xr-ay, cesium)
- **In Vivo**—cGLP safety pharmacology (acute and sub-chronic dosing), biodistribution studies
- **Project Management**—e.g. quotes and budgeting for research funding or other applications

Manufacturing & Quality Management CORE SERVICES

- **Formulation**—lipid-based, emulsions etc. (extrusion, microfluidics etc.)
- **Analytical**—development of validated assays (UV/Vis spectrophotometry, UPLC with UV, ELSD & Fluorescence detectors, NICOMP, ZetaPal etc.)
- Sterilization/depyrogenation of equipment and packaging of materials
- **Kit Assembly**
- **Scale up**—batch record, non-GMP bench batch
- **cGMP**—(facility cleaning and environmental monitoring, batch record, aseptic fill -up to 10L*, product inspection and labeling (i.e. fill/finish), supported by 850 sq ft. clean room and additional archiving room) *depends on vial size
- **Stability**—varying temp and time
- **Quality management**—standard operating procedures, inspections, archiving, etc.