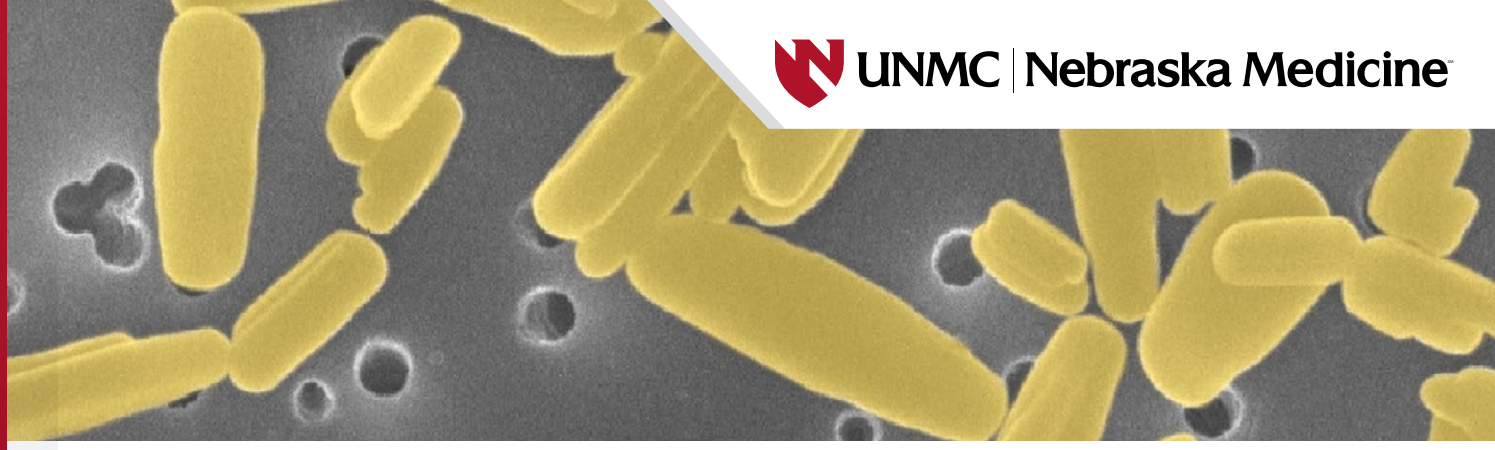

UNMC | Nebraska Medicine

Opening in 2018

Nebraska Nanomedicine Production Plant

The NNPP provides contract development and manufacturing services to academic laboratories, small start-ups, small/medium-sized enterprises, and large pharmaceutical companies for FDA compliant batch scale up of candidate nanoformulations to support investigational new drug applications, clinical trials, and subsequent technology transfer for large scale manufacturing.

Pre-Production Facility

- Resource for optimizing the production, purification, lyophilization, and characterization of nanoformulations using GLP guidelines.
- Development and implementation of scale-up production for preclinical toxicology and Phase 1 studies.
- A clean and regulated space for nanoformulation preparation.

GMP Facility

- Housed in the Lied Transplant Center, which provides regulatory product oversight including controlled facility access points, temperature-controlled reagent storage, and automated management systems.
- Clean room suite capable of achieving Class 10,000 to Class 100 (ISO 7-5) air quality used for scale-up under careful oversight following FDA-compliant cGMP production.
- Provides environmental safeguards, quality management, and security to transition from small-scale research to Phase I clinical trials.

The Nebraska Nanomedicine Production Plant provides a unique resource for Nebraska to transition nanomedicines from preclinical screening to human clinical trials.

"The abilities to enable discoveries to move efficiently from the laboratory to the patient bedside is integral to our academic health center's mission. We applaud all those who have worked tirelessly to see the dream of a nanomedicine production plant come to a highly functional reality. Terrific opportunities are ahead in using this facility to transform the health care of the future her in Nebraska and around the world."

Jeffrey P. Gold, M.D., Chancellor, University of Nebraska Medical Center

MANAGEMENT TEAM

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Operations Manager

JoEllyn McMillan, Ph.D.
Senior Advisor

Lara Slack
Quality Consultant

Howard E. Gendelman, M.D.
Chief Operating Officer

ADVISORY BOARD

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Senior Licensing Specialist, UNeMed

NNPP Services

- Provide internal contract manufacturing for different types of nanoformulations.
- Create FDA-compliant pilot-scale GMP production of nanoformulations.
- Improve access of medicines to underserved populations including those in resource-limited settings.
- Act as an external contract manufacturing resource for companies in need of a GMP production facility. One-stop-shop for basic research, an operative pre-production facility, and a GMP facility that will take a pre-clinical product and see it through to clinical grade materials for Phase I testing.
- Provide expertize not found in large pharmaceutical companies or in most GMP facilities.

Contact Information

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