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**European Medicines Agency—News and Events** 

Link to Site

Food and Drug Administration—News and Events

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## AABM Individual Membership

AABM offers individual membership!

If you are not associated with a Facility, you can still join as an individual member at

http://www.aabmonline.org/users/register

## **Get Involved!**

The AABM is calling for members to contribute facility SOPs!

Please email SOPs to aabm@aabmonline.org.

You can also visit this link to view our growing SOP Library

Log on to the Library

## **FEATURED FACILITY**

Molecular and Cellular Therapeutics (MCT) Facility
University of Minnesota

The Molecular and Cellular Therapeutics (MCT) Facility is a GMP facility located on the Saint Paul campus of the University of Minnesota. Constructed in 1992, this 36,000 sq foot facility supports manufacturing of biotherapeutic products for use in phase I and II clinical trials of advanced cell-tissue-, and gene-based therapies by translating research methodologies into clinical applications.

MCT's overall design and architectural systems meet regulatory requirements and provide the flexibility to manufacture a variety of products (Figure 1 and 2). A total of 11,000 square feet of dedicated ISO Class 7 and ISO Class 5 areas are available for development and production. Products manufactured within the facility include hematopoietic stem cells, immunotherapies such as natural killer cells, T-regulatory cells, mesenchymal stem cells, and various tumor vaccines, as well as pancreatic islet cells, targeted toxins and small molecule production.

An independent Quality Assurance department oversees all production. MCT's core competencies including:



- Quality and Compliance
- Operations/Materials Management
- Control of Critical Systems
- Program Budgets/Forecasts/Cost Accounting
- Project Management
- Equipment Management
- Document Change Control
- Process Development, Qualification, Validation







Scientific/ Medical Director David McKenna, M.D

