## ASGCT Scientific Symposium

## Gene and Cell Therapy Clinical Trials: Manufacturing Challenges for the Next Horizons

Jointly planned by the AABM

Chair: John Fraser Wright, Ph.D. Center for Cellular & Molecular Therapeutics Children's Hospital of Philadelphia

May 19, 2012 • 3:15 PM - 5:15 PM

Room: 201 AB

15<sup>th</sup> Annual ASGCT meeting Philadelphia, PA May 16-19 2012

See us at Booth 406!

New SOPs Added This Month Management o

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Management of Radioactive Materials Sterile Techniques Quality System AABM NEWSLETTER MARCH 2012

## A Warm Welcome to our New Member

MD Anderson Cancer Center SCTCT GMP Facility

Director: Elizabeth J. Shpall, M.D.

Thank You

o our

members for sharing SOPs.

To contribute please email <a href="mailto:aabm@aabmonline.org">aabm@aabmonline.org</a>



Facility Director Isabelle Rivière, Ph.D

## FEATURED FACILITY

The Gene Transfer and Somatic Cell Engineering Facility (GTF) supports investigators who are conducting early-stage clinical trials that require biological materials for immunotherapies, vaccines, and stem-cell-based therapies. The facility investigates new strategies for cell engineering and gene transfer, including vector development, methods for the genetic modification of hematopoietic

cells (currently T lymphocytes, dendritic cells, CD34+ cells) and artificial antigen presenting cells, as well as new strategies for vaccines against cancer. We also manufacture vectors for clinical gene transfer studies and we carry out the expansion and genetic modification of patient cells. We have now established a number of platforms that allow for 1- the production of clinical grade master cell banks and gamma-retroviral vector stocks 2- the production of clinical grade plasmid DNA 3- the genetic modification and expansion of autologous or allogeneic T lymphocytes and CD34+ hematopoietic cells using semi-closed systems and bioreactors.

The facility occupies 1200 sq. feet and consists of 1) a vector production cubicle 2) two cubicles devoted to the expansion and transduction of patient cells 3) a plasmid DNA production cleanroom 4) Support facilities. The air meets class 100,000 throughout the facility and is exchanged in excess of 15 times per hour. The facility is designed to meet all manufacturing standards required by the FDA to ensure patient safety.

Gene Transfer and Somatic Cell Engineering Facility (GTF)

Memorial Sloan Kettering Cancer Center (MSKCC)



