

WELCOME!

Innovative Cellular Therapies and Methods at GMP Cell Therapy Facilities

May 5-6, 2008

Introduction & Welcoming Remarks

The EMMES Corporation



**National Heart Lung
and Blood Institute**

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**Production Assistance for Cellular Therapies
National Heart Lung and Blood Program**

Workshop Participating Centers



University of Pittsburgh Cancer Institute



CAGT - Baylor College of Medicine



MCT - University of Minnesota



Production Assistance for Cellular Therapies
National Heart Lung and Blood Program

PACT MISSION

Committed to the Advancement of Effective Cellular Therapies

Offer scale-up capability and expertise in the translational development needed to produce cell therapy products under cGMP and cGTP regulations for use in clinical trials.

PACT MISSION

-EDUCATION-

Promoting interest in cellular therapy

Training support for investigators to develop knowledge and experience with regulatory requirements

- ↳ Educational Web Seminars
- ↳ On-site Workshops
 - ↳ Didactic and interactive training materials
 - ↳ Cell therapy facility tours
- ↳ Cell Therapy Book

Educational Web Seminars

February 2008

Cryopreservation of Cell Therapy Products

October 2007

Preparing for an FDA Inspection

July 2007

Interpreting AABB & FACT Cellular Therapy Standards-FACT

Adverse Event Reporting for 351 Products

February 2007

Adverse Event Reporting in IND Studies

October 2006

Cell Therapy Data Management

Facility Master Files

SOP Development

July 2006

Development & Operation of a QA System for Deviations from SOPs in a Clinical Cell Therapy Laboratory

January 2006

Managing Multiple Specimens in a Cell Processing Facility

Rapid Release Testing

Packaging and Shipping of Human Cell Tissue Products

July 2005

Biological Product Deviation Reporting

Chemistry, Manufacturing, and Controls Writing for Investigational New Drug Applications

Staff Training & Competency Training

March 2005

Facility Cleaning and Disinfection

Cell Processing: Validation and Performance Qualification

Equipment Qualification

For more information visit www.pactgroup.net

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Production Assistance for Cellular Therapies
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Previous On-site Workshops

- ↳ **Design and Operation of GMP Cell Therapy Facilities**

April 11-12, 2007

University of Minnesota

Molecular and Cellular Therapeutics

Earle Browne Continuing Education and Conference Center

- ↳ **Design and Operation of GMP Cell Therapy Facilities**

April 4-5, 2006

Baylor College of Medicine

Houston, Texas

For more information visit www.pactgroup.net

PACT WEBSITE: www.pactgroup.net



Production Assistance for Cellular Therapies
National Heart Lung and Blood Program

A Production Assistance for Cell Therapies (PACT) sponsored*
Innovative Cellular Therapies and Methods at GMP Cell Therapy Facilities
Two-Day Workshop

Monday and Tuesday, May 5-6, 2008

Hosted by the University of Pittsburgh Cancer Institute
Pittsburgh, PA

Registration is now open!
Limited space. To register and for workshop details visit www.pactgroup.net

*Travel and hotel accommodation costs not included



AABB will offer CME for this program



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PACT is accepting r

Click the image above or [here](http://www.pactgroup.net) to learn more or register for the upcoming PACT workshop in Pittsburgh, PA.



Applications



Education



Resources

Sign up for updates on future web seminars and workshops
at info@pactgroup.net

WORKSHOP OBJECTIVES

To develop a fundamental understanding of how Good Manufacturing Practice operates in a cell therapy facility

To provide a clinical as well as a practical understanding of various innovative cell therapies

To learn valuable laboratory skills and techniques through observation

CME Accreditation Statement

AABB is an approved, accredited provider (Provider number 0000381) by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. AABB designates this education activity for a maximum of **8.5 category 1 credits** toward the AMA Physicians Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.



CME Credit

If you are interested in obtaining CME credit for attending this web seminar, please note that each attendee must:

- ↳ Sign the roster
- ↳ Complete the survey



AABB Live Learning Center

After the rosters have been processed, you will receive an email from AABB with instructions on how to print your CME/CE certificates.



Advancing Transfusion and
Cellular Therapies Worldwide



Production Assistance for Cellular Therapies
National Heart Lung and Blood Program

Let's Get Started!

