


***WELCOME!***

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



**April 10-11, 2007**

**Introduction & Welcoming Remarks**

**Debbie Wood**

**The EMMES Corporation**



National Heart  
Lung and Blood  
Institute



# Workshop Participating Centers



MCT - University of Minnesota



CAGT - Baylor College of Medicine



University of Pittsburgh Cancer Institute



MAYO CLINIC



# ***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



[Department of Health and Human Services](#) ■ [National Institutes of Health](#)



National **Heart Lung and Blood** Institute

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## *Production Assistance for Cellular Therapies*



Production Assistance for Cellular Therapy



Production Assistance for Cellular Therapies

*Committed to the Advancement of Effective Cellular Therapies*

The PACT Group provides education, leadership and production assistance to the cell therapy community through contract manufacturing of therapeutic cell products.

*Make your clinical funds go further, leave the manufacturing to us.*

PACT is an NHLBI-funded contract manufacturing program aimed at helping investigators develop novel somatic cell therapy products.

### PLEASE NOTE:

Application Review Dates:  
April 2, 2007  
May 7, 2007

[Call For Applications](#) 

### Education Sessions

**Sign up** to receive information about upcoming web seminars and other general updates.

### PACT Workshop

April 10-11, 2007  
University of Minnesota  
St. Paul, Minnesota

Design and Operation of GMP Cell Therapy Facilities

Sign up for updates on future web seminars and workshops at [info@pactgroup.net](mailto:info@pactgroup.net)

# ***WORKSHOP OBJECTIVES***

**Provide you with approaches to maintain GMP Compliance and Quality Assurance in the manufacture of cell therapy products**

**Prepare you to establish and document a system of GMP controls required to manufacture cell therapy products**

**Introduce you to the concepts and requirements necessary for compliance with Good Manufacturing Practice (GMP) for cell therapy facilities**

# ***DAY 1 AGENDA - Morning***

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- ↻ Facility Design
- ↻ Facility Cleaning & Monitoring
- ↻ Supplies and Reagents
- ↻ Staff training



# ***DAY 1 AGENDA - Afternoon***



- ↻ Documentation and Batch Records
- ↻ CMC Writing
- ↻ Product Development
- ↻ Tour of UMN GMP Facility





# ***DAY 2 AGENDA - Morning***



- ↳ Cryopreservation
- ↳ Data Management
  - ↳ Deviations & Processing
- ↳ Lot Release
- ↳ IND - Cell Therapy



# ***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 7.5 category 1 credits toward the AMA Physicians Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.



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# ***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***

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



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***Let's Get Started!***

