



# GMP Report

**Facilities Working Group**

**March 9, 2009**

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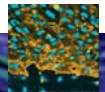
**CIRM CSO**

Thursday, March 12, 2009



# GMP

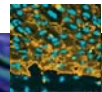
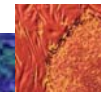
- GMP is standard operating procedure for cell therapies that are expanded/manipulated before clinical transplantation
- -Blood banks have similar but distinct SOPs
- -Precise recommendations for GMP related to pluripotent stem cells have not been published by FDA
- -Workshop timing: Scientific maturity and impending stem cell IND applications from Disease Team awards



# Contributing Background



- Literature searches and site visits
- Workshop: November 2008
  - Contract GMP facilities
  - Biotechnology experts in GMP
  - Academic experts in GMP
  - CIRM Science Office
  - Regulatory experts
  - PACT (NIH consortium) participants
- Summary report from D. Weber (BDG)

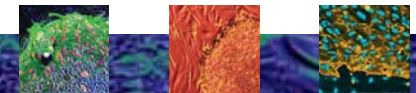


# Major workshop insights



## 1. Industry needs trained technical staff for GMP facilities

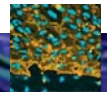
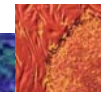
- CIRM can respond by focusing a Bridges program on GMP
- Currently researching best educational programs in this area and precise industry needs in anticipation of RFA next year



# Major workshop insights



2. Significant commercial expertise in expansion of adult stem cells, with several major contract organizations in California
  - Progenitor, Lonza, Cognate among largest
  - 2/3 have California GMP and are looking for business
  - Several other manufacturers identified after the workshop

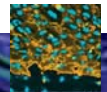
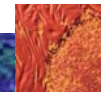


# Major workshop insights



## 3. CIRM Grantees would benefit from a California-based PACT program

- NIH consortium of 4 University-based GMP facilities
  - Major effort in developing SOPs
  - Intellectual infrastructure gives support to investigators developing new cell therapies
  - NIH will expand program to 5
  - Survey of eligible programs in California identified City of Hope GMP as the only qualified program ready to apply
  - CIRM is working to facilitate a relationship between our investigators and a CA-based PACT



# Major workshop insights



## 4. Optimization of GMP should be ongoing part of our research portfolio

- Basic biology: Derivation under GMP conditions
- Early translation: Optimizing media, reducing costs, SOPs for safe scale-up of cell products
- Disease Teams: Teams expected to capture expertise to develop GMP-compliant cell products
- Training programs

