Association of Academic Biologics Manufacturers

NEWSLETTER AUGUST 2012

New SOPs This Month

A big thank you to our members who contributed the following SOPs:

Visitors Policy

Incoming Equipment – Receiving, Inspection and Documentation

Transfer of Materials Into and Out of The Classified Areas

Laboratory Notebook Maintenance

Incoming Materials –Receiving, Inspection and Documentation

Log on to the Library

AABM Individual Membership

AABM now 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 new members to join the Communications Committee!

Contact aabm@aabmonline.org to find out how your talent will be put to use.

FEATURED FACILITY

Facility Director
Gerhard Bauer

UC Davis Good Manufacturing Practice Laboratory
UC Davis Institute for

The GMP facility at the University of California Davis Institute for Regenerative Cures which opened in March of 2010 is a multi-use, 6 manufacturing suite, Class 10,000 laminar air flow clean room facility for the manufacturing of clinically applicable biologics under cGMP.

All 6 manufacturing rooms are independent of each other, applying one way personnel, product and waste flow. The manufacturing, entry and exit areas are separated by air pressure gradients, two manufacturing rooms feature validated switchable room pressurization to create pressure sinks for gene therapy vector manufacturing or for FACS sorting. The fully validated environment is electronically controlled and automatically monitored, with additional 7 day per week manual monitoring. A strict QC/QA program with environmental cleaning and monitoring procedures has been implemented. Additionally, a CLIA licensed GMP facility Quality Control laboratory performs all tests needed for QC of the facility and products manufactured.

Sign up for the AABM Newsletter at http://aabmonline.org/users/newsletter