



University of Connecticut Health Center

POLICY NUMBER 2005-12

May 15, 2005

**POLICY: MANUFACTURING OF DRUGS, DEVICES, AND BIOLOGICS
 USED IN HUMAN RESEARCH**

PURPOSE:

To ensure that the manufacturing of drugs, devices, or biologics for use in human subject experimentation and/or clinical care is conducted in compliance with U.S. Food and Drug Administration Good Manufacturing Practices (21CFR210) regulations.

POLICY STATEMENT:

1. It is the policy of the University of Connecticut Health Center that all manufacturing of investigational test articles be done in compliance with Good Manufacturing Practices (GMP) regulations, as established by the U.S. Food and Drug Administration.
2. For products manufactured outside of the University of Connecticut Health Center, the principal investigator must obtain from the manufacturer written assurance of compliance with GMP. Such assurance must be provided to the Institutional Review Board upon request.
3. For products manufactured at the University of Connecticut Health Center:
 - a) those involved in the manufacturing process must be trained in GMP or receive direct supervision from someone who has been trained in GMP.
 - b) evidence of recent (within the prior 36 months) GMP training certification must be provided to the Associate Vice President for Research Administration.
 - c) the Associate Vice President for Research Administration will retain an independent consultant with expertise in GMP compliance, at least tri-annually, to audit the manufacturing process, and certify compliance with GMP.
 - d) the results of the GMP compliance audits, and any corrective action , will be provided to the Principal Investigator, Executive Vice President for Health Affairs, Associate Dean for Research Planning and Coordination, Associate Vice President for Research Administration, Director of Research Compliance, Director of the Human Subjects Protection Office and the IRB Chairs.
 - e) the Health Center's Authorized Institutional Official has the authority to suspend or terminate a study using the manufactured article, based on the audit findings and follow-up. In such an

event, the Director of the Human Subjects Protection Office will be responsible for reporting such findings to all institutional officials and external agencies.

- f) the investigator must demonstrate to the Associate Vice President for Research Administration that funds will be available for required training and compliance.

Leonard P. Paplauskas

5/5/05

Associate Vice President for Research Administration

Date

Richard D. Berlin, MD

6/1/05

Associate Dean for Research/Planning & Coordination

Date

Peter Deckers, MD

6/3/05

Executive Vice President for Health Affairs

Date

Replaces: NEW POLICY