

Institutional Handbook of Operating Procedures	
Policy 11.2.2	
Section: Research	Responsible Vice President: Executive Vice President and Provost
Subject 11.2: Nonclinical	Responsible Entity: Regulated Studies

I. Title

cGMP Manufacturing & Testing – Nonclinical

II. Policy

The Office of Regulated Nonclinical Studies (ORNcS) will exclude and deny any submitted applications that include cGMP manufacturing at the University of Texas Medical Branch at Galveston (UTMB) facilities.

Studies regarding cGMP development of methods, procedures, characterization, and application may be approved by ORNcS with the understanding that the manufacturing will go to a licensed and ORNcS approved cGMP manufacturing off-site location.

Site Survey of all CGMP off-site manufacturing and testing will be completed under the direction of ORNcS. A letter documenting approval will be provided to the Principal Investigator of the study.

Violation of this policy will result in disciplinary action by the University of Texas Medical Branch up to and including termination of Study Director, Principle Investigator, Department Personnel and any and all other personnel associated with responsibility for the said study; a termination of employment relationship in the case of contractors or consultants; or suspension or expulsion in the case of a student employee. Additionally, individuals may be subject to loss of access privileges and civil and/or criminal prosecution.

III. Definitions

Current Good Manufacturing Practice (CGMP): The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. (Title 21, Food and Drug Administration.)

IV. Related UTMB Policies and Procedures

21 CFR Part 210/211, Drug Good Manufacturing Practice.
IHOP 11.02.01 Institutional Office of Regulated Nonclinical Studies

V. Dates Approved or Amended

<i>Originated:</i> 10/06/2011	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
	6/22/2016

VI. Contact Information
Research Services
(409) 266-9400