*BME 695 Engineering Nanomedical Systems*
*November 10, 2011*


# Lecture 16: FDA and EPA Regulatory Issues

16.1 Introduction and overview
- 16.1.1 How does the FDA think about nanomedical systems?
- 16.1.2 The 2006 Nanotechnology Task Force

16.2 Some details of the Nanotechnology Task Force Report
- 16.2.1 General findings of the report
- 16.2.2 Some initial recommendations of the Task Force
- 16.2.3 Where the FDA may need to meet EPA on nanoscale materials
- 16.2.4 Will FDA re-visit GRAS products containing nanomaterials?

16.3 How will the FDA consider nanomedical systems?
- 16.3.1 Nanomedical systems are integrated nanoscale drug and drug delivery devices
- 16.3.2 Either a drug or a device? How about a "Combination Product"?
- 16.3.3 Drug-Biologic combination products

16.4 Types of human clinical trials
- 16.4.1 IND
- 16.4.2 “Phase 0”
- 16.4.3 Phase 1
- 16.4.4 Phase 2
- 16.4.5 Phase 3
- 16.4.6 Phase 4

16.5 EPA and other regulatory agency issues
- 16.5.1 Assessing environmental impact of emerging nanotechnologies
- 16.5.2 Concept of life cycle assessment (LCA)
- 16.5.3 Toxicity of nanomaterials
- 16.5.4 Some recommendations of the 2006 International Conference on Nanotechnology and Life Cycle Assessment

16.6 Nanotechnologies and the workplace
- 16.6.1 NIOSH – Formulating workplace safety standards for nanotechnology
- 16.6.2 Protecting workers in the workplace
- 16.6.3 Assessing hazards in the workplace
- 16.6.4 Establishing a Nanotechnology Safety System

16.7 The future of nano-healthcare products

# References

1. Nanotechnology A Report of the U.S. Food and Drug Administration Nanotechnology Task Force July 25, 2007 at http://www.fda.gov/nanotechnology/taskforce/report2007.pdf

2. Environmental impact of nanotechnology documents: Life Cycle Assessments - http://www.nanotechproject.org/111/32007-life-cycle-assessment-essential-to-nanotech-commercial-development

3. NIOSH workplace documents: http://www.cdc.gov/niosh/docs/2007-123/pdfs/2007-123.pdf

4. Nano Healthcare Products assessment: The Freedonia Group, Inc http://www.freedoniagroup.com

5. Chinese FDA http://eng.sfda.gov.cn/WS03/CL0755/