BME 695 Engineering Nanomedical Systems
November 8, 2011

Lecture 15: GMP and issues of quality control manufacture of nanodelivery systems

15.1 Overview
- 15.1.1 What does cGMP mean?
- 15.1.2 Why GMP? Controlling processes means more predictable outcomes…
- 15.1.3 Enforcement
- 15.1.4 What can be learned from the semi-conductor industry clean-room and manufacturing?
- 15.1.5 What doesn't fit this paradigm?

15.2 cGMP-level manufacturing
- 15.2.1 Predictable methods lead to predictable products
- 15.2.2 The CFR (Code of Federal Regulations) sections on GMPs
- 15.2.3 What is covered under cGMP?

15.3 Bionanomanufacturing
- 15.3.1 So what is special about biomanufacturing?
- 15.3.2 Nano-clean water necessary for nano-pharmaceuticals
- 15.3.3 Contaminants at the nano-level
- 15.3.4 Can you scale up the process?

15.4 Some quality control issues – how to test
- 15.4.1 Correctness of size – size matters!
- 15.4.2 Composition – atomic level analyses
- 15.4.3 Monodispersity versus agglomeration
- 15.4.4 Order and correctness of layers2
- 15.4.5 Correctness of zeta potentials
- 15.4.6 Does the nanomedical system contain the correct payload?
- 15.4.7 Targeting (and mis-targeting) specificity and sensitivity

References

CFR (Code of Federal Regulations) sections on GMPs.
http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200421
Go into the "Browse Parts" column and select Parts 200-299. The GMP sections are 210 and 211.