

**Lecture 20: GMP and issues of quality control manufacture
of nanodelivery systems**

I. Overview

- A. What does cGMP mean?
- B. Why GMP? Controlling processes means more predictable outcomes...
- C. Enforcement
- D. What can be learned from the semi-conductor industry clean-room and manufacturing?
- E. What doesn't fit this paradigm?

II. cGMP-level manufacturing

- A. Predictable methods lead to predictable products
- B. the CFR (Code of Federal Regulations) sections on GMPs
- C. What is covered under cGMP?

III. Bionanomanufacturing

- A. So what is special about biomanufacturing?
- B. Nano-clean water necessary for nano-pharmaceuticals
- C. Contaminants at the nano-level
- D. Can you scale up the process?

IV. Some quality control issues – how to test

- A. Correctness of size – size matters!
- B. Composition – atomic level analyses
- C. Monodispersity versus agglomeration
- D. Order and correctness of layers
- E. Correctness of zeta potentials
- F. Does the nanomedical system contain the correct payload?
- G. 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.