

**Stony Brook University**  
**Corporate Education  
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*The Center for Biotechnology Presents:*

## ***Good Manufacturing Practices for BioExecutives***

This course offers biopharmaceutical executives/managers an opportunity to understand the regulatory framework that is required to provide strategic leadership when designing and implementing a quality driven cGMP system.

FDA's new guidance entitled Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations indicates that management has the ultimate responsibility to provide the leadership needed for successful functioning of a company's quality driven CGMP system. The guidance outlines five specific management duties:

- Provide leadership
- Review the system
- Structure the system
- Build the quality system to meet product requirements
- Establish policies, objectives and plans

Who Should Attend: Biotechnology managers and executives who want to learn what their responsibilities and roles are when creating and operating a cGMP compliant manufacturing program.

**To register:** [www.biotech.sunysb.edu/educWork/BioExecutivesCourse.html](http://www.biotech.sunysb.edu/educWork/BioExecutivesCourse.html)

For more information call the Center for Biotechnology at 631-632-8521.

Course is held at:  
**Stony Brook University**  
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