which are updated regularly. If students become involved in biomanufacturing for pharmaceuticals, they will need to consult these sources. However, certain key concepts do not change. These concepts are written documentation, consistency of procedures, consistency of product, and demonstrable measures of product quality, particularly purity and safety. These tasks are demanding and require careful attention to detail. Bioprocess engineers will often find that much of their effort will be to satisfy these regulatory requirements.

The key point is that process changes cannot be made without considering their considerable regulatory impact.

SUGGESTIONS FOR FURTHER READING

A. History of Penicillin

ELDER, A. L., ed., *The History of Penicillin Production*, Chem. Eng. Prog. Symp. Ser. *66* (#100), American Institute of Chemical Engineers, New York, 1970.

HOBBY, G. L., *Penicillin. Meeting the Challenge*, Yale University Press, New Haven, CT, 1985.

MOBERG, C. L., Penicillin's Forgotten Man: Norman Heatley, *Science* 253: 734–735, 1991.

MATELES, R. I., ed., *Penicillin: A Paradigm for Biotechnology*, Candida Corp., Chicago, IL, 1998. (This contains the work by Elder which is no longer in print plus two additional chapters on current pratice.)

SHEEHAN, J. C., *The Enchanted Ring. The Untold Story of Penicillin*, MIT Press, Cambridge, MA, 1982.

B. Regulatory Issues

DURFOR, C. N., AND SCRIBNER, C. L., An FDA perspective of manufacturing changes for products in human use, *Ann. NY Acad. Sci.* 665:356–363, 1992.

NAGLAK, T. J., KEITH, M. G. AND OMSTEAD, D. R., Validation of fermentation processes, *Biopharm* (July/Aug.):28–36, 1994.

REISMAN, H. B., Problems in scale-up of biotechnology production processes, *Crit. Rev. Biotechnol. 13*:195–253, 1993.

PROBLEMS

1.1. What is GMP and how does it relate to the regulatory process for pharmaceuticals?

1.2. When the FDA approves a process, it requires *validation* of the process. Explain what validation means in the FDA context.

1.3. Why does the FDA approve the process and product together?