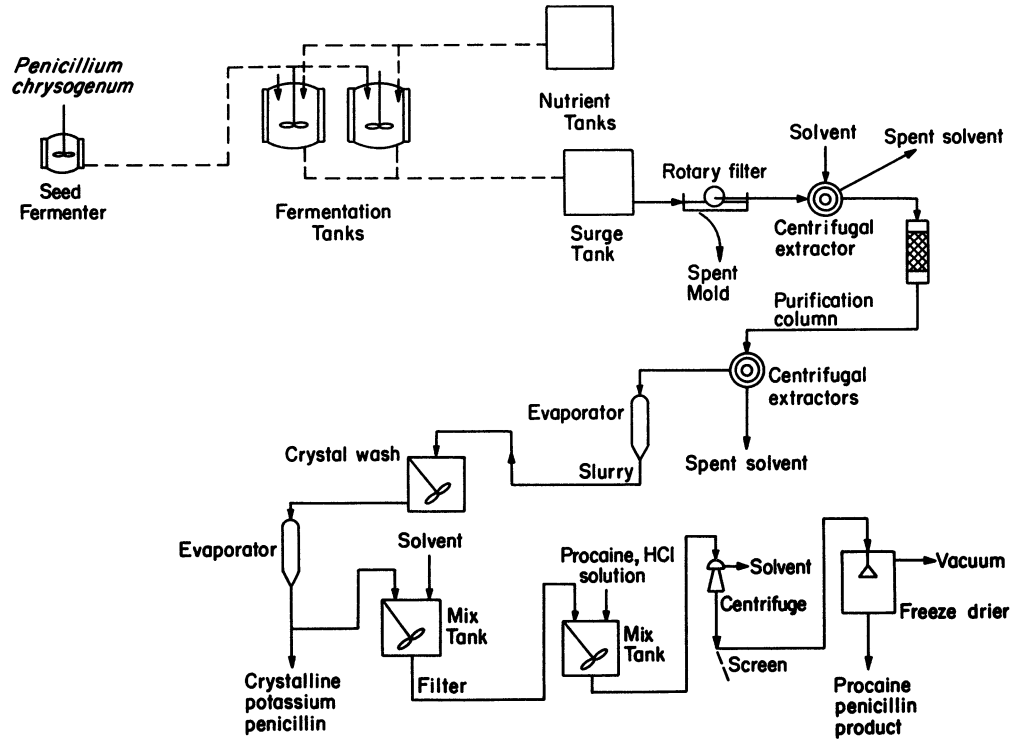

Figure 1.3. Schematic of penicillin production process.

Before the penicillin process, almost no chemical engineers sought specialized training in the life sciences. With the advent of modern antibiotics, the concept of a bioprocess engineer was born. The penicillin process also established a paradigm for bioprocess development and biochemical engineering. This paradigm still guides much of our profession's thinking. The mind set of bioprocess engineers was cast with the penicillin experience. It is for this reason that we have focused on the penicillin story, rather than on an example for production of a protein from a genetically engineered organism. Although many parallels can be made between the penicillin process and our efforts to use recombinant DNA, no similar paradigm has yet emerged from our experience with genetically engineered cells. We must continually reexamine the prejudices the field has inherited from the penicillin experience.

It is you, the student, who will best be able to challenge these prejudices.

1.5. BIOPROCESSES: REGULATORY CONSTRAINTS

To understand the mind set of a bioprocess engineer you must understand the regulatory climate in which many bioprocess engineers work. The U.S. FDA (Food and Drug Administration) and its equivalents in other countries must insure the safety and efficacy of