

### **34d Mixing Scale-up for Pharmaceutical and Biological Processes**

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Mixing scale-up should begin with the first laboratory test, because waiting until after the last experiment may be too late. A key part of any series of laboratory experiments should be tests to observe the effects of mixing on the process. Knowing what to look for in the laboratory will help with later scale-up, even if the observations are only a matter of keeping complete records. Often a failure caused by poor mixing can be an important element in the scale-up process. Scale-up to avoid a failure condition can provide criteria for good results. Small mistakes are better than big ones. Small-scale tests for mixing do have some limitations. Poor mixing characteristics in typical laboratory apparatus and less than turbulent conditions cause problems for typical scale-up rules. Mixing is important, but it has many different characteristics that must be observed to be understood. Complicated pharmaceutical and biological processes make proper mixing scale-up even more important to the success of a large-scale process.