composition, mixing times, shear rates, pH). The variables that are chosen for inclusion in the study should be those that have the most dramatic effects upon the critical product characteristics. Likewise, variables that are unlikely to affect final product characteristics, or variables that are constrained because of equipment or procedural limitations, should be held constant throughout the trials. Finally, the terms *response* and *level* should be discussed. As stated earlier, each trial will result in a finished formulation possessing a set of properties. The resultant characteristic properties of this formulation are called the *responses*. The variable levels and corresponding responses are combined by use of an appropriate regression analysis to empirically derive a function. For two variables and one response, an easily visualized three-dimensional response surface results when this function is plotted. As the number of variables or responses increase, a multidimensional response surface will result that cannot be easily visualized. However, any three-dimensional "slice" of the multidimensional surface can be plotted. For each variable, a range of values exist that could be tested. In this section, the *level* of the variable will refer to the value of a variable selected for a particular trial. If the variable range is viewd in terms of highest, middle, and lowest values, then the phrases *level of the variable* and *variables at three levels* can be understood. Similarly, one might be required to evaluate 10 levels of an excipient between 10 and 20 wt% in a formulation. In summary, an experiment is a carefully designed set of trials in which variable levels have been selected. Each response can then be empirically modeled to provide a response surface. The optimum value of the response surface is located, and the corresponding variable values are obtained, thus providing an *optimized* formulation (i.e., optimized critical product characteristics).

The quality of an optimized formulation is only as good as the design of the experiment used for optimization. The techniques to be described minimize the number of trials in a manner to maximize the amount of information obtained by setting up a statistically valid experimental design. These techniques require that the response surface is smooth and continuous and, thus, for disperse systems in which a phase boundary might be crossed, it is necessary to have established the phase behavior as detailed earlier. Because the application of statistical methods for optimization of disperse dosage forms (e.g., suspension, emulsions) has recently been reviewed by Franz and co-workers (3), these topics will be only briefly described to serve as an introduction to the reader who is unfamiliar with experimental design, modeling, and optimization strategies.