

Absent this commitment, it is likely that a stability program will be regarded simply as a burdensome, nonproductive expense. If such an attitude pervades top or middle management—although such attitudes are rarely expressed directly in writing but rather transmitted by a nod and a wink—it is quite possible that the stability testing group will be starved of essential equipment and personnel. One sometimes visits companies where stability testing is two or three months, or even more, behind schedule. Top managers say they cannot understand how the problem has developed since, as everyone in the company knows, their personal dedication to product quality is second only to their commitment to God, the flag, and the family. Unfortunately, such individuals sometimes “talk big but spend little.”

6.2. Firm Grasp of Underlying Scientific Theory

It should hardly need to be stated that stability testing of pharmaceuticals requires in-depth education in the science of pharmaceutical formulation, evaluation, analysis, and statistics. Unfortunately, there still are companies where personnel with such education are lacking.

6.3. Up-to-Date Knowledge of All Relevant Policies of Regulatory Agencies and Applicable Pharmacopoeial Standards

Official regulations and standard test methods continue to evolve. Thus it is important that at least one person in every company be charged with the responsibility of keeping up-to-date files on data from the FDA, the USP, or such other entities as may be relevant that impinge on any aspect of the design, execution, or interpretation of stability tests. Perusal of *Pharmacopoeial Forum (PF)*, the journal in which the USP provides trailer-type information about possible new or modified test methods or monographs, should be mandatory in all companies for which USP standards may be of relevance.

6.4. Effective Communication Between R&D, Production, QC/QA, Complaints, and Regulatory Affairs

In order to have a successful stability testing program, it is important that there be clear, effective, and rapid communication between all the various organizational entities in a company that can provide useful input into the stability program.

6.5. A General Understanding of the Limitations of the Analytical Methods Used in the Stability Testing Program

Everyone with any degree of responsibility for decisions about a stability program—not just those performing the tests in the laboratory—should have a general understanding of the parameters that characterize the test methods used in stability testing (accuracy, precision, sensitivity, reproducibility, transferability, etc.). We do not require that everyone be expert at say HPLC (high-performance liquid chromatography) or ELISA (enzyme-linked immunosorbent assay), but we should expect that the decision makers be aware of the salient characteristics of the test methods, the results of which are used in decisions about stability.