6.6. Careful Monitoring of the Stability Budget

It is surprising that some companies have no stability budget. It is even more surprising to find that there are scientists designing stability protocols who select test method A instead of test method B (both of which might be technically satisfactory but of significantly different cost), who have knowledge of or interest in the relative costs of the two tests.

It is not easy to devise a mechanism for evaluating a stability budget such that we can be quite certain that we have accounted for all monies spent on the program. However, even though the budget that we estimate may be relative, rather than absolute, it still can be of substantial value.

6.7. Managerial Skills to Coordinate and Optimize the Program

The capstone of a high-quality cost-effective stability program must be managerial skills that nurture and coordinate the personal and professional skills of all involved with the program.

7. CONFORMANCE PERIODS, SHELF LIVES, AND EXPIRATION DATES

The conformance period of drug product is defined by the most vulnerable time-dependent quality attribute. As has already been indicated in Sec. 2.1 of this chapter, loss of potency is, for many products, the critical parameter. In those cases where some other attribute is more vulnerable, it will be that property that defines the conformance period. The same general approach as that shown in Fig. 1 should be followed; however, instead of plotting potency as a percentage of label claim on the y-axis, one plots the appropriate critical stability parameter. The conformance period is then determined from the intersection of the lowest (or highest) acceptable value of the parameter and the 95% confidence bound of the regression line. In the rather rare event that there are two stability attributes of about the same criticality, then both should be quantified and the lower conformance period used as the basis for the assignment of the shelf life of the product.

As has been previously indicated, the shelf life assigned to a product is equal to, or less than, the conformance and is usually a convenient round number (e.g., 7 days, 1 month, 1 year, 18 months, or 2, 3, or 5 years).

The expiration (or expiry) date placed on the label of any given batch indicates the date at which the shelf life ends for the batch. Thus if the product is stored in accordance with label instructions, it is expected that the product will retain fitness for use up to that date. With the exception of products that have very short shelf lives, it is conventional in many parts of the world to give only the month and year of the expiration date. It is expected that for such dates, e.g., May '03, the product should remain of acceptable quality until the *end* of the stated month.

When products have a 5-year shelf life, the practice of only giving expiration dates for the months of January or July seems to be becoming more common. This practice simplifies stock control, since there are fewer dates to deal with. This approach is used as follows: Suppose we have a product that has a five-year shelf life, and we manufacture batches of the product in February, April, June, August, and November of 2002. The first three batches would be dated January '07; the last two would be dated July '07.