to fully understand the software to develop and execute an appropriate validation protocol. Stability software supplied by vendors is usually accompanied by a validation package for on-site execution. Regardless of whether validation is conducted by internal or external validation specialists, the QA Department's approval will be required before use of the software. To facilitate the approval process, QA personnel will require computer software validation training, whether provided by vendors or through various computer validation seminars, to develop the necessary expertise to assess the validation report before sign-off.

21 CFR Part 11

21 CFR Part 11 (commonly referred to as "Part 11") states the regulatory requirements for electronic records and electronic signatures. In the regulation, electronic records are defined as records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted electronically. The regulations also define electronic signatures that can be used instead of manual signatures and require complex controls to assure the security and integrity of electronic signatures. By definition, all stability software and stability data maintained and processed by the software are electronic records. In many companies, manual signatures may still be employed, which will obviate the need to adhere to the additional and complex requirements for electronic signatures. To clarify the requirements for complying with Part 11, the FDA initially published a guidance that was subsequently withdrawn because of objections from the industry. To facilitate the process of compliance for electronic records and electronic signatures, the FDA developed a simpler guidance which was published in August 2003 [29]. It is important for stability testing laboratories to understand and utilize the guidance for compliance with Part 11.

VALUE OF STABILITY

Long-term stability studies assure, on an ongoing basis, that the products continue to conform to quality control specifications and thus maintain their safety and efficacy requirements throughout their shelf-lives. The studies consistently build up a long-term track record of stability data. Stable results continue to demonstrate that raw materials, manufacturing processes, packaging components, and packaging processes have all been in a state of control and have resulted in stable products until at least their expiration periods. The ongoing stability studies also serve as an invaluable tool in the quality-control system to detect any unexpected spikes in the test result(s) during the shelf-life of a product and allow for implementation of corrective actions after investigating and ascertaining the root causes of the problem.

COST OF STABILITY

Annual stability studies assure that production processes continue to be in a state of control to produce stable drug products. Regulations require that, for each marketed product, one lot produced per year must be set up on long-term stability studies for at least the duration of the expiration period of the product. Thus, for a given number of