the facility's CGMP status. Examples of typical issues that may delay FDA approval of applications and adversely affect acceptable CGMP status are as follows:

- Inadequate resolution of impurities and degradants from the main peak in the HPLC analysis
- Inability to detect and accurately quantify small impurities in the 0.1% range
- Unsatisfactory investigations of out of specification (OOS) stability data
- Failure to follow stability testing procedures submitted in the application
- Inadequate method validation
- Inadequacy of the SOPs for stability testing
- Omission of testing time points
- Missing temperature and humidity charts for the stability chambers
- Lack of periodic calibration of the chambers

Documentation

21 CFR Part 211.180, which contains regulations on general requirements for records and reports, requires that all records must be retained for at least 1 year after the expiration date of the batch. The regulations require that all records must be readily available for FDA inspections during the retention period at the establishment where the activities described in such records occurred. It is important to interpret this regulation correctly for retention of stability data. It is essential that the original accelerated and long-term stability data in support of the shelf-life of a product are maintained indefinitely because such data provided the foundation for the established expiration date assigned to all lots of the product. For a product, the particular lot introduced into the ongoing annual stability testing program also represents the continued validity of the expiration dates assigned to all lots of the product manufactured in that year. Therefore, annual stability data for a given year should be retained for at least 1 year past the expiration date of the last lot manufactured in that year. Complete records must be maintained of all stability testing performed as required by 21 CFR Part 211.194(e).

Training

21 CFR Part 211.25 on personnel qualifications is also applicable to personnel engaged in stability testing. The regulation requires that each person shall have education, training, and experience, or an appropriate combination thereof, to enable that person to perform the assigned functions. In addition to hiring personnel with the necessary academic background and skills, it is important to certify the newly hired personnel in the analytical procedures employed by the company. The certification process should be formalized in an SOP and should be based on having the new employee and an experienced person conduct the same critical tests, such as assay, impurities, and dissolution on selected lots of the product. The results obtained by the new and experienced employees should be compared. If the new employee's results are unsatisfactory, the certification process should be repeated until satisfactory results are