Validation should extend to those operations determined to be critical to the quality and purity of the API.

Before initiating process validation activities, appropriate qualification of critical equipment and ancillary systems should be completed. Qualification is usually carried out by conducting the following activities, individually or combined:

- *Design qualification*: Documented verification that the proposed design of the facilities, equipment, or systems is suitable for the intended purpose
- *Installation qualification*: Documented verification that the equipment or systems, as installed or modified, comply with the approved design, the manufacturer's recommendations, and/or user requirements
- *Operational qualification*: Documented verification that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges
- *Performance qualification*: Documented verification that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications

WEB REFERENCES

1. http://www.fda.gov/cder/OPS/PAT.htm
2. http://www.automsoft.com/products/solutionsforpat.asp
3. http://www.sas.com/
4. http://www.thermometric.se
5. http://www.brukeroptics.com/terahertz/

RECOMMENDED READING

Allen, L. V., Jr. (2008). "Dosage form design and development." *Clin Ther* 30(11):2102–2111.

BACKGROUND: Drugs must be properly formulated for administration to patients, regardless of age. Pediatric patients provide some additional challenges to the formulator in terms of compliance and therapeutic efficacy. Due to the lack of sufficient drug products for the pediatric population, the pharmaceutical industry and compounding pharmacies must develop and provide appropriate medications designed for children. OBJECTIVE: The purpose of this article was to review the physical, chemical, and biological characteristics of drug substances and pharmaceutical ingredients to be used in preparing a drug product. In addition, stability, appearance, palatability, flavoring, sweetening, coloring, preservation, packaging, and storage are discussed. METHODS: Information for the current article was gathered from a literature review; from presentations at professional and technical meetings; and from lectures, books, and publications of the author, as well as from his professional experience. Professional society meetings and standards-setting bodies were also used as a resource. RESULTS: The proper design and formulation of a dosage form requires consideration of the physical, chemical, and biological characteristics of all of the