The second edition was published in 1992 and the latest edition was published in 2008. The 2008 edition was divided into two parts: Part I for medicinal products for human and veterinary use and Part II for active substances used as starting materials.

During the 15 years of the FDA and industry debating on the final wording of the GMP regulations, the industry had fought vigorously for the GMP regulations not to be substantive; rather allowing the industry to have freedom to interpret and apply the regulations. Once GMPs became official in 1978 and FDA inspections began to enforce their compliance, the industry found that more help was required to better understand how the FDA was interpreting the regulations. Thus, guidance documents began to be issued, giving the industry more specific information on FDA expectations, especially in areas of validation and documentation (Table 25-1 contains a partial list of FDA Guidance documents). Guidance documents are not legally binding, but the basic attitude of the FDA is that if the industry chooses not to follow the guidance documents, it needs to justify why not.

GMPs are enforced in the United States by the FDA, under Section 501(B) of the 1938 Food, Drug, and Cosmetic Act (21USC351). GMPs are legally considered industry standards such that

Table 25-1 Examples of Relevant FDA Guidance Documents for GMP Compliance

- Guidance for the submission of documentation for sterilization process validation in applications for human and veterinary drug products
- Guidance for industry: sterile drug products produced by aseptic processing—current good manufacturing practice
- Guideline for validation of Limulus Amebocyte Lysate Test as an end product endotoxin test for human and animal parenteral drugs, biological products, and medical devices
- Compliance program guidance manual 7356.002 A, sterile drug process inspections
- Guide to inspections of lyophilization of parenterals
- Guide to inspections of high purity water systems
- Guide to inspections of microbiological pharmaceutical quality control laboratories
- Guide to inspections of sterile drug substance manufacturers
- Draft guidance for industry on process validation: general principles and practices—11/18/2008
- Draft guidance for industry: submission of documentation in applications for parametric release of human and veterinary drug products terminally sterilized by moist heat processes—8/5/2008
- International Conference on Harmonisation (ICH); guidance for industry: Q3 A impurities in new drug substances—6/5/2008
- Guidance for industry: container and closure system integrity testing in lieu of sterility testing as a component of the stability protocol for sterile products—2/22/2008
- International Conference on Harmonisation (ICH); draft guidance: Q10 pharmaceutical quality system—7/12/2007
- Guidance for industry: quality systems approach to pharmaceutical CGMP regulations—9/29/2006
- International Conference on Harmonisation (ICH); guidance for industry: Q9 quality risk management—6/1/2006
- International Conference on Harmonisation: (ICH); guideline for industry: Q2 A text on validation of analytical procedures—3/1995
- International Conference on Harmonisation (ICH); guidance for industry: Q2B validation of analytical procedures: methodology—5/19/1997
- International Conference on Harmonisation (ICH); guidance for industry: Q5E comparability of biotechnological/biological products subject to changes in their manufacturing process—6/29/2005
- Guidance for industry: nonclinical studies for the safety evaluation of pharmaceutical excipients—5/18/2005
- International Conference on Harmonisation (ICH); guidance for industry: Q1E evaluation of stability data—6/7/2004
- International Conference on Harmonisation (ICH); guidance for industry: Q1 A(R2) stability testing of new drug substances and products—11/20/2003
- International Conference on Harmonisation (ICH); guidance for industry; Q1D bracketing and matrixing designs for stability testing of new drug substances and products—1/15/2003
- Guidance for industry: container closure systems for packaging human drugs and biologics; questions and answers—5/13/2002

Check http://www.fda.gov/cber/guidelines.htm for latest versions.