TABLE OF CONTENTS

**Compliance Program Guidance Manual: Drug Manufacturing Inspections** .................................. Section 1
FDA manual explains how inspectors apply the systems-based inspection techniques, including overview of six quality systems to be reviewed.

**Analytical Procedures and Methods Validation** ................................................................. Section 2
FDA draft guidance on chemistry, manufacturing and controls documentation for drugs subject to Type II drug master files (as well as in NDAs, ANDAs, BLAs and PLAs).

**Drug Product Chemistry, Manufacturing and Controls Information** .................................. Section 3
Guidance provides recommendations on the chemistry, manufacturing and controls (CMC) information for drug products submitted in original new drug applications (NDAs) and abbreviated new drug applications (ANDAs).

**Bioanalytical Method Validation** .......................................................................................... Section 4
This guidance provides assistance to sponsors of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs) and supplements.

**Comparability Protocols — Chemistry, Manufacturing and Controls Information** .......... Section 5
Guidance provides recommendations on preparing and using comparability protocols for postapproval changes in chemistry, manufacturing and controls (CMC).

**Postapproval Changes — Analytical Testing Laboratory Sites** ............................................ Section 6
FDA guidance advises on changing an analytical testing lab for components, containers, closures, packaging materials, in-process materials or drug products.

**Formal Dispute Resolution: Appeals Above the Division Level** ......................................... Section 7
FDA guidance on resolving scientific or procedural disputes with staff of the Drug Center or the Biologies Center, including materials to provide FDA to aid in the resolution.

**BACPAC1: Intermediates in Drug Substance Synthesis** ..................................................... Section 8
Guidance on postapproval changes to the site of manufacture, scale of manufacture, equipment, specifications and/or manufacturing process of intermediates to drug substances.

**Part 11 Electronic Records; Electronic Signatures** .......................................................... Section 9
Guidance narrowing the FDA's interpretation of the scope of Part 11, defining Part 11 records and revising the FDA's approach to specific Part 11 requirements.

**Good Manufacturing Practices Guidance for Active Pharmaceutical Ingredients** .......... Section 10
FDA guidance explaining how to create an appropriate quality system for active pharmaceutical ingredients (APIs) used in manufacturing drugs, including responsibilities of the quality unit.
Powder Blends and Finished Dosage Units — Stratified In-Process Dosage Unit Sampling and Assessment

The guidance assists manufacturers of human drug products in meeting the requirements of 21 CFR 211.110 for demonstrating the adequacy of mixing to ensure uniformity of in-process powder blends and finished dosage units.

Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice

The guidance describes procedures and practices that will enable a sterile drug manufacturing facility to meet cGMP requirements relating to facility design, equipment suitability, process validation and quality control.

Bioavailability and Bioequivalence Studies for Orally Administered Drug Products — General Considerations

This guidance provides recommendations regarding the study design and development of dissolution methods; comparisons of measures, definition of proportionality and waivers for bioequivalence studies.

Drug Master Files for Bulk Antibiotic Drug Substances

The guidance explains the purpose of DMFs, discusses the type of information expedited in Type II DMF, outlines administrative procedures governing review of DMFs and clarifies responsibilities as a DMF holder.

PAT — A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance

The scientific, risk-based framework outlined in this guidance assists manufacturers in developing and implementing new efficient tools for use during pharmaceutical development, manufacturing and quality assurance.