

Systems-Based Approach to Laboratory Compliance with the Current Good Manufacturing Practice (CGMP) Regulations

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1 INTRODUCTION

In January 2001 the FDA issued the document Compliance Program Guidance Manual (CPGM) 7356.002 titled “Drug Manufacturing Inspections (Pilot Program).” This manual provided guidance to FDA personnel for conducting inspections of pharmaceutical manufacturing sites in an efficient and structured fashion (1). The objective of this manual was to implement a quality systems-based approach to enforcing 21 CFR parts 210 and 211, the Current Good Manufacturing Practice (CGMP) regulations (2). In February 2002 the FDA formally adopted this guidance