7 Quality Control and Quality Assurance

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INTRODUCTION

In August 1989, the U.S. Food and Drug Administration (FDA) made it clear to members of the generic drug industry that many aspects of current good manufacturing practices (cGMPs) apply to the product development process. The unfortunate problems uncovered at that time led agency investigators to request, for the first time, records showing how formulations were developed. Disappointingly, many firms had little documentation related to product development activities.

In the past, the process of formulation development has often had an almost mystical quality. We have seen a formulator listen to the sound of a listed reference tablet breaking, watch its behavior in 5 mL water, close his eyes, commune with the laws of the universe, and then write down a formulation and manufacturing process. At times, he was so confident that the firm proceeded to produce the abbreviated new drug application (ANDA) batch directly thereafter. Such ex nihilo batches passed the FDA bioequivalence requirements more frequently than one would expect.

Unfortunately, the product development process described in the previous paragraph does not lend itself to acceptable record-keeping. In today's regulatory environment, this form of development has become essentially obsolete. Sponsors are well aware that their developmental records are subject to extensive scrutiny during preapproval inspections (PAIs). Given that satisfactory completion of a