

产品感兴趣, 所以使成交率大为提高。而对那些以美国为主要销售市场的制药企业来讲, 未能通过 FDA 的现场检查, 其后果有时可能是致命的。请参阅本书第九章第三节中美国制药企业 (Able) 在没有通过 FDA 的现场检查后而导致企业倒闭的案例。

结束语

本章通过介绍 FDA 进行 CGMP 现场检查的目的和范围详细的论述了制药企业中六个重要业务部门的职能和责任。对 FDA 进行 CGMP 现场检查的重点部门——质量部门进行了全面的讨论, 并列举实例说明制药厂家必须遵守 CGMP 和建立有效的管理制度才能确保产品的质量。

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