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《药品不良反应报告和监测管理办法》下药品生产企业不良反应监测工作模式探讨

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中文摘要:目的:探讨药品生产企业在《药品不良反应报告和监测管理办法》(新《办法》)下顺利开展ADR监测工作的模式。 方法:通过对新《办法》解读、现状及制约因素分析,探索生产企业ADR监测工作开展模式。 结果与结论:生产企业在短期内一步到位完全按照新《办法》要求开展ADR监测工作与现状跨度较大,可以通过一"平台"四"拓展"的模式,分块逐步突破,开展ADR监测工作,最终完全达到新《办法》的要求,履行主体地位的责任和使命。

中文关键词:药品不良反应 生产企业 工作模式

Discussion on adverse reactions monitoring modes of drug manufacturers under new measures for administration of adverse drug reaction report and monitoring

Abstract:Objective: To discuss the modes for smooth progress of ADR monitoring under the new Measures for the Administration of Adverse Drug Reaction Report and Monitoring.**Method:** Work modes for ADR monitoring in drug manufacturers were explored by explaining the new Measures and analyzing current state and constrains. Result and Conclusion:As there is a larger gap between the requirements of new Measures and current status, it is difficult for drug manufacturers to meet all the requirements in short term. Therefore, drug manufacturers are suggested to gradually complete ADR monitoring under the mode of one platform and four expansions, and thereby finally meeting the requirements of new Measures and fulfilling their duties and missions.

keywords:adverse drug reaction drug manufacturer work mode

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