

新医薬品国内臨床試験における GCP 遵守の方策
—医薬品医療機器総合機構の GCP 調査結果より—

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（受付：平成 20 年 3 月 13 日，受理：平成 20 年 5 月 13 日）

**Methods to Ensure GCP Compliance in Clinical Trials:
Findings Generated by GCP Audit of the Office of Conformity Audit of PMDA**

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Summary

The notification and findings of the GCP audit of approved new drugs in FY2001~2003 were previously reported. In this study, the notification and findings of the GCP audit of approved new drugs in FY2004~2006 were reviewed and compared with the previous results. As the Pharmaceuticals and Medical Devices Agency (PMDA) was established in FY2004, review reports on new drugs approved in FY2004-2006 showed that GCP audits were carried out in part by the Organization for Pharmaceutical Safety and Research and in part by PMDA. The number of GCP audits conducted by the PMDA is increasing, with the rate of audits performed by the PMDA on approved new drugs in FY2006 being 79.3%. This suggests that improvements in GCP notification are leading to a concomitant increase in GCP audits conducted by the PMDA. The review report revealed two types of finding: deviation and violation. The PMDA encourages both pharmaceutical companies and investigators to improve their rate of GCP compliance and to avoid violations. If the findings constitute a GCP violation, the PMDA requests action from the pharmaceutical company in question, such as the exclusion of the clinical data from the clinical data package of the common technical documents for new drug applications. GCP aims to ensure the protection of the human rights, safety and welfare of the trial subjects, as well as the scientific quality and conformity of the results. The methods outlined in the review report for the protection of human subjects and the integrity of the clinical data were discussed, in order to contribute to the improvement of clinical trials conducted in Japan.

* This is neither an official PMDA guidance nor a policy statement.

Key words

Good clinical practice, GCP, Clinical trial, GCP audit, New drug approval, Clinical trial environment