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"Start of Consulting Support for post-Production GVP Validation Methods for PV Systems with AI functions"

HiroPharmaConsulting® Co., Ltd. (Head Office: Osaka City, Osaka Prefecture, Representative Director: Hirotsugu Atsumaru) will start providing the AI-PV Consulting Service in CY2025/1Q for "PV with AI: Validation Method for Pharmacovigilance System for GVP."

This service is an AI-PV System Post-Go-Live Support Consulting Service for the additional application of GVP/CSV reliability Assurance and Validation Methods after the Production Operation of a PV System implemented with AI functions, whose application to PV: Pharmacovigilance business has been rapidly spreading recently.

There have been reports that PV Systems equipped with AI functions (AI, AI/ML, GenAI, LLMs, and ChatGPT, etc.) have improved the operational efficiency of Intake & Triage for individual adverse event cases. In such cases, "PV System How to guarantee and Re-Validate the reliability of AI functions (Validated Computerized System) after production operation?" has become a regulatory requirement issue for the GVP CSV domain.

Regarding GxP/CSV before production operation, it is possible to Validate PV Systems, including AI functions, by applying the conventional GAMP 5® Guide 2nd Edition V-Model or CSV Method conforming to GVP regulatory requirements such as FDA/EMA/MHRA/PMDA/NMPA/MFDS, etc.

However, in the "Machine Learning, Automatic version-up" phase of the PV System after Production Operation, the reliability assurance verified environment once Validated is dynamically and automatically updated with AI functions. In such a case, how do we verify and report to the Regulatory Authorities whether the validated function of individual case safety assessment in the PV field is still maintained? GVP PV CSV has become an Issue.

In the PV consulting service for PV Systems with AI functions announced this time, we will provide a consulting service for applying the Validation Method to PV Systems after production operation, using the "PV with AI: Validation Method of Pharmacovigilance System for GxP (Patent pending: Japanese Patent Application 2024-213393)" patent-pending from our company as the “Application PV CSV Method + CSV Documents Kit + Test Cases Template + Training Set”. In addition, we will provide information on the Regulatory Trends of the Regulatory Authorities (FDA, EMA, MHRA, PMDA PIC/S, etc.) for AI functions.

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