

"Launch of GVP validation consulting service for evaluation of PV System introduction with AI function"

[HiroPharmaConsulting® Co., Ltd.](#) (Head Office: Osaka City, Osaka Prefecture, Representative Director: Hirotsugu Atsumaru) will start the "GVP Validation Consulting Service for PV System Installation Evaluation with AI Functions" in March 2025.

This PV Service Supports GVP/CSV reliability assurance and Validation when conducting a "Feasibility Study (FS)" of PV Systems with AI functions, whose application in PV: Pharmacovigilance business Cost Reduction is rapidly spreading recently.

"Business efficiency improvement and Cost Reduction cases such as Individual Adverse Event Case Evaluation and literature Evaluation" by PV Systems with AI functions have been reported at Conferences and Seminars in Japan and overseas. In this case, "When considering the introduction of an AI PV System, how can we verify, validate, and guarantee the reliability of AI functions in production (before and after) and prepare a GVP CSV report?" has become a regulatory regulation requirement issue.

To solve the above Issues, our Company will provide a Consulting Service by applying the PV Validation Method "[\[Title of the Invention\] Validation system and method for proper standards equipped with AI function \(Patent Pending/Request for Examination: Japanese Patent Application 2024-213393\)](#)" for PV Systems with AI functions, "**Patent Pending**" announced in December 2024, to CSV at the time of implementation evaluation and at the time of implementation (before and after implementation).

For Pharma customers considering the introduction of PV Systems with AI functions in FY 2025, we will first hold the "AI PV GVP Validation Consulting Service Briefing Session" where they can rationally conduct and report "FS: Feasibility Study." If you would like to do so, please contact the following Contact points.

The following [\[PV services\]](#) are still available, so please let us know if you have any requirements or requests.

- 1) SAP ERP System (S4/HANA, Solution Meager, MDG) GxP CSV
- 2) Provision of consulting services to develop RFIs and RFPs for a single global safety system
- 3) Proposals to improve safety event case data entry and evaluation and agency reporting
- 4) Provision of safety regulatory information to regulatory authorities in Japan, USA, Europe and Asia
- 5) Provision of training sessions on ICH E2B (R2)/R3 guidelines
- 6) Support for user acceptance testing (UAT) script creation and execution

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Reference: HiroPharma Web [\[NEWS\]](#) and [\[Press Release 20241206\]](#), [\[Press Release 20250211 Japanese\]](#)