Hiro Pharma Consulting

provides specialized

consultation on

Pharmacovigilance &

Adverse Drug Reaction Safety System

from 1st July 2019.

ヒロファーマコンサルティング

HiroPharmaConsulting

ビジョンと戦略
Vision & Strategy

High Quality and Completely Validated

ヒロファーマコンサルティングは、2019年7月1日より「ファーマコヴィジランス（Pharmacovigilance）」、「有害事象安全性情報システム」に専門特化したコンサルテーションを提供いたします。

2019年からは、製薬企業のPV業務の効率化や、日本・北米・欧州・アジア（中国）でのグローバルな有害事象処理の統合化が重要な課題になってくると考えられます。このような製薬業界の変化に適応し競争力を維持するのをご支援してまいります。長年の経験からお客様のビジネスの成功を最優先することがいかに重要であるかを心得ています。

法令遵守、GVP対応だけではなく、ファーマコヴィジランス業務改革の戦略を専門コンサルタントと一緒に築きましょう。まずは、お問合せフォームかお電話で最初のご相談をご予約ください。

HiroPharmaConsulting provides specialized consultation on [Pharmacovigilance] and [Adverse Drug Reaction Safety System] from 1st July 2019.
From 2019, it will be important to streamline the PV business of pharmaceutical companies and integrate global adverse event processing (Global Single Case Database and Global Single Workflow process between Japan, US, Europe, also China/Asia)
We will adapt to these changes in the pharmaceutical industry and help maintain our competitiveness. From years of experience, we know how important it is to put your business success first
Build a strategy for pharmacovigilance business innovation as well as compliance and GVP with a professional consultant.
Please make a reservation first by Contact Form and/or Telephone.

コンサルティングサービスメニュー
Consulting Services Menu

1 Providing consulting services for drafting RFI and RFP for Global Single Safety System
2. Proposal for improvement of Safety Case Entry and Evaluation processing and Authority Reporting.
3. Providing information on Safety Regulations in Japan, the US, Europe, and Asia in Health Authority (PMDA, FDA, EMA, MHRA and CFDA/CDE/NMPA: National Medical Products Administration)
4. Provision of Training Session for the ICH E2B(R2)/(R3) Guidelines
5. Support for UAT (User Acceptance Test) Script and Execution
6. Pharmacovigilance System quick Q&A
7. Support for the PMDA EDI/GW Connectivity Test (when updated DCs: Digital Certificates)

プロフィール Profile

ヒロファーマコンサルティング :ファーマコヴィジランス コンサルタント

Contact information:
Office: Hiro Pharma Consulting, Osaka-city, Osaka, Japan 532-0012
HIROTSUGU ATSUMARU <hiro_atsumaru@hiropharmaconsulting.com>

Technical Skills:
● PMDA/EMA/FDA/CFDA (NMPA) Regulation (R2/R3) Compliant
● PV(Pharmacovigilance) Safety Application
● Pharmaceutical R&D Application ● Network Technology
● Oracle DBA ● EDI Service and Server ● Windows OS, Unix Solaris

Certifications:
Class-I Information Technology Engineer (Certified by METI/Japan)

集 弘就（あつまる ひろつぐ）

技術要素
Technical Background

Summary:

- 13 years' experience in Applying Major Global Pharmacovigilance System and Signal Detection and Risk Management System to Global and Japanese Pharmacutical companies and CRO users, planing marketing strateging in Japan, as part of the Global sales development of IT vendor.
- 30 years' experience in planning, consulting and operation information processing system, supporting Research and Development Division at Top-5 Japan Pharmaceutical and Top-2 Japan Pharmaceuical Company.
  - ○Extensive knowledge of computerization technology covering hardware, Software and Network.
- Track record in participating in Information System Sub-committee representing Top-5 Japan Pharmaceutical (in 2005) infrastructure group and contributing to the success of Top-3 and Top-5 Japan Pharma Company in 2005) merger project.

業務経験
Professional Experiences

Professional Experience:

PV System and Signal Detection Functional Work Experience in IT vendor

1. ICH/PMDA/EMA E2B(R2)/(R3) Compliance Support for the Major PV Japanese/ English System for Global and Japanese Pharmacutical Customer: 2017-2019
2. Technical Support for the China Authority (CFDA/CDE/NMPA) Global PV System (in Chinese): 2018
3. Japan Pharmaceutical Company Project (Major Signal Detection and Risk Management System): 2017-2018 : Project Manager
4. Japan Pharmaceutical Company Project (Major Global PV System in Japanese/ English): 2014-2019 : Validation Manager and SME (Solution Matter Expert)
5. Major Cloud base PV System Project (PV Case processing, Electronic Case Submission via EDI Server) : 2012-2015 for Japan-CRO, Japan/US/EU Pharma/Chemical companies : Project Manager and SME (Solution Matter Expert)
6. Global Mega Pharmaceutical Company Project (HQ:US and Japan Subsidiary), (Major PV System with EDI server): 2009-2011 : Project Manage and Validation Manager
7. Global Pharmaceutical Company Project (HQ: France and Japan Subsidiary), (Major PV System with EDI server): 2009 - 2010 : Project Manager and Validation Manager
8. Japan top-5 Pharmaceutical Company Project (Major PV System with EDI server): 2008-2009 : SME (Solution Matter Expert)
9. Global Pharmaceutical Company Project (HQ France and Japan Subsidiary) (Major PV System with EDI server with Data Migration): 2008 - 2010 : Project Manager and Validation Manager
10. Japan Top-5 Pharmaceutical Company Project (HQ: US/Major PV Systems and Japan Subsidiary) (Major PV System with EDI server with Data Migration) : 2007 - 2009 : Project Manager and Validation Manager

Contact

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