TransformPV

Vitrana

Implementation Success Story

Vitrana's **TransformPV**, the preferred solution for meeting **R3** requirements recently went live at biggest Pharma organization in the world. Despite the significant complexities the implementation went very smoothly and implementation was achieved within a timeframe of 10 months. In current scenario with a defined FDA Guidelines and no major updates expected, the **TransformPV** implementation can be managed through an accelerated approach and can be accomplished between 3-5 months based on the chosen validation methodology.

TransformPV is the only solution in the market to have successfully gone live with both Vaccine **R3** and Device **HL7** reporting.

Since the go-live there have been hundreds of successful submission to **FDA VAERS** and **eMDR**.

During the course of the project there were significant updates introduced in the guidance, but due to design of **TransformPV** platform there was minimal impact of these updates and we were to able turnaround with updated solution within weeks instead of months.

As we look back at this significant milestone, there are few critical success factors we would like to share for organizations who are planning or in process of implementing an **R3** capable solution:

Detailed requirements Assessment

- To Identify impact to company's system and processes
- How to manage new data in **R3** e.g. Amendment, EU Causality Assessment, Vaccine fields, nullflavors
- Manage organization specific customization
  Prepare the business for upcoming regulatory changes and **R3** framework
- Additional data needs and business process updates required
- Identify upstream/downstream implications

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Close coordination with regulatory agency

- Multiple discussions with **FDA** resulted in significant updates in **VAERS** regional guidance in July/Aug 2016 (the updates prevented one of top 5 pharma organization to roll back their **R3** solution)

Here's some interesting details from the last implementation:

- First solution to successfully go-live on Vaccine **R3** and **eMDR HL7** format
- Project completed in 10 months despite multiple updates to regional guidance
- Before the formal pilot with **FDA**, approx 200 **R3** and **HL7** were submitted to **FDA** as part of informal pilot
- Feedback from project team to **FDA** resulted in major updates to **VAERS** guidance
- Agency acknowledged the positive impact by the project on the final guidance

TransformPV platform allows organization to manage their **R3** compliance needs without significant investments and allows them to focus on more pressing needs. The platform is scalable to meet future requirements and comes with features like **R3** only viewer, **R2-R3** view for transmissions, Integration with **LDAP** and Documentum.

For more details about the solution please reach us at
contact@vitrana.com or www.vitrana.com/products/transformpv