Pharmacovigilance and process validation in the pharmaceutical industry

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Understanding pharmacovigilance

Medicinal products and medical devices must always be used responsibly, so product information is required to include all relevant details and be updated regularly. The question remains, however, how this information is collected and who ensures that it is up-to-date.

The answer is pharmacovigilance (PV), which involves experts who oversee patient safety, collecting information about the benefits and risks associated with treatment. The main goal of such activities is to, on the one hand, minimize the identified risks and simultaneously maximize the benefits of the treatment for the patient.

Pharmacovigilance systematically monitors whether all information (on the medication package or in the leaflet) is up-to-date, by evaluating scientific publications, patients' experiences, and adverse effects analyses.

Process validation in pharmaceutical manufacturing

Imagine having a process or a rule for manufacturing an item or a computer program to control something – the pharmaceutical industry uses validation for such purposes.

The Food and Drug Administration (FDA), the U.S. regulator of pharmaceutical manufacturing, defines validation as follows:
"Process validation is defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering a quality product. Process validation involves a series of activities taking place over the lifecycle of the product and process."

Considered from this perspective, validation can be understood as an evidence trial, referring to a process, activity, or system that provides a repeatable and consistent result.

The same process is used during the development of IT solutions for the pharmaceutical industry to ensure that the used computer systems meet the GxP requirements.

Therefore, all activities performed within such a system and their results are predictable and repeatable. Validation supports the creation and processing of documents related to the entire process of preparing extensions and additions to the IT system.

Why are validated IT solutions so important in the pharmaceutical industry? For instance, they can help a company to avoid unexpected financial losses or business risks, but most importantly, they can detect drug defects to prevent unfortunate adverse effects and avoid significant harm to potential drug consumers. CSV allows a pharmaceutical company to become more efficient in dealing with unexpected setbacks and can provide the following benefits:

Regulatory compliance (required documents can be shared with regulators)

Early detection of potential system defects

Simplification of how to provide regulators with evidence that the information system is working as expected

Support for pharmaceutical companies that consistently add new features, while all development activities must be closely tested and verified

Sii's end-to-end approach to project delivery

Sii is the largest and the fastest-growing technology consulting, digital transformation, BPO and engineering services vendor in Poland.

Our long-standing experience in cooperation with clients across multiple industry sectors enables us to propose a versatile and flexible approach to project delivery.

Sii's expertise covers the delivery of validated systems for the pharmaceutical industry, therefore we ensure full compliance with the relevant international regulations. The collaboration with Sii comprises all stages of project development, i.e. requirements elicitation, business analysis, solution development, testing, implementation, and validation as well as assuming full responsibility for system release.

Areas of project delivery covered by Sii include:

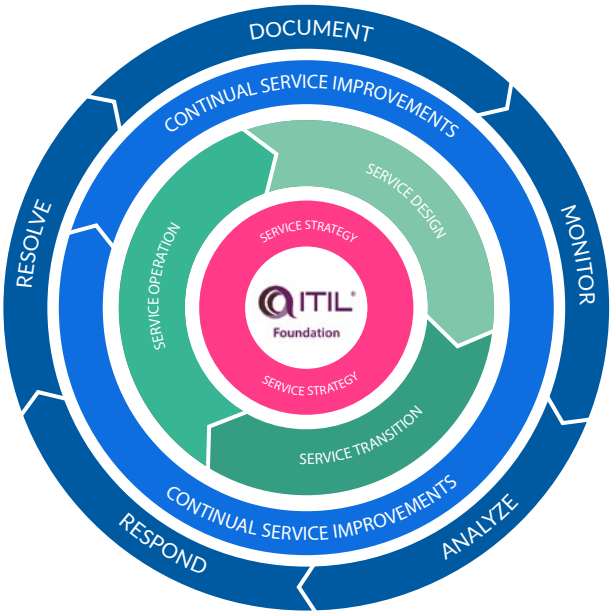
- Business and system analysis
- Consulting
- Design
- Specifications
- Software development
- System acceptance testing
- User acceptance testing
- Implementation
- Release management
- Training
- User manuals
- System integration

To provide high-quality delivery and operational service support mode, Sii relies on the expertise of a variety of subject-matter experts. The project teams include professionals having various competencies from a range of areas including, among others, software development, system analysis, testing, and IT support areas. Having expertise in delivering validated system changes, we can provide overall application lifecycle support according to Scrum & ITIL methodologies with the highest quality.

We assist our clients on various levels, ranging from incident management to problem and change management according to the highest standards and process definition, and the RACI matrix.

Examples of Sii's implementations include:

- Adverse Events Management Solution
- Signal Management Solution
- Analytics, Visualization, Supporting Solution



ITIL Service Strategy

Sii's support within the pharmacovigilance area

Literature search & review system

The system performs literature search and review activities that should be performed by the Marketing Authorization holder, required by the EU Pharmacovigilance Legislation, European Medicines Agency, and Food & Drug Administration.

Main goals of literature reviews:

- **Meeting pharmacovigilance requirements**
- **Providing academic information for development purposes**

Additionally, identifying adverse events helps to prioritize the review of publications.

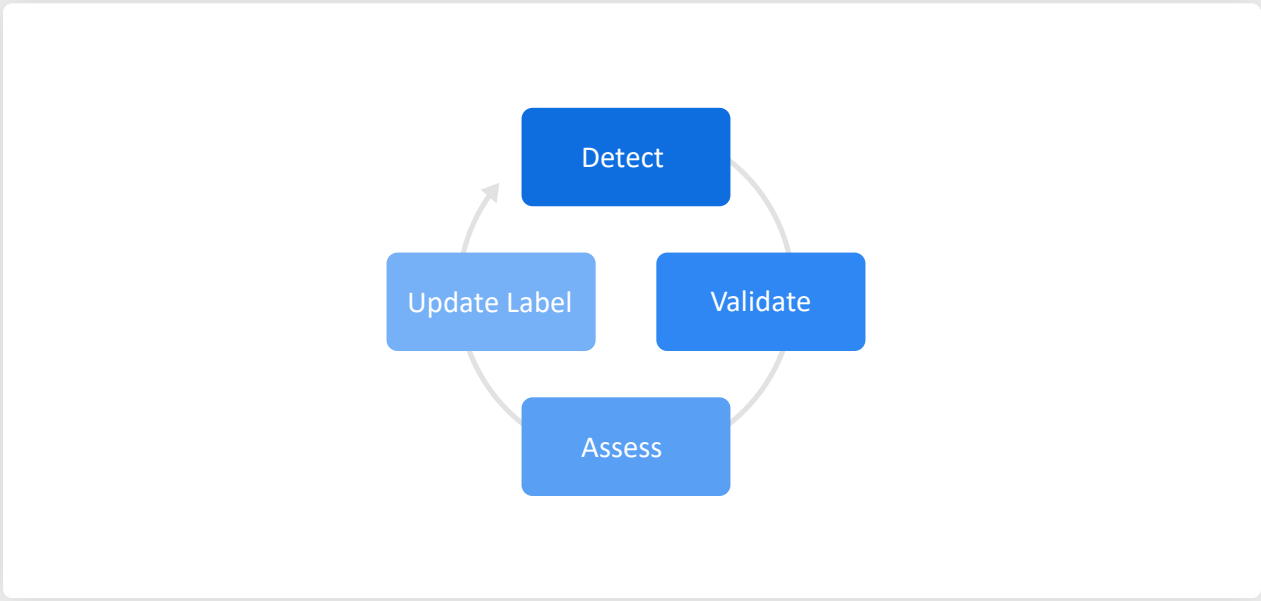
Data aggregation and consolidation system

The system fulfills the following business needs:

- **Delivering a reporting platform that can generate standardized business reports**
- **Providing standardized reports to Drug Safety, affiliates, and relevant business partners**
- **Facilitating calculation of KPIs and metrics to be used in reports**
- **Producing management oversight reports based on data from multiple sources**

Signal tracking system

The system aims at signal detection and management, from the time they are first identified until they are designated as adverse drug reactions and handled properly in safety labels, along with related drugs, risks, issues, and actions. It can serve as a golden source of data to support regulatory reporting such as ISMP Medication Error Reports or Periodic Benefit-Risk Evaluation Reports (PBRER).



Signal tracking workflow

Validated testing process based on risk assessment

A dedicated testing team is involved in the process from the very beginning of the release, right from requirements analysis, through planning, design, and test execution, until software testing summary reports. Every requirement that is added or changed is covered in the script documented in the Traceability Matrix.

We support all system changes with a validated testing process based on risk assessment.

Testing is performed entirely on validated environments, based on scripts previously approved by a Validation Team. About 90% of defects are found during exploratory and System Acceptance Testing (SAT), which reduces the number of discrepancies in the production environment. All the defects are tracked and handled in such tools as ALM and Jira, but other tools can be involved as well. The scope of each release is analyzed in terms of the need for testing automation (performed in Micro Focus UFT) or performance testing.

Major benefits of cooperation with Sii

- Scientific and domain expertise in PV processes to ensure regulatory compliance
- Increased product approval process and shorter time-to-market
- Effective risk identification and mitigation
- Expertise in adjusting various technologies & frameworks to specific business models
- Cost optimization due to integrated services delivered by proficient healthcare experts
- Complementary team of specialists available (incl. developers, testers, solution architects business analysts, etc.)
- Flexible scalability capabilities

Looking for support? Contact Sii!

Find out how you can benefit from our expertise in pharmacovigilance and discover Sii's one-stop-shop offer with solutions dedicated to the healthcare sector.

Contact us!

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