PHARMASOL
enabling excellence

WHITE PAPER

COMPLETE CONFIDENCE IN YOUR PV SYSTEM

RAPIDLIVE ARGUS – BEST PRACTICES ON DEMAND

EXECUTIVE OVERVIEW

LifeScience companies are challenged with a continuously changing and globally diverse regulatory landscape and with increasing pressure to deliver safe new products faster than ever before and at a competitive price. This pressure is reaching all departments including Regulatory and Pharmacovigilance, increasing the need to have systems available which support the latest regulations and allow efficient processing according to industry best practices. **rapidLIVE Argus is an end to end solution** to quickly deliver a Drug Safety system, standardized according to best practices and providing each function in the pharmacovigilance team with exactly what they need.

EXECUTIVE OVERVIEW

Why rapidLIVE?

In recent years pharmacovigilance has matured substantially and become much more integrated with other functions. This integration frequently comes with a higher complexity for the safety systems and processes which imapcts upon even small and medium sized business, as well as CROs.

In order to support companies of any size pharmasol has leveraged the experience from many implementations of different pharmacovigilance systems, and industry best practices, and developed rapidLIVE Argus. Based on the industry leading safety database Oracle Argus™, rapidLIVE Argus provides a complete, proven configuration and support across the complete project lifecycle to reduce the arduous task of implementing and maintaining the safety system. The result is a ready-to-use system.

While rapidLIVE Argus can be used for an on-premise installation, if it is combined with pharmasol's hosting and managed services offerings it delivers a complete ready-to-use experience. A safety database with the standard "Golden" configuration can be available and ready to use on demand.

The need:

Argus Safety offers many options that require configuration prior to implementation.

The solution:

pharmasol developed the Argus Safety rapidLIVE package, incorporating industry best practice to provide a ready-to-use Argus Safety application, including validation documentation.

The benefit:

Small and mid-sized companies in need of a safety solution can implement Argus Safety rapidLIVE immediately, saving time, money and effort.

"We continuously update our Argus rapidLIVE package to meet the challenges of a changing regulatory landscape."

Cheryl James
Director, Pharmacovigilance

WHAT IS RAPIDLIVE ARGUS?

rapidLIVE Argus is an accelerated implementation approach for a fast, validated deployment of an effective pharmacovigilance system. It provides all components in a comprehensive package, aligned with industry best practices.

At the heart of rapidLIVE Argus stands the workflow for the processing of safety data. The rapidLIVE Argus workflow includes Data Entry, Medical Review, and Reporting as its core elements which allow for proven, effective processing.

Aligned with the workflow rapidLIVE Argus provides secure access management for users through multiple roles. These roles allow different groups to perform separate tasks, but in small organizations individual users can also take on multiple roles.

Creation of narratives, one of the most time-consuming tasks in case processing, is automated in the rapidLIVE Argus environment and incorporates relevant information from the available case data. This auto-narrative not only considerably reduces the processing time for a case, but also frees up a medical reviewer to concentrate on the medical assessment of the case.

rapidLIVE Implementation and Validation

Validation is always an important consideration, and typically a major effort, in the implementation and maintenance of a safety database and other computerized systems. rapidLIVE Argus includes everything to minimize the effort on the customer side. It comes with a complete set of validation documentation which has successfully passed multiple inspections and audits for existing customers. Design and configuration documents as well as test scripts are ready for signature and execution.

Documented training is another important element when implementing a validated system. The rapidLIVE Argus training provides a complete set of training documents in line with the rapidLIVE configuration. Instructor-led classes and hands-on exercises provide a high level of understanding among the users and increased acceptance at go-live. The associated training records that we provide are part of the complete validated system.

Validation

Validation is a term which is used in different ways and needs to be differentiated from verification and qualification. Where the FDA considers software validation to be "confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled", in the ISO 9000 environment a distinction is made between verification and validation. Verification tests whether a product is manufactured according to specifications (which is roughly the second part of the above FDA clause). Validation according to ISO usually follows verification, and confirms, through objective means, whether users in a specific usage context can achieve the pre-defined target when using the product. This can be translated as follows:

- **Verification:** Are we building the product correctly?
- **Validation:** Are we building the right product for the intended use?

For a complete system validation, the user organization must provide evidence that approved documentation associated with the system to control its operation and ensure its maintenance is created, followed and regularly reviewed for appropriateness. This includes user, functional and design documents, standard operating procedures, training records as well as review and audit documentation.

WHAT IS RAPIDLIVE ARGUS?

Every business has its own ways of working. This is recognized by our team and rapidLIVE Argus therefore includes a consulting package to allow adjustments to be made to meet any specific needs that you may have. The highly experienced consultants will be able to make clear recommendations as to how to cater to specific requirements while considering the implemented industry best practices.

To run a validated system requires at least a validation environment in addition to the production environment. rapidLIVE Argus includes an additional development environment to allow for informal testing and confirmation of individual or new concepts before going through a formal change. All environments are rolled out on up to date software releases and pre-configured. They are also initially populated with validation seed data to kick-start validation and training tasks.

rapidLIVE Argus Delivery

rapidLIVE Argus can be delivered on premise, but due to a growing demand in recent years, it can also be fully deployed as either a dedicated hosted or SaaS offering to bring the effort of maintaining the system to an absolute minimum.

Whether to choose a hosted or a SaaS environment depends on the needs of the client organization.

The hosted delivery offers substantially more flexibility, as the environment is dedicated to each customer at the level of the application and the data.

In a SaaS environment, the application and hardware is shared across multiple customers, while the data is segregated. The result is delivery at minimal cost, but with limited modification allowed of the system configuration. The SaaS offering is usually ideal for small or young companies with low case volumes. A migration to the more flexible hosted offering is possible at any time.

For CROs rapidLIVE Argus provides a multi-tenant setup which allows comprehensive oversight over the client databases, with data segregation at the level of the sponsor to maintain full integrity.

Regardless of the delivery method used, rapidLIVE Argus includes the required Argus licenses tailored to your needs.

rapidLIVE Argus Support

For our hosted customers, technical support questions can be logged 24*7 in our web based ticketing system.

Ongoing, functional support, for both hosted and on-premise deployments, is also managed using this ticketing system, on a per pay use model.

The phase after go-live of a new system is always critical. Therefore, rapidLIVE Argus includes a 3-month phase of priority functional support to help customers during their initial usage phase.

Trust in rapidLIVE Argus

rapidLIVE Argus is a complete offering. It lets you decide on the level of ownership and control through the various delivery methods. pharmasol is a seasoned implementer and provider of hosting and SaaS offerings for the strictly regulated LifeSciences industry. *The data centers for these offerings are in Germany and the offering complies with all relevant regulations such as 21 CFR Part 11 or EU data privacy laws, but also with standards such as ISO 27001 for data security.*

FIND OUT MORE

If you are interested in further information or would like to arrange a demo, please contact:

Tim Billington
tim.billington@pharmasol.de
+44 (0)7768 336 302

Or visit our website where you can find further information about the product:

www.pharmasol.de/rapidlive

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ABOUT PHARMASOL

PHARMASOL IS A LEADING PROVIDER OF INNOVATIVE APPLICATIONS, GXP COMPLIANT HOSTING AND IMPLEMENTATION SERVICES TO THE LIFE SCIENCES INDUSTRY. WITH TOOLS TO AUTOMATE COMPLEX BUSINESS PROCESSES AND THE DEPLOYMENT OF APPLICATIONS IN A SECURE MANAGED DATA CENTRE, PHARMASOL IS TRUSTED BY LEADING PHARMACEUTICAL, MEDICAL DEVICE AND CONTRACT RESEARCH COMPANIES TO SUPPORT THEIR CORE BUSINESS PROCESSES AND ENSURE COMPLIANCE.

To learn more about us visit our website at:
www.pharmasol.de