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EMVS Community Newsletter

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Introduction:

Welcome to this special summer edition of the EMVS (European Medicines Verification System) Community Newsletter! For this special

issue, we have compiled some important updates from the EMVS and its Customer Groups. We hope you will enjoy the read!

If you have any comments or feedback, **reach out to us on communications@emvo-medicines.eu.**

The EMVS and its Customer Groups

Working on the EMVS together – Creating Visibility and Predictability

By Ricardo Valente, MVO Portugal & EU CCB Chair

From the early stages of the EMVS implementation, it became clear that an integrated way to govern the EMVS as a complete system, and not as the sum of its parts, was necessary. Based on the stakeholder model, EMVO and the NMVOs established the European Change Control Board (EU CCB) (as presented in our EMVS Community 2021 Holiday Bulletin).

Under the EU CCB, a set of change management processes have been created and are continuously being improved and refined. Changes to the EMVS are assessed individually and release planning has focused primarily on when the changes needed to be scheduled for deployment, with less focus on the coordination and alignment of the contents of these releases.

The need for more integrated planning and decision-making has become clearer over time. As the overall governance processes keep growing and maturing, the EMVS is now moving towards a more sophisticated way of joint planning and decision-making. To make that possible, the EU CCB has been developing and adopting the following planning tools:

- EMVS Long-Term Planning: a long-term view (up to 5 years ahead) enabling continuous planning in order to increase the visibility on the overall development of the EMVS, and to make financial and resource planning easier;
- EMVS Pipeline Management: a mid-term view, capturing the changes that require alignment amongst the system owners, as the impact of these changes spans across more than one system. Based

on this, a set of common priorities can be defined, enabling the alignment and coordination of the content of the releases;
- EMVS Release Plan: a short-term view, planning the releases for the coming year, from a calendar point of view. This release plan is expected to remain stable from one year to the next;

Based on these tools and considering the overall maturity of our governance processes, the EU CCB can now evolve towards working on a set of common priorities for the coming year. By moving towards this way of working, we expect to collect important benefits including but not limited to:

- Increase the visibility and understanding amongst the system owners concerning each other's views and priorities;
- A wider and more integrated view of the EMVS' evolution, considering the interdependencies amongst systems;
- Better understanding of how improvements to the EMVS could be made available faster and with the least entropy possible, especially for OBPs, End-Users and NCAs;
- Make the evolution of the EMVS more predictable to all, both from a calendar and a content perspective;
- Enable clearer and more effective communication, both internally and externally (towards OBPs, End-Users an NCAs) and manage expectations better;
- Enable better financial and resource planning.

In conclusion, today, we have a set of structures and processes that have allowed the governance of the EMVS to significantly improve and mature. The potential of what we already built together has not been fully maximized yet. So now is the time to take the next step to jointly define, agree and commit to a set of common priorities aimed at the implementation of releases over the coming year. This process is expected to become part of our change management process, so we can fully materialise the benefits of the entire governance structure we've successfully built over the last years, to ensure that the EMVS provides safety to the pharmaceutical supply chain in keeping the counterfeit medicines away from patients.

The role of the IT, QA and IOT groups

By Nina Nikolova, BgMVO and Gustavo Rangel & Alice Borghi EMVO

IT Groups

The complex system landscape, the scale and the technology of the EMVS demand strong technical skills and expertise which are provided collectively by the IT Operations Managers in the project.

The majority of NMVOs have IT Operations Managers who oversee the country specific IT operations like system performance and availability, End-Users technical on-boarding, local IT suppliers of pharmaceutical software, alert management, etc.

EMVO, Arvato and SolidSoft Customer Groups have their IT/Tech Working Groups where EMVO as well as all the NMVOs are represented. These groups are valuable advisory bodies that discuss common topics related to NMVS and EMVS operations, stability, security, performance, development, release strategy, testing, etc.

The EMVO IT Working Group has two representatives, Product Owner and Business Analyst. EMVO Change Manager also provides support to facilitate the change management process. The group is responsible for coordinating the interactions with the other two Customer Groups Technical Groups and ensure that any proposal for adapting the EMVS is properly analysed from a technical perspective by all representatives. The main goal of the analysis is to ensure that any interoperability impact is identified and addressed in the EMVS as a whole.

The EMVO IT Working Group also provides guidance to the EU Hub Development Team from the IT Supplier Solidsoft Reply on how the system shall be adapted and maintained as defined in the EMVO and EMVS Roadmap.

The SSR IT Working Group has a representative from each country, usually IT and Operations Managers. The group appoints a Lead who is responsible for the overall organisation and liaises with the rest of the working groups and parties involved.

The purpose of the SSR IT Working Group is to understand the technological side of the System, assess how new requirements may impact the System, and suggest functionalities that benefit all stakeholders. The targeted impact is to improve the System while keeping

it stable and secure. One of the main activities is the IT Security Audit that is performed each year by using an external partner.

The group benefits from the different domains of its participants and their diverse experiences. The activities are based on transparency, knowledge sharing and open communication. Another key success factor is the already established good cooperation with the IT supplier Solidsoft Reply and their skilled personnel.

The Arvato IT Working Group has an IT Manager representative from each country. A Tech Council of 3 IT Managers from 3 different countries leads the group and is responsible for the overall coordination, participates in Management Meetings and liaises with the Arvato QA Council, EU CCB, SSR and EMVO.

The group has two directions of work – operational topics and new system requirement management. Its purpose is stable operations of the System, security, performance monitoring, new functionalities suitable for all stakeholders. The goal is to ensure the EMVS works correctly and serves the users in the best way. Frequently asked questions in the group are "how the business processes work" and "what can be the impact on the other Systems".

The Arvato Tech Working Group appoints a responsible person for each system requirement but performs joint information sessions and joint User Acceptance Tests (UATs). For a variety of topics like reporting and security, the taskforces are created to oversee and report back. Regular meetings are set for features review. The group benefits from good cooperation between the NMVOs and EMVO. The cooperation with the System IT Provider Arvato is based on good relations and discussions and is recognised as essential.

The IT Managers within the EMVS Community are the keepers of technical knowledge and System understanding. They are the "Translators" of the FMD and User Requirement Specifications (URS) into System and the core competency for the overall success of the EMVS.

QA Groups

The EMVS must be aligned with the requirements of the Falsified Medicines Directive and the other pharmaceutical regulations which define the integral role of Quality Assurance (QA). The Quality Assurance

within the project functions at two levels – national and joint project activities.

At national level, most of the countries have Quality Assurance Manager responsible for the implementation of the NMVO's Quality Management System (QMS) and the local legal requirements. The QA Manager makes sure validated systems are in place to ensure their proper functioning and data integrity and performs risk analyses, reviews of the NMVO's operations and suppliers. The purpose of the QMS is to have up-to-date set of standard operating procedures (SOPs), policies and working instructions.

While the QA Managers of each NMVO are responsible for the local NMVO processes, both SSR and Arvato Customer Groups have their QA Working Groups to review and discuss common topics on a group level and make sure that the EMVS is compliant with the FMD and GAMP 5 requirements.

SSR QA Working Group consists of a shared QA Manager who is responsible for all joint activities that the SSR countries perform together and a QA Manager or representative from each NMVO. Since the SSR CG has implemented a blueprint model, the group leverages from many shared processes and procedures. It also demonstrates good collaboration between the QA Managers and fair split of joint actions, for example joint validation, common SOPs, and audit of the IT system supplier Solidsoft Reply. Regular meetings are organised to share knowledge and information, exchange best practices and provide trainings. All NMVOs have access to information and are asked for their opinion. Decision-making is based on consensus.

Arvato QA Working Group consists of 1 or 2 QA Managers and representatives from each NMVO. A QA Council of 3 QA Managers from 3 different countries leads the group and is responsible for the overall coordination, participates in Management Meetings, liaises with Arvato Tech Council, and establishes priorities. The purpose of the Arvato QA Working Group is to validate the System, prepare common SOPs, audit the IT system supplier Arvato and other common suppliers, ensure GAMP 5 compliance, and highlight concerns. A QA Release coordinator is appointed for every major system release. A good practice in the group is responsibility rotation, so everyone can learn and benefit from the

different experiences. All participants are encouraged to express their opinion, share experience, best practices, and learn from each other.

The QA team of the EMVO Customer Group is responsible for the interoperability and security of the EMVS and the validated status of EMVO owned systems. The team also plays a vital role in the EU CCB Secretariat.

In the first place, EMVO QA team ensures that the EU Hub (the central repository of the EMVS) is kept in a validated status and meets the user and compliance requirements with the applicable regulations and guidelines.

Besides the EU Hub, EMVO also has many supporting systems, like e.g., the EMVO gateway, the EMVO Portal, the OBP Portal, the AMS Hub and the AMS Portal. All EMVO systems are risk assessed and classed whether these are subject to validation.

To ensure validation, an extended EMVO QMS has been developed in close collaboration with the EMVO Operational Department and its IT suppliers. An extended audit program is defined which is carried out by external, independent auditors. This covers regular IT security audits to identify cyber security risks of EMVO owned systems. Also, internal audits on EMVO processes and systems are led by external auditors. The findings are captured in Corrective Actions and Preventive Actions (CAPA's). These are the foundation which drives quality improvements to the EMVO systems and processes. Also, EMVO's IT suppliers are scheduled for audits to verify that their processes are in line with EMVO's quality expectations.

Finally, EMVO QA triggers NMVO audits. With the help of an external auditor, EMVO performs 2 to 3 audits on NMVOs per year. The aim is to ensure that the National systems and related processes are managed in line with the contractual agreements between EMVO and NMVOs. This provides to the full EMVS community a level of confidence on interoperability and security of all the connected systems operating within the EMVS by applying the same quality/security standards.

Key factor to fulfilling the EMVO QA vision of 'Driving quality to ensure patient safety' is the fruitful collaboration with the QA representatives of the other two Customer Groups. This occurs on the following levels:

1. EU QA Team

This team is responsible for the alignment on EMVS Change Management related topics, which are discussed in the context of the EU CCB framework where each Customer Group (CG) have QA representatives to ensure the review, governance, and approval of each request for change.

2. EU QA Council

This EU QA Council was established to organise joint meetings for QA representatives of each Customer Group to further ensure interaction and collaboration on common QA topics and issues that are not related to change management.

3. Inter-Operability Testing (IOT) Team

See below

The QA Managers within the EMVS Community can be considered as the "Guardians of the System" who keep track of the processes, so the System is validated, well-connected, interoperable, aligned with the URS and compliant with regulations. Therefore, the open communication and knowledge sharing between the QA representatives of the 3 Customer Groups are, for EMVO, key factors to guarantee the Quality of the EMVS Systems, the integrity of the data shared via the EMVS and consequently the safety of the patient.

Inter-Operability Testing (IOT)

The three software solutions of the EMVS - the EU Hub, the SSR NMVS, and the Arvato NMVS, communicate with each other via interfaces to allow the OBPs and the End-Users to exchange data. Before a new release of the EMVS is deployed in production, interoperability between the three software solutions must be confirmed and here comes the role of the Inter-Operability Test Group.

The IOT Group has 20 representatives from the 3 Customer Groups – EMVO, Solidsoft CG and Arvato CG. A Test Manager leads the group and oversees the overall organisation. Test Leads from each Customer Group support the process, on-board and train new members. The QA Managers ensure the overall compliance of the process.

The purpose of the IOT Group is to ensure interoperability and harmonization between the three software solutions within the EMVS through functional testing and guarantee that no critical or high priority

defects are present in the release subject to test. If a critical defect is detected during IOTs, the release is not recommended for deployment. Since the IOTs are in place, there have been no major incidents with the EMVS caused by lack of interoperability.

In the long term, the goal of the IOT Group is to fully automate their regression testing, a practice that ensures the existing functionalities work as expected in the new release. This automation will significantly reduce the overall IOT time, help avoid human error and allow full test coverage for all URS functionalities that require interoperability.

To conclude, the IOT Group is "the school" where one can learn how to operate the EMVS through hands-on experience.

Stay up to date with the EMVS!

EMVO wishes you a great summer! We will see you again in October with a new issue packed with the latest news from our EMVS community.

In the meanwhile, if you haven't yet done so yet, make sure to mark your calendar for the two last NCA workshops of the year, **Tuesday 11th of October and Wednesday 30th of November!**

We'd love your feedback!

If you have any questions, please do not hesitate to contact our Helpdesk.

Kind Regards,

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