NMVO On-Boarding presentation

Please check
https://www.emvo-medicines.eu/
for the latest version of this presentation and the On-boarding Guideline.

European Medicines Verification Organisation (EMVO)
www.emvo-medicines.eu
helpdesk@emvo-medicines.eu

Version 1.0

18 April 2017
This On-boarding Guide for NMVOs and the related Power-Point presentations (the "Guides") are provided "AS IS" by EMVO. They are provided for your information only and do not amount to professional advice or recommendations from EMVO. No warranty of any kind is made or given by EMVO with respect to these Guides or use thereof, including, but not limited to, as to the accuracy or the completeness thereof. Use of these Guides is at your own risks and perils. To the fullest extent permitted by applicable law, EMVO expressly disclaims all warranties of any kind, whether expressed or implied, including, but not limited to the warranties for hidden or latent defect, of merchantability, fitness for a particular purpose and non-infringement. EMVO shall not be liable for any direct or indirect damage, loss or claims, including loss of use, data, profits, benefits, data, business, opportunity, goodwill, clientele, for third party’s claims, or for any other indirect, special, incidental or consequential damages of any kind in connection with or arising out of the use of any information disclosed hereunder, whether alleged as a breach of contract (including grave fault), tort, negligence (including gross negligence), hidden/latent defects, strict liability or any other legal theory, even if the EMVO had been advised of the possibility of such damage. Nothing herein shall, however, operate to limit or exclude any liability for fraud or other liability that cannot be legally excluded. EMVO reserves the right to amend this NMVO On-boarding Guide at any time without prior notice.
Content

- General Information
- NMVO On-Boarding & QA goals
- Cooperation Agreement with EMVO
- Technical On-Boarding
- Quality Assurance
- Audit
General Information

NMVO On-Boarding & QA goals

Cooperation Agreement with EMVO

Technical On-Boarding

Quality Assurance

Audit
FMD Legislation and Delegated Act

- **Establish National Systems in 32 countries**
- Connect approx. 2,500 On-boarding Partners (OBPs) to the EU Hub
- Connect many thousand Pharmacies and Wholesalers
- Serialise all affected pharmaceutical packs (10.5 bn)

**Timeline**

- **2011**
  - July 2011: Publication of FMD

- **2016**
  - 9 Feb 2016: Publication of Delegated Regulation

- **2017**
  - ~600 days remain

- **2018**
  - 9 Feb 2019: Mandatory verification of all packs in scope

**FMD**: Falsified Medicines Directive
Responsibilities of the Supply Chain Partners

Serialization by MAH
Risk based verification by Wholesalers
Verification and check-out at point of dispense

Safety features:
Code (‘unique identifier’) + Tamper evidence

System set up and Governance by MAH together with other stakeholders
Oversight by competent authorities

Product #: 09876543210982
S/N: 12345AZRF1234567890
Batch: A1C2E3G4I5
Expiry: 140531
Organisational chart

EMVO Board of Directors
President: Hugh Pullen (EFPIA)
Vice-President: Sonia Ruiz Morán (PGEU)
Treasurer: Richard Freudenberg (EAEPC)
Monika Derecque-Pois (GIRP)
Adrian van den Hoven (Medicines for Europe)

General Manager
Andreas Walter

- Christoph Krähenbühl
- Markus Gerigk

Commercial & Partner Management
Tobias Beer
- Fanny Trenteseaux
- NN

Operations
Paul Mills
- Willem Theunissen

Office Manager
Marisa Jimenez Sanchez

Quality Assurance
Stephan Theunissen
System Landscape I
**OBP**: On-boarding Partner  
**NMVS**: National Medicines Verification System  
**NMVO**: National Medicines Verification Organisation
Content

- General Information
- On-Boarding process & QA goals
- Cooperation Agreement with EMVO
- Technical On-Boarding
- Quality Assurance
On-boarding process

**Contractual**
- Negotiate & sign off the EMVO Cooperation contract

**Prequisites & System Assessment**
- SPOC Appointed
- Certification start test criteria met
- UAT witnessed by EMVO (*)
- System capability assessed by EMVO

**Technical On-boarding**
- System Connection to IQE Test environment
- Certification testing
- System Connection to Productive environment

**Quality Assurance Goals**
- QA person assigned
- Set-up QMS @ NMVO
- Ensure QMS @ IT Service Provider
- Ensure a validated NMVS

**Audits**
- System Operation
- QMS implemented

(*) Exception as of 2nd implementation of the same blueprint supplier possible
Content

- General Information
- On-Boarding process & QA goals
- Cooperation Agreement with EMVO
- Technical On-Boarding
- Quality Assurance
- Audit
Organisation Prerequisites

NMVS must be governed and managed by a national stakeholder organisation (NMVO)

- Alignment between all Stakeholders
- NMVO Statutes agreed
- NMVO established
  → non-profit legal entity compliant with DR Article 31

**NMVS:** National Medicines Verification System
**NMVO:** National Medicines Verification Organisation
**DR:** Delegated Regulation
NMVO Contract Landscape

EMVO: European Medicines Verification Organization
Solidsoft: IT Service Provider for implementation and operation of European HUB
NMVO: National Medicines Verification Organisation
IT Supplier: IT Service Supplier of the NMVS (e.g. one of the Blueprint suppliers)
Purposes of the Agreement

- Contractual framework for the Cooperation between EMVO and NMVO during the EMVS Implementation Phase.
- Set the parties’ respective rights and obligations in relation to the:
  - Development, implementation, testing and operation of the NMVS
  - Connection between the European HUB and the NMVS
  - Use of the European HUB and NMVS to transfer data between them
- Target is to allow End Users to verify authenticity of medicines in accordance with Falsified Medicines Directive and Delegated Regulation latest on the 9\textsuperscript{th} of February 2019
- As part of the Implementation Phase it is agreed that the EMVS or any of its components may be substantially changed or amended.
Parties for the Agreement

1. European Medicines Verification Organisation A.S.B.L. at 1040 Brussels – Belgium ("EMVO")
2. National Medicines Verification Organisation ("NMVO") – the legal non for profit Organisation of that Country

In case of a national two tier structure:

3. Affiliate of the NMVO (bound jointly and severally with the NMVO) – e.g. operational ltd.

All involved parties are directly bound to the provisions of the Agreement
Protection of the System Security is one of the guiding principles that shapes the Agreement

- The Parties shall implement state-of-the-art security measures and at least the security measures as requested in the SDK
- Strict confidentiality for SDK and other confidential information, provided only on need to know basis
- Use of SDK restricted to the Purposes of the Agreement
- Each Party has the right to disconnect the NMVS from the HUB in case it believes that the NMVS immediately or substantially endangers the security or functioning the EMVS in whole or in part
- Exchange of reports on a regular basis
- Legitimacy checks and control for all System Users in accordance with Falsified Medicines Directive (FMD) and Delegated Regulation
In order to handle a Security Breach in a cooperative manner, a procedure is foreseen:

- Information within 24 hours after awareness
- Cooperation in investigation
- Take all measures to solve the issue
- Take all measures to mitigate the consequences
- Take all measures to prevent reoccurrence

If required by applicable law

- Notification of public authorities or individuals
- Undertake Remedial Actions
EMVO’s Main Obligations

- Develop and operate the Hub for the Purposes in accordance with FMD and Delegated Regulation
- Provide documentation and SDK for the development and use of the HUB-NMVS interface
- Provide a Contact Person for this Agreement
- Provide information about key facts, project status and project progress on hub interface development
- Undertake best efforts to provide HUB functionality in a diligent manner and to protect it with state-of-the-art security measures
- Provide copy of insurance, if any
NMVO’s Main Obligations

- Develop and operate the NMVS for the Purposes, in accordance with the SDK, the Agreement and FMD and Delegated Regulation
- Protect its NMVS with state-of-the-art security measures (and at least the security measures set forth under the SDK).
- Ensure that its IT Company is subject to equivalent obligations
- Carry out legitimacy check and ensure that End Users are held with appropriate terms to use the EMVS
- Provide a Contact Person for this Agreement
- Be responsible towards EMVO for activities carried out on its NMVS
- Provide copy of insurance, if any
Limitation of Warranty and Liability

- The guiding principle is a back to back provision that:
  - Excludes implied warranties; the HUB and NMVS are provided “as is”
  - Excludes indirect or consequential damages
  - Allows a Party to recover direct damages from the other Party (provided that the other Party can itself recover such damages from its IT Company to the extent it relates to a breach of its obligations by such IT Company in relation to the design, builds, test and deployment of the Hub/NMVS)
  - Excludes EMVO’s liability for inaccurate, incomplete or corrupted data, or any malicious software

- The Liabilities of all Parties will be capped on a level still to be defined.
Termination of the Agreement

- Automatic expiration on 8th of February 2019
- Mutual extension by way of amendment possible for the Operational Phase
- EMVO to make suggestion for extension provisions latest 9 months before automatic expiration
- The agreement can be dissolved by either Party
  - Breach of material obligation under the DR
  - Change of legislation affecting the capacity of a Party to operate the HUB or the NMVS
  - If the other Party loses its competence to act in its role
Disclaimer for this chapter

- This presentation is provided for information purposes only and is not binding EMVO in any manner. It only provides a general overview of the main provision of the Cooperation Agreement, which should not be regarded as exhaustive. Only the Cooperation Agreement signed by EMVO’s representation will bind EMVO. The Cooperation Agreement and this presentation may still be revised and adapted.

- [No warranty of any kind is made or given by EMVO including, but not limited to, the accuracy or the completeness thereof. To the fullest extent permitted by applicable law, EMVO expressly disclaims all warranties of any kind, whether expressed or implied, including, but not limited to the warranties for hidden or latent defect, of merchantability, fitness for a particular purpose and non-infringement. EMVO shall not be liable for any direct or indirect damage, loss or claims, including loss of use, data, profits, benefits, data, business, opportunity, goodwill, clientele, for third party’s claims, or for any other indirect, special, incidental or consequential damages of any kind in connection with or arising out of the use of any information disclosed hereunder, whether alleged as a breach of contract (including grave fault), tort, negligence (including gross negligence), hidden/latent defects, strict liability or any other legal theory, even if the EMVO had been advised of the possibility of such damage. Nothing herein shall, however, operate to limit or exclude any liability for fraud or other liability that cannot be legally excluded. EMVO reserves the right to amend this presentation at any time without prior notice. ]
Prerequisites & System Assessment

- SPOC Appointed
- Certification start test criteria met
- UAT witnessed by EMVO (*)
- System capability assessed by EMVO

(*) Exception as of 2nd implementation of the same blueprint supplier possible
Technical On-Boarding Prerequisites

- Single Point of Contact (SPOC) has been assigned
- Certification start test criteria met
- UAT witnessed by EMVO:
  - Valid for all NMVS implementations
  - Exception as of 2nd implementation of the same blueprint supplier possible
- NMVS System capability assessment performed by EMVO
Technical On-Boarding

- System Connection to IQE Test environment
- Certification testing
- System Connection to Productive environment
Technical On-boarding of a NMVS

- Development
- ITAT
- UAT
- System Assessment
- Certification test
- Operational

IT Supplier controlled
NMVS environment(s) required from the development stage to the UAT

NMVS software

EU hub
Dedicated EU Hub Test Environment(s) controlled by the IT supplier as rented from Solidsoft - Reply

EMVO-Relevant for On-boarding to EU hub

NMVS_A
IQE
Cert Test

EU hub
IQE - Test environment
Cert. Test

PRD

NMVS_A
EU hub
PRD
Technical On-boarding of NMVS

- Starts after positive System Assessment
- Will connect NMVS client sequentially to:
  - the IQE test environment to certify the interface
  - The PRD environment to use the interface
- Exchange of certificate information identical for IQE as PRD
  - NMVO creates CSR file
  - Solidsoft signs CER certificate
  - IT Service Supplier to provide connection
EMVO’s EU Hub environments for NMVO’s

**IQE environment**
- Integrated Quality Environment
- Used for Quality- & Certification testing by NMVO’s & OBP’s
- Validated environment

**PRD environment**
- Productive Environment
- Validated environment

**IQE:** Integration Quality Environment  
**PRD:** Productive Environment
General Information
On-Boarding process & QA goals
Cooperation Agreement with EMVO
Technical On-Boarding
Quality Assurance
Audit
Quality Assurance Goals

- QA person assigned
- Set-up QMS @ NMVO
- Ensure QMS @ IT Service Provider
- Ensure a validated NMVS
Quality Assurance goals

• QA person assigned
• QA readiness of NMVO / NMVS is not an EMVO prerequisite for on-boarding
• Each System Owner is responsible for the validation of his system
  – EMVO for the EU hub
  – Each NMVO for its NMVS
Set-up QMS of NMVO

- For Blueprint model based countries: EMVO provides QA templates Free of Charge
- The tailoring of the QMS to the specific NMVO organisation is to be managed by the NMVO
- Tailoring service for Blueprint model based countries may be provided by EMVO and are subject to payment
Ensure QMS @ IT Service Supplier

- EMVO performed audits at all Blueprint Suppliers and are as such approved to have the ability.
- Exact operating procedures to be agreed on NMVO level
- IT Service Providers are to be audited by NMVO to ensure their QMS meets Quality expectations
Audits

- System Operation
- QMS implemented
Audit purpose & objective

Purpose:

- To verify that the NMVS, its system operation and support processes comply with:
  - EMVO quality standards
  - Regulation

Objectives

- To verify the capability to operate the system in a validated status
- Achieve high degree of confidence that NMVS will perform as intended
- Ensure QMS of IT provider meets EMVO Quality expectations
- NMVO complies to Article 31 of the DR and if financially stable
Audit Applicable Regulation & Best Practices

- Directive 2011/62/EU and Delegated Act
- GAMP5 A Risk-Based Approach to Compliant GxP Computerized Syst.
- Eudralex Volume 4 and Annexes (e.g. Annex 11, Annex 15)
- ISO/IEC 27001: 2013 Information security management systems
- ISO/IEC 38500: Information Technology Governance
- ISO/IEC 20000: IT service management
Audit focus i.a.

- URS compliance with DR
- System design and architecture compliance with DR
- On-boarding procedure for end-users (to ensure compliance with DR Article 37(b))
- Legitimacy check of end-users & potentially manufacturers (if applicable)
- Interface with EU Hub developed according to EMVS specification (EMVS URS & SDK)
- Data integrity, access and ownership
- Compliance of NMVO to Article 31 of the DR
# Audit minimum requirements to QMS

## QMS deliverable implemented
- SOP template
- Form Template
- NMVO controlled document list
- Document management
- Validation policy
- Validation plan template
- Validation report template
- User requirements specification template
- Roles and Responsibilities
- Risk management
- Risk assessment template
- Information security management
- QMS manual
- Initial system assessment template
- Test management
- Release and deployment management

## QMS deliverable implemented
- Change management
- Change request template
- Training management
- Training registration form template
- QMS Training requirements
- Access management
- Onboarding process
- User requirements specification
- Incident management
- Incident investigation report template
- CAPA management
- CAPA Form
- Audit management
- Complaint management
- Business continuity management
**Authored by:**

<table>
<thead>
<tr>
<th>Stephan Theunissen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
</tr>
</tbody>
</table>

**Approved by:**

<table>
<thead>
<tr>
<th>Andreas Walter</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Manager</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tobias Beer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial &amp; Partner Manager</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Paul Mills</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Operations Manager</td>
</tr>
</tbody>
</table>
Revision History:

<table>
<thead>
<tr>
<th>Version Date</th>
<th>Version</th>
<th>Author</th>
<th>Reason For Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>18/04/2017</td>
<td>V1.0</td>
<td>Stephan Theunissen</td>
<td>Initial Document</td>
</tr>
<tr>
<td>Date</td>
<td>Signature</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 APR 2017</td>
<td>Paul Mills</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27/04/2017</td>
<td>Tobias Beer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27/04/2017</td>
<td>Andreas Walter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27-4-17</td>
<td>Stephan Thuensessen</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>