NMVO On-Boarding presentation

Please check

https://www.emvo-medicines.eu/

for the latest version of this presentation and the On-boarding Guideline.

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European Medicines Verification Organisation

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European Medicines Verification Organisation

Content

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

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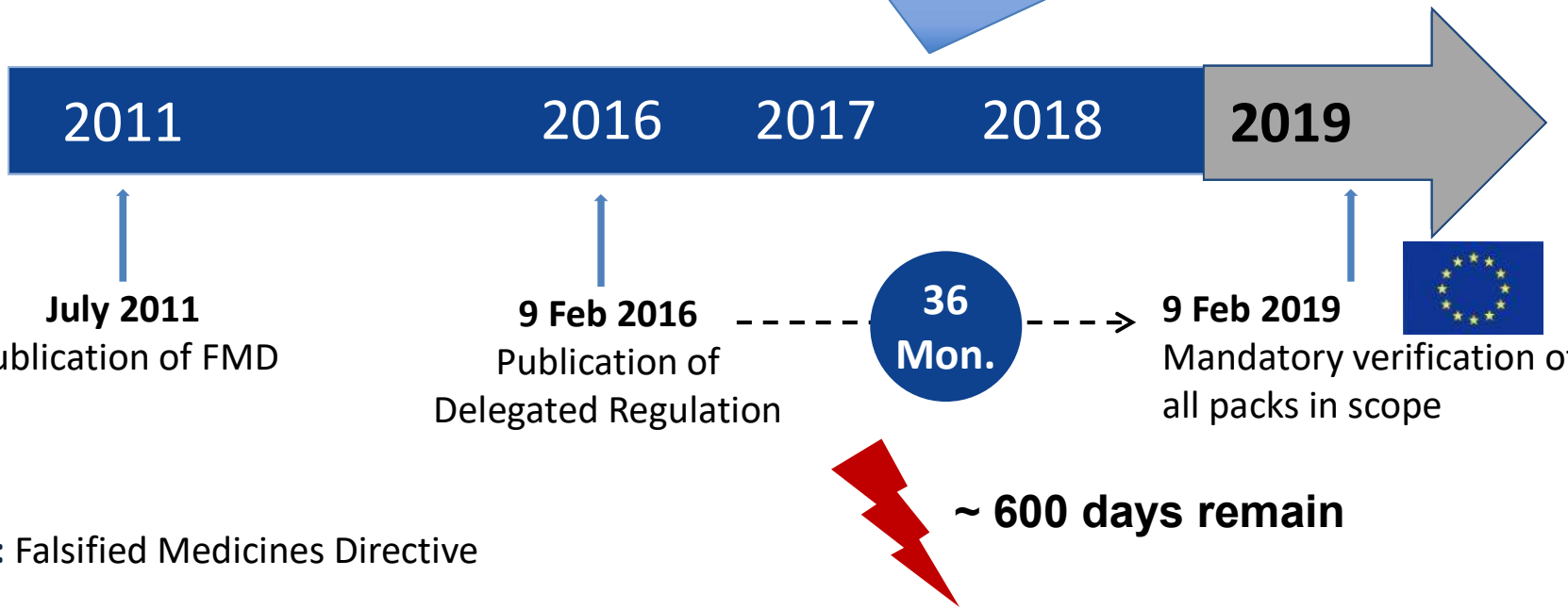
FMD Legislation and Delegated Act

- **<u>Establish National Systems in 32 countries</u>**
- 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)



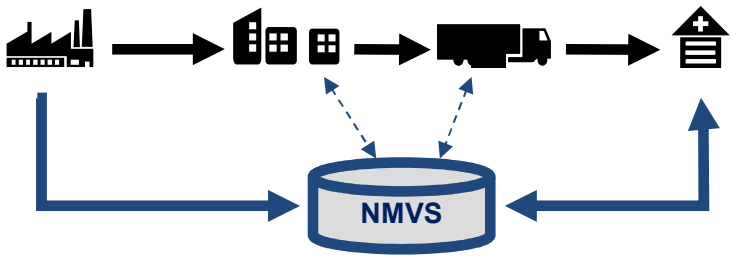
FMD: Falsified Medicines Directive

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')

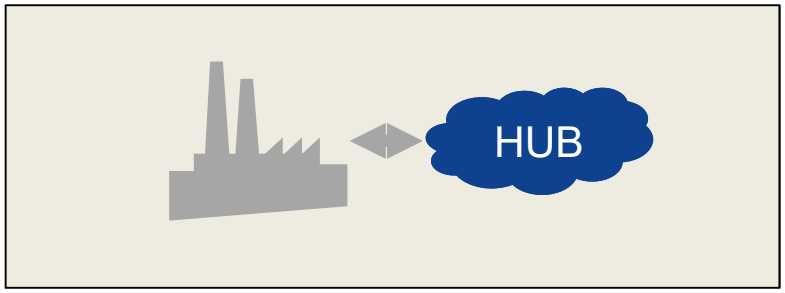
+

Tamper evidence

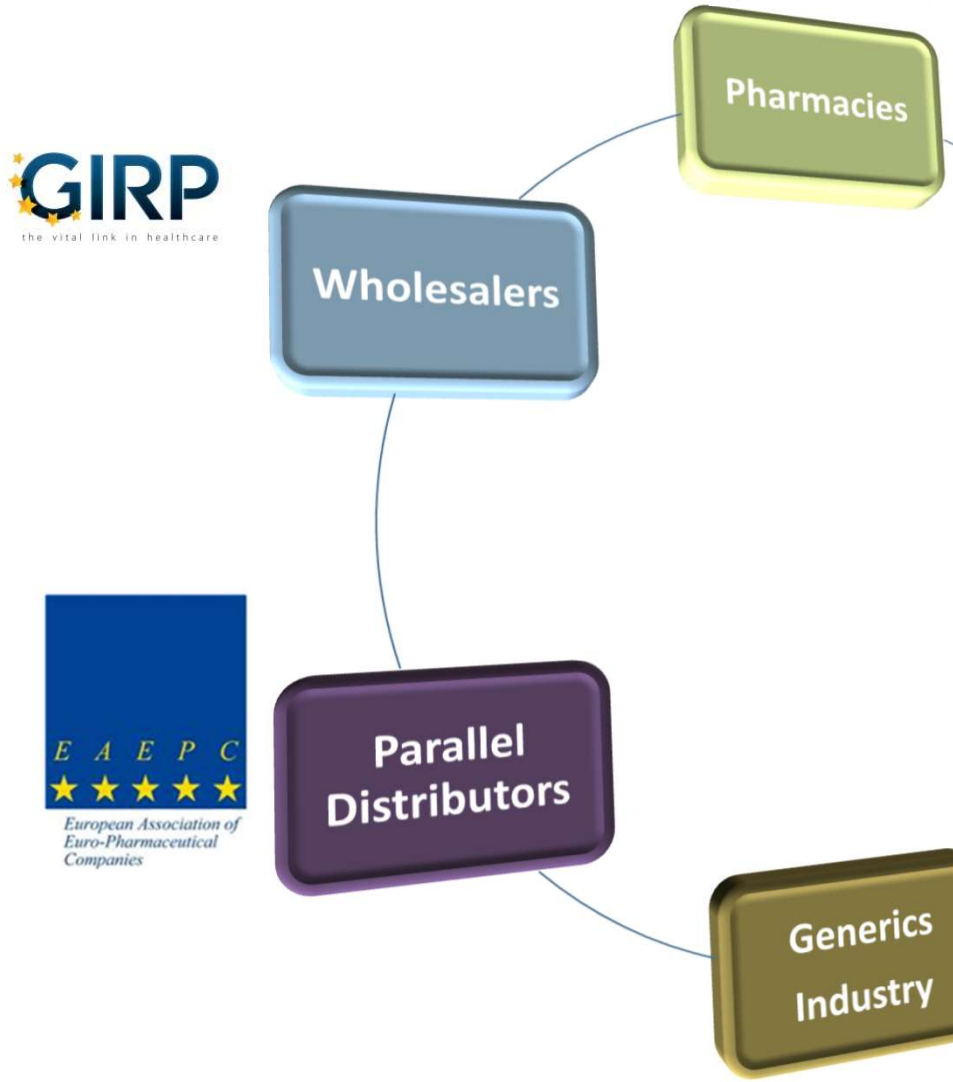
Product #:	09876543210982
S/N:	12345AZRQF1234567890
Batch:	A1C2E3G4I5
Expiry:	140531

System set up and Governance by MAH together with other stakeholders

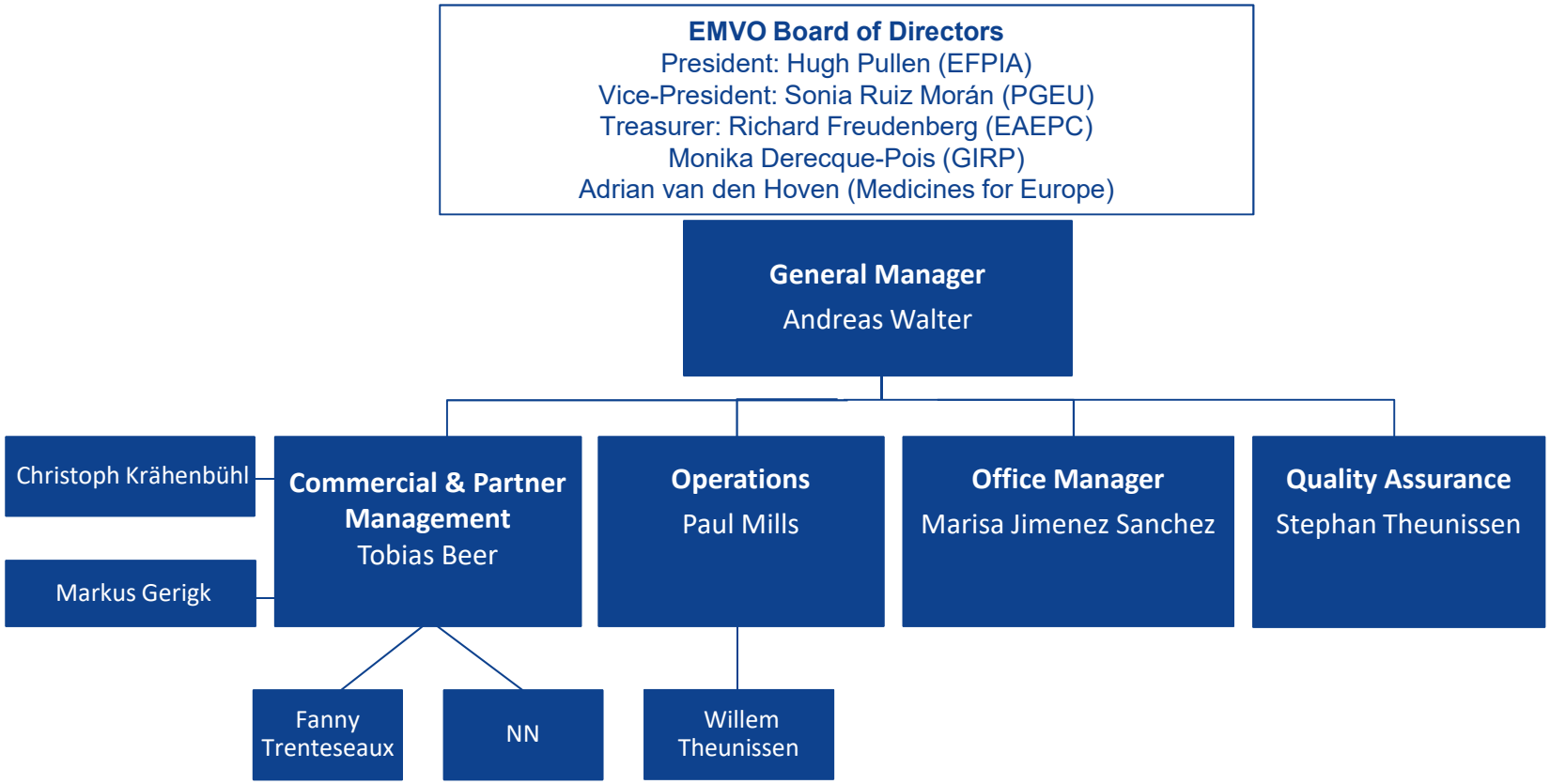
Oversight by competent authorities



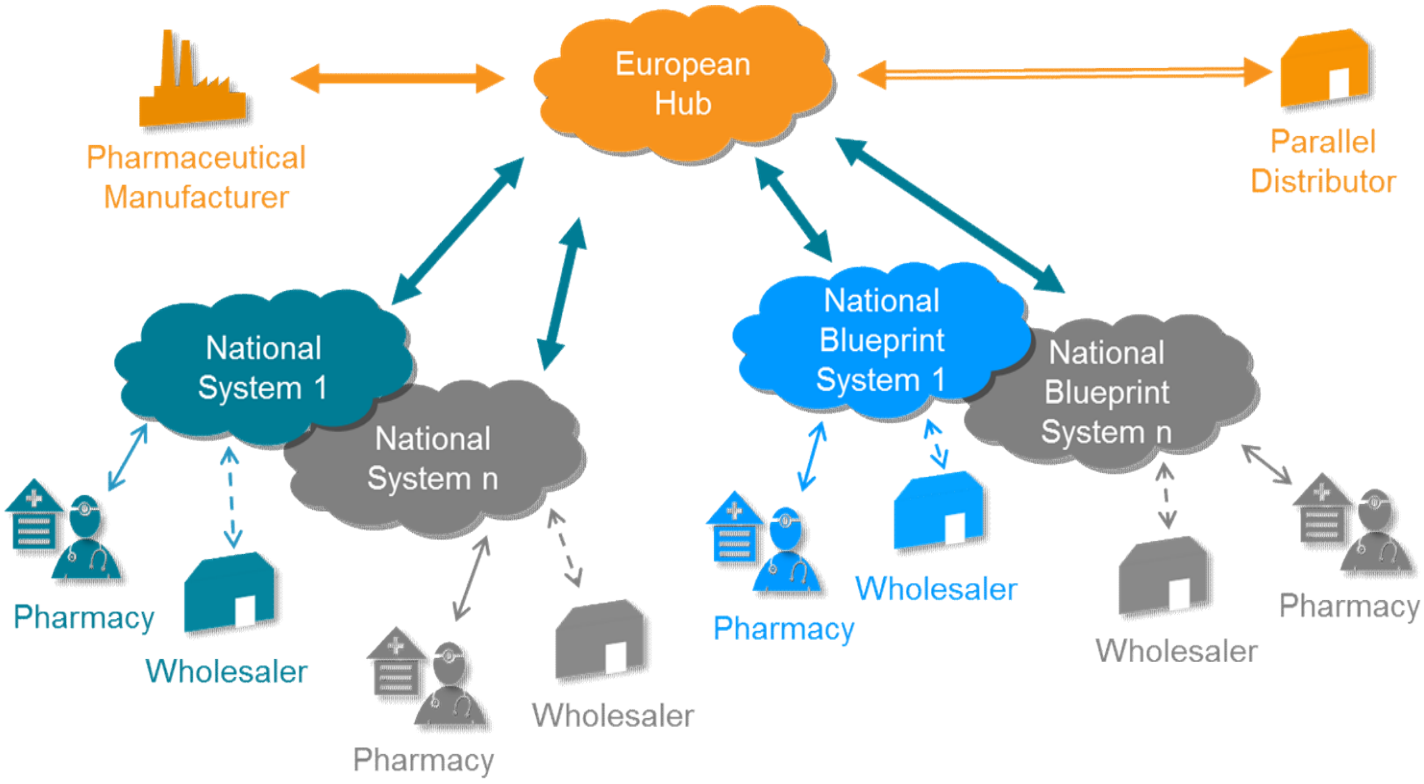
EMVO Members



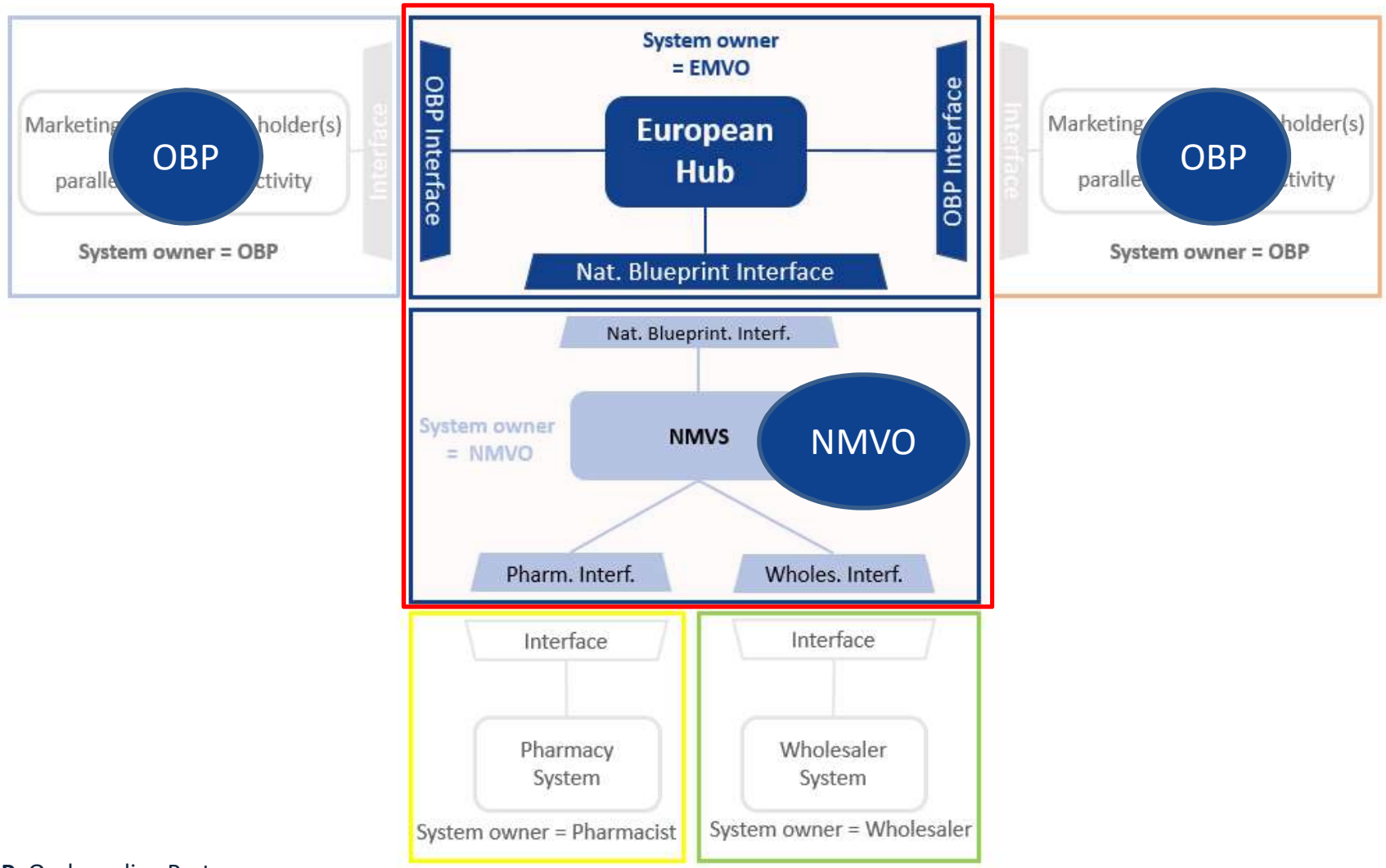
Organisational chart



System Landscape I



System Landscape II



OBP: On-boarding Partner
NMVS: National Medicines Verification System
NMVO: National Medicines Verification Organisation

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On-boarding process

Contractual	Prequisites & System Assessment	Technical On-boarding
• Negotiate & sign off the EMVO Cooperation contract	• SPOC Appointed • Certification start test critera met • UAT witnessed by EMVO (*) • System capability assessed by EMVO	• System Connection to IQE Test environment • Certification testing • System Connection to Productive environment

Quality Assurance Goals	Audits
• QA person assigned • Set-up QMS @ NMVO • Ensure QMS @ IT Service Provider • Ensure a validated NMVS	• System Operation • QMS implemented

Time

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

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Organisation Prerequisites

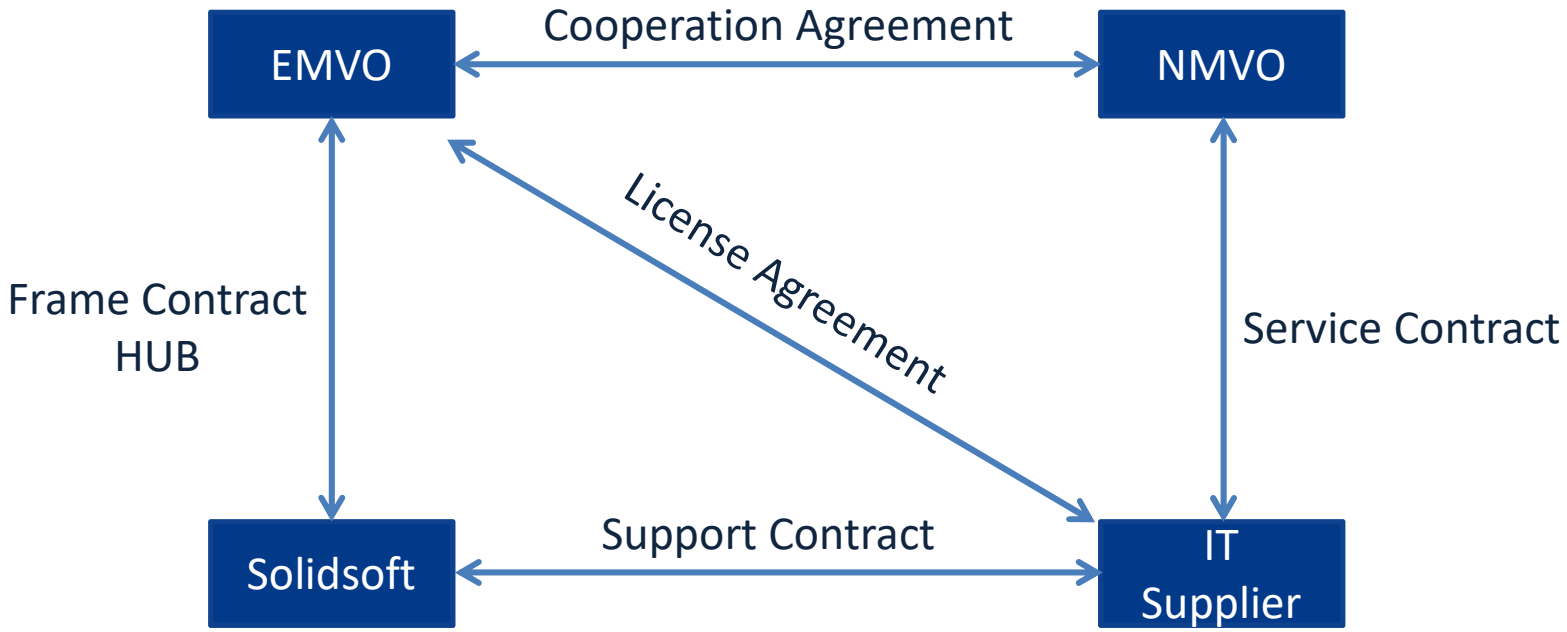
NMVS must be governed and managed by a national stakeholder organisation (NMVO)

- ❑ 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)

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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 9th 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

System Security

- 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

Security Breach

- 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 exent 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 looses 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.
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Prerequisites & System Assessment

Prequisites & System Assessment

- SPOC Appointed
- Certification start test critera 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

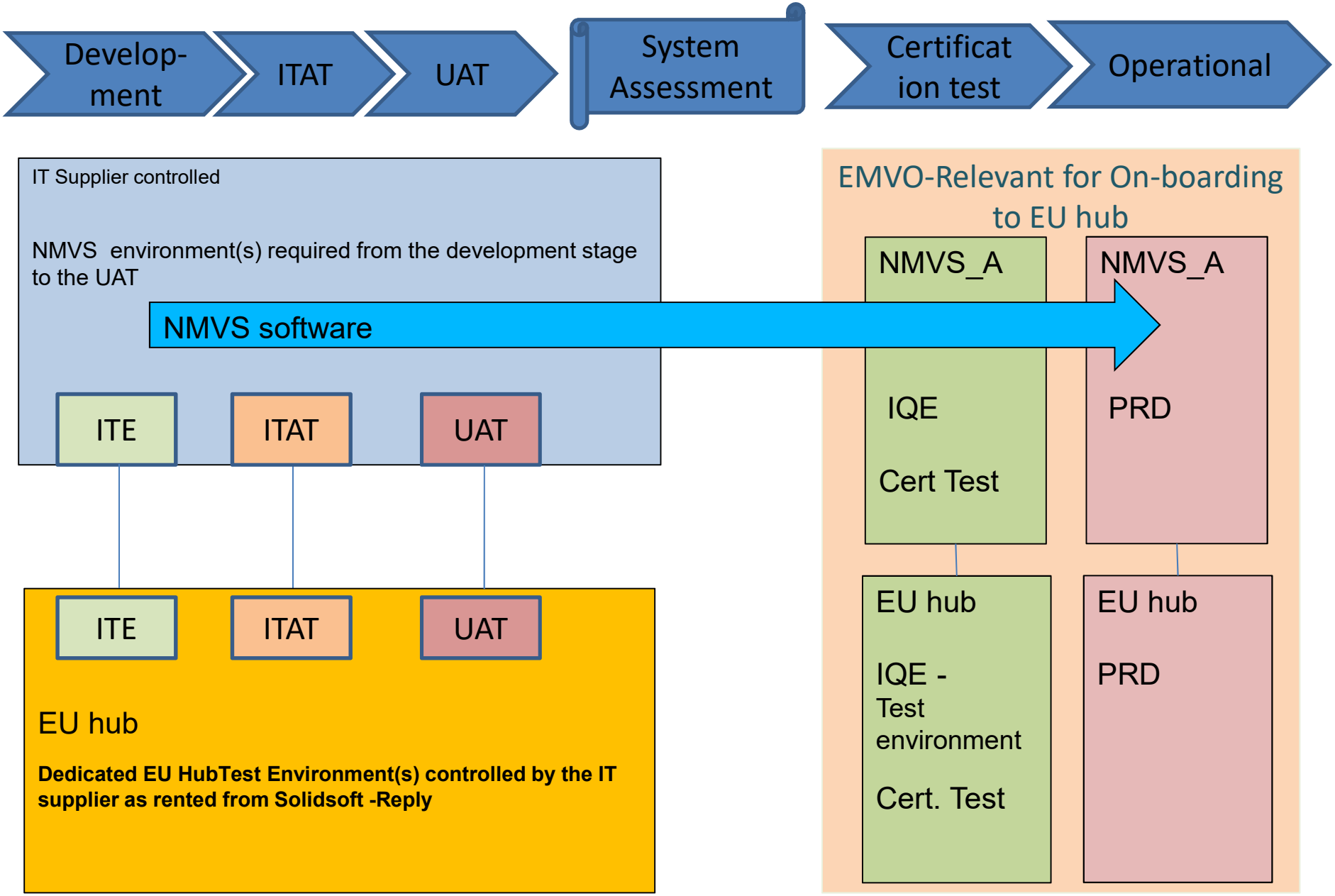
- ❑ Single Point of Contact (SPOC) has been assigned
- ❑ Certification start test criteria met
- ❑ UAT witnessed by EMVO:
  - Valid for all NMVS implementations
  - Exception as of 2nd implementation of the same blueprint supplier possible
- ❑ NMVS System capability assessment performed by EMVO

Technical On-Boarding

Technical On-boarding

- System Connection to IQE Test environment
- Certification testing
- System Connection to Productive environment

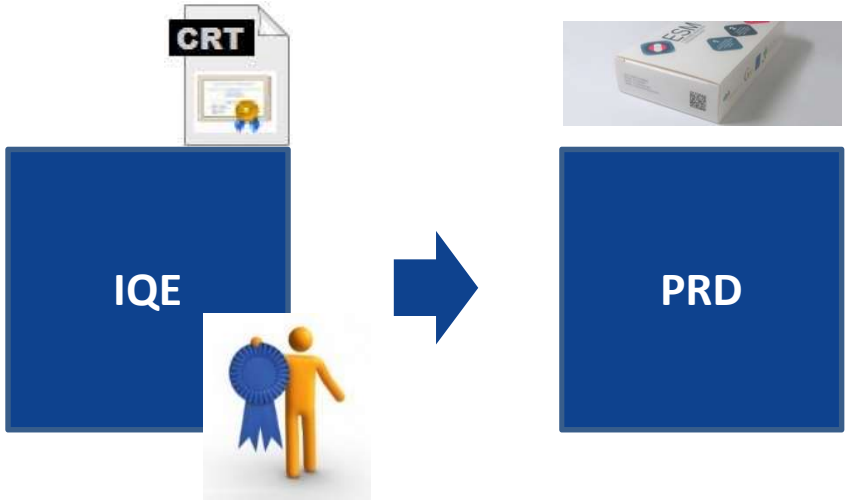
Technical On-boarding of a NMVS



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

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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

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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

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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 27002: 2013 Code of practice for information security man.
- ISO/IEC 27005: Information security risk management.
- 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 Responsabilities
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

Sign-off page

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Version History

Revision History:

Version Date	Version	Author	Reason For Changes
18/04/2017	V1.0	Stephan Theunissen	Initial Document

Sign-off page

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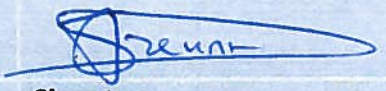
Stephan Theunissen		27-4-17
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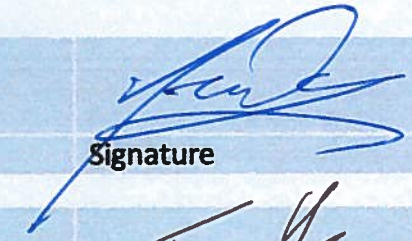
Andreas Walter		27/04/2017
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