FiMVO

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Quality in FiMVO operations

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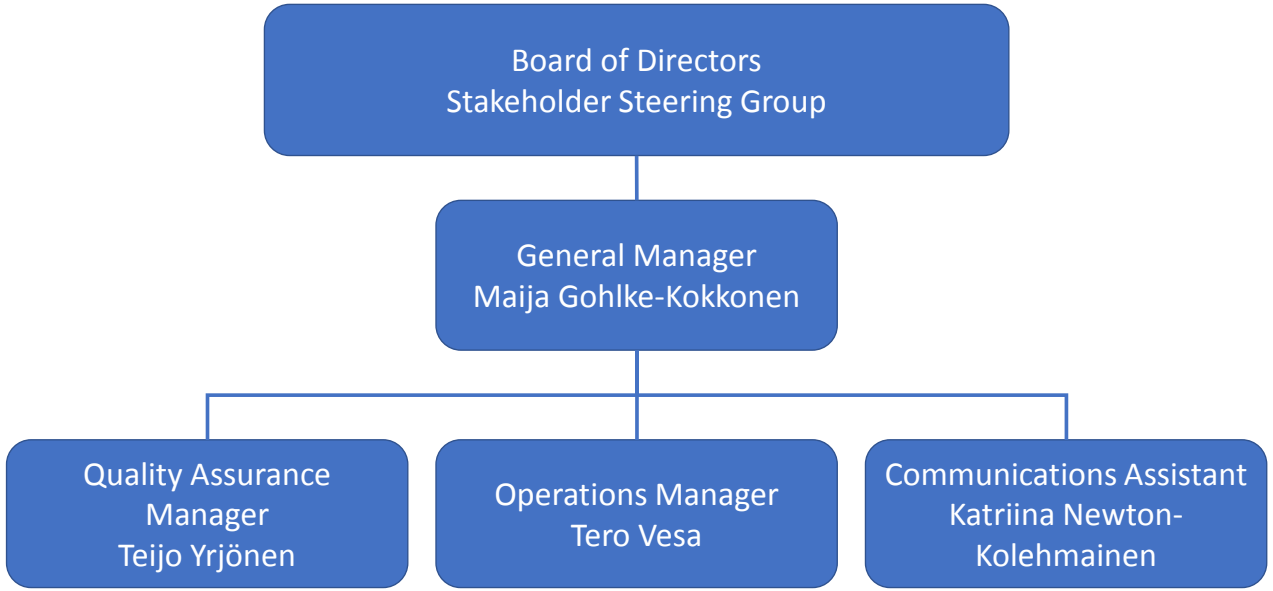
Introduction

- Finnish Medicines Verification Organisation FiMVO
  - Not-for-profit limited company
  - Established by pharmaceutical manufacturers and marketing authorisation holders, pharmacies and wholesalers participate on a voluntary basis
  - Governs the implementation and operation of the Finnish Medicines Verification System (FiMVS), which will be connected to the EU Hub of the European Medicines Verification System (EMVS)
  - Currently has two full-time employees and two part-time employees

Introduction

- FiMVO organisational chart



Quality Management System

- Scope
  - All core processes within FiMVO
- Regulations and guidances applied in setting up the QMS
  - EU GMP guide (*Chapter 1 Pharmaceutical Quality System, ICH Q9 Quality Risk Management, ICH Q10 Pharmaceutical Quality System, Annex 11 Computerised Systems, Annex 15 Qualification and Validation*)
  - ISO 9001:2015 Quality Management Systems – Requirements
  - ISO/IEC 27002:2013 Information technology – Security techniques – Code of practice for information security controls
  - ISPE – GAMP 5 A Risk-Based Approach to Compliant GxP Computerized Systems

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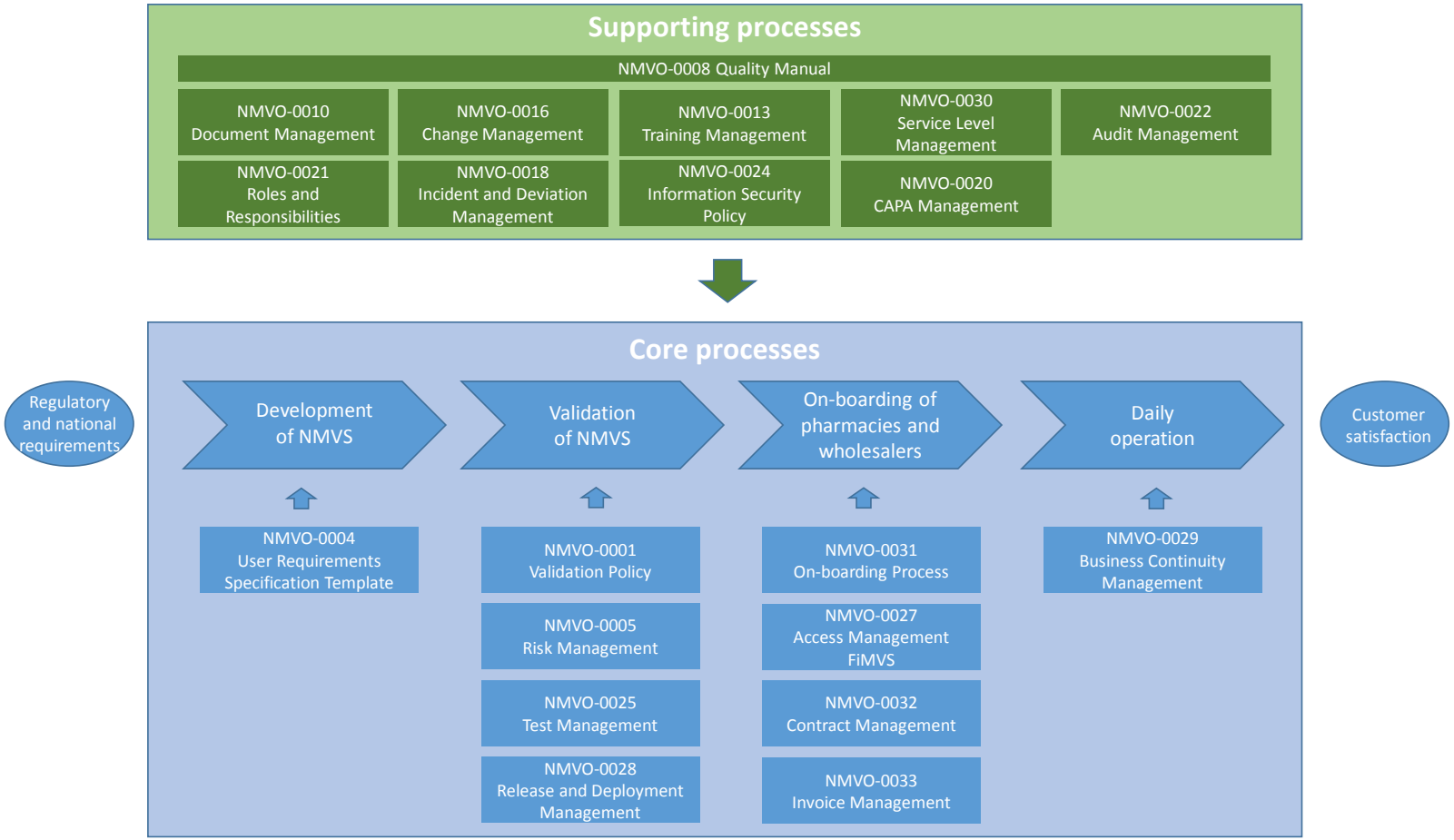
QMS Processes & Respective SOPs



Roles and Responsibilities

- Described in NMVO-0021 Roles and Responsibilities
- General Manager
  - Overall responsibility of FiMVO operations
  - Plans and manages the provided budget
  - Manages the human resources of FiMVO
  - Represents FiMVO towards all stakeholders
  - Reports to the Board of Directors and to EMVO
- Operations Manager
  - Responsible for the technical implementation of FiMVS
  - Supervises the activities of the IT suppliers
  - Monitors the performance of the IT systems owned by FiMVO

Roles and Responsibilities

- QA Manager
  - Responsible for establishing and maintaining a QMS within FiMVO
  - Supervises the quality management activities of suppliers and process owners
  - Ensures that FiMVS is validated and compliant with applicable regulations
  - Represents FiMVO during external audits
- Communications Assistant
  - Manages communications towards stakeholders as instructed by GM
  - Manages contracts between FiMVO and end users/MAHs
  - Assists GM in public communications

Document Management

- Described in NMVO-0010 Document Management
- Applies to SOPs, forms, specifications, work instructions and controlled records
- Includes the coding convention used, lifecycle of controlled documents, retention periods and repositories of paper and electronic documents
- Currently a more or less paper-based system, but an Integrated Management System (IMS) has been purchased and will be implemented within the next couple of months → electronic archiving of controlled documents

Training Management

- Described in NMVO-0013 Training Management
- Incorporates training of QMS issues as well as training in the technical aspects of the IT systems owned by FiMVO
- QMS training requirements for different jobs within FiMVO are described in a separate training matrix (NMVO-0015 QMS Training Requirements)
- System training is required for FiMVO employees using those systems
- Trainings are documented on a separate registration form (NMVO-0014 Training Registration Form Template)

Change Management

- Described in NMVO-0016 Change Management
- The procedure covers all non-standard changes to systems owned by FiMVO
- Changes categorised into two classes:
  - Emergency changes
  - Normal changes (with priorities Low, Medium and High)
- In case a change impacts the EU Hub, the change request is forwarded to EMVO QA for review
- All changes to FiMVS will be implemented in test environment first, tested and, if successful, implemented in the production environment

Incident and Deviation Management

- Described in NMVO-0018 Incident and Deviation Management
- Includes unplanned events experienced during operational phase
  - Tickets
  - Complaints
  - Incidents
  - Deviations
- Documented using NMVO-0019 Incident Report Template or NMVO-0036 Deviation Report Template
- Defects observed during testing are handled according to NMVO-0025 Test Management and audit findings according to NMVO-0022 Audit Management

CAPA Management

- Described in NMVO-0020 CAPA Management
- The process covers FiMVO QMS and IT systems within FiMVO
- A ”basic” CAPA procedure
  - Problem identification
  - Review of the problem
  - Assignment in CAPA log
  - Root cause analysis
  - Determination of corrective and preventive actions
  - Execution of CAPAs
  - Documentation of the actions
  - CAPA closure
- Documented on NMVO-0034 CAPA Report Template

Audit Management

- Described in NMVO-0022 Audit Management
- The procedure includes internal audits performed by FiMVO QA and FiMVO audits performed by external parties
- Supplier audits performed by FiMVO are described in NMVO-0030 Service Level Management
- Internal audits are divided in two categories
  - Periodic review of systems
  - Review of QMS (incl. management reviews and internal audits)
- The frequency of system reviews depends on the criticality of the system

Information Security Management

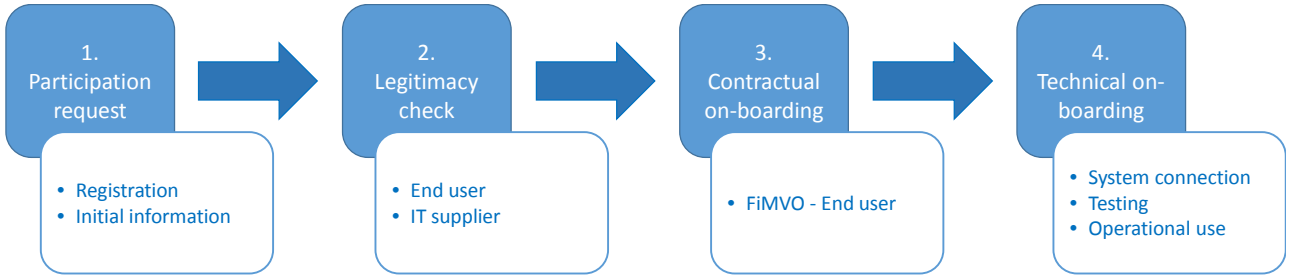
- Described in NMVO-0024 Information Security Policy
- The structure of the document follows ISO/IEC 27002:2013 Information technology – Security techniques – Code of practice for information security controls
- Sets requirements for confidentiality, integrity and availability for FiMVO members, employees and external parties
- Establishes controls for protecting FiMVO information and information systems against theft, abuse and other forms of harm and loss

Validation of FiMVS

- An overview of the required validation activities is provided in NMVO-0001 Validation Policy
- Based on ISPE – GAMP 5 A Risk-Based Approach to Compliant GxP Computerized Systems
- All systems categorised as GxP or Non-GxP → GxP systems have to be validated prior to release for business use and maintained in a compliant state during their entire life cycle
- System Life Cycle
  - Concept
  - Project
  - Operation
  - Retirement

On-boarding of pharmacies and wholesalers

- Described in NMVO-0031 On-boarding Process
- On-boarding process



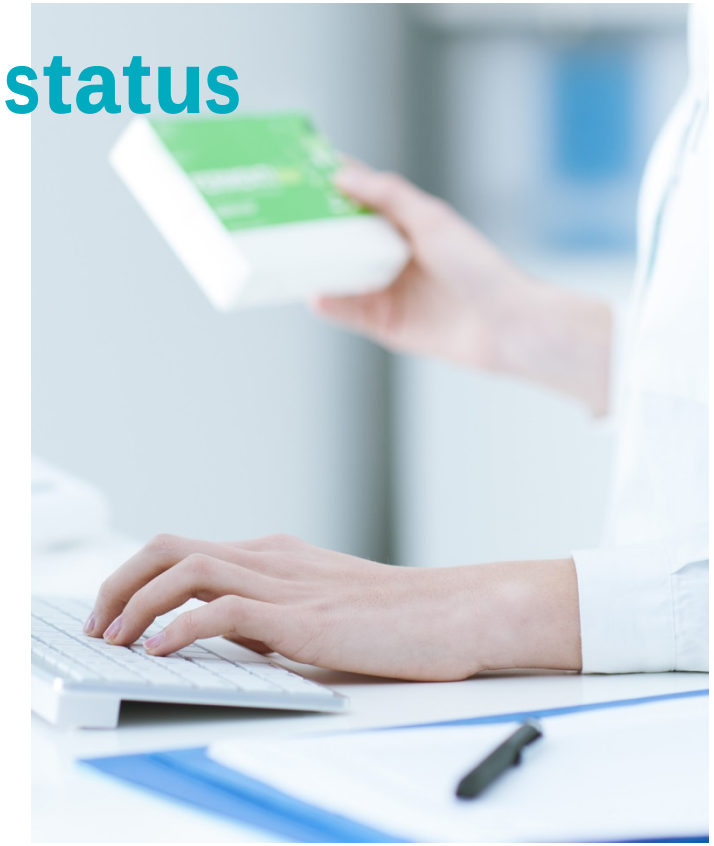
- NMVO-0037 Access Request Form (in English) or NMVO-0039 Access Request Form (FI)
- NMVO-0027 Access Management FiMVS describes the life cycle of a user account within FiMVS

Daily operation

- Business continuity and disaster recovery processes are described in NMVO-0029 Business Continuity Management
- The need for business continuity and disaster recovery is determined based on system criticality → required for GxP systems
- Business continuity plan (BCP) will be compiled by the system owner and QA representative of FiMVO
- When defining the strategy for disaster recovery the technical owner of the system and the IT service provider must be involved
- BCP must be periodically reviewed and rehearsed

FiMVO QMS / Current implementation status

- Approx. 75% of planned SOPs/FORMs have been approved and 25% are available as drafts
- Currently the focus is slowly changing from ”in place” to ”in use”
- IMS will be taken into use within the next couple of months allowing the change from paper-based document management to electronic document management and archiving
- The aim is to have a fully operational QMS in place and in use by the end of October 2018



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Thank you!

Any questions or comments?