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Pharmaville
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EU ePI Readiness Report

Prepared for **Pharmaville** · A snapshot of your organisation's readiness across the six core dimensions.

OVERALL READINESS

Mixed readiness

Strongest area: Governance and Lifecycle Management (Nearly Ready). Lowest readiness: HL7 FHIR, XML, and Validation (Partly Ready).

Not Ready	Partly Ready	Mostly Ready	Nearly Ready	Ready
0	2	2	2	0

PER-SECTION POSITION

01 **Content Architecture** — Partly Ready
0 Ready · 6 In Progress · 0 Not Started

02 **Metadata and Structural Requirements** — Mostly Ready
0 Ready · 6 In Progress · 0 Not Started

03 **Structured Authoring Workflow** — Mostly Ready
4 Ready · 0 In Progress · 2 Not Started

04 **HL7 FHIR, XML, and Validation** — Partly Ready
0 Ready · 6 In Progress · 0 Not Started

05 **Governance and Lifecycle Management** — Nearly Ready
5 Ready · 0 In Progress · 1 Not Started

06 **Organisational Readiness** — Nearly Ready
5 Ready · 0 In Progress · 1 Not Started

NEXT STEP

Email epi@docuvera.com to discuss this profile.

Structure. Govern. Scale.

Where to focus next

For each area: where you sit based on your answers, and what typically needs to be in place to reach Ready.

01 Content Architecture

Partly Ready

Based on your inputs, profiles at this stage typically have cataloguing under way but mapping to the EU ePI Common Standard incomplete. The next concentration of work is finishing the mapping, deciding which components will be authored once and reused, and naming a single authoritative source for approved content.

IN FLIGHT

JUST STARTED Existing SmPC, package leaflet, and labelling content has been inventoried. — *test*

JUST STARTED Product information has been mapped to the EU ePI Common Standard and applicable EMA/PLM guidance. — *test*

JUST STARTED Content has been broken into reusable, machine-readable, component-level structures. A governed, structured content authoring platform is ideal for this. — *test*

JUST STARTED Has safety, dosing, contraindication, and interaction language been intentionally written and reviewed for reuse across products and documents, with controlled terminology applied consistently? — *test*

JUST STARTED Teams understand the difference between document-level and component-level versioning. — *test*

JUST STARTED A single, authoritative source has been identified for approved product information components. A governed, structured content authoring platform is ideal for this. — *test*

02 Metadata and Structural Requirements

Mostly Ready

Based on your inputs, profiles at this stage typically have the metadata model largely operational. The close-out work is confirming orphan-detection and broken-link checks fire before publication rather than after, and verifying clean integration with downstream authoring, submission, approval, and publication.

IN FLIGHT

NEARLY DONE Required metadata fields have been defined for each content component. — *test*

NEARLY DONE Metadata includes effective dates, regulatory status, language version, document type, authorisation context, and change flags. — *test*

NEARLY DONE Language-specific and language-agnostic metadata have been separated. — *test*

NEARLY DONE Relationship data has been modelled for cross-references, dosage forms, warnings, populations, and interactions. — *test*

NEARLY DONE Orphaned references and broken links can be detected before publication or submission. — *test*

NEARLY DONE Metadata can support PLM Portal authoring, submission, approval, and publication workflows. — *test*

03 Structured Authoring Workflow

Mostly Ready

Based on your inputs, profiles at this stage typically have the workflow operational. The close-out work is closing remaining training gaps, confirming the reviewer interface holds under real submission pressure, and validating that escalation paths work in practice rather than just on paper.

NOT STARTED

- Authors can work in a structured content environment without relying only on Word documents and email review.
- Reviewers can view content in a user-friendly interface, not only as raw XML or database records.

04 HL7 FHIR, XML, and Validation

Partly Ready

Based on your inputs, profiles at this stage typically have FHIR understanding in place but operational validation not yet running. The next work is confirming the selected system can produce FHIR-conformant XML, requesting sample files from vendors, and validating against the EU ePI Common Standard.

IN FLIGHT

- UNDERWAY **The organisation has reviewed the current EMRN ePI Implementation Guide.** — *test*
- UNDERWAY **The selected system can generate valid FHIR-conformant XML.** — *test*
- UNDERWAY **Sample FHIR XML files have been requested from technology vendors or implementation partners.** — *test*
- UNDERWAY **Sample files have been validated against the EU ePI Common Standard and current implementation guidance.** — *test*
- UNDERWAY **FHIR validation has been built into recurring quality gates, not treated as a one-time check.** — *test*
- JUST STARTED Regulatory Affairs and IT understand the role of HL7 FHIR in EU ePI. — *test*

05 Governance and Lifecycle Management

Nearly Ready

NOT STARTED

- ○ Resubmission and regeneration of FHIR XML have clear operating procedures.

06 Organisational Readiness

Nearly Ready

NOT STARTED

- ○ Leadership understands that ePI readiness spans content, workflow, governance, and technology.

NEXT STEP

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