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EU READINESS

EU Readiness Assessment Checks

De-risking your EU submission through a structured readiness check.

Marketing Authorization Holder (MAH) as a Service

Your compliant footprint in Europe without operational overhead.

Post – Market – Services

Full lifecycle execution, from regulatory strategy to post-market pharmacovigilance.

Pre - Submission Checks

EU Readiness Assessment Packages

De-risking your EU submission through a structured readiness check.

CMC / GxP Readiness Check

Clinical Evidence Readiness Check

Regulatory Strategy & and Market Access Readiness Check

Post - Market Service

Marketing Authorization Holder (MAH) as a Service and Post Market Activities

Your compliant footprint in Europe without operational overhead.

- EU-based **MAH function.**
- Responsible Person for Wholesaling (**GDP**).
- **QP** batch release under our Manufacturing & Importation Authorization (**MIA**).
- EU QPPV and local pharmacovigilance.
- Scientific Services, Promotional Material Review (including responsible functions like DIO and MIO).
- Variation handling and lifecycle management.

EU Readiness Assessment Packages

De-risking your EU submission through a structured readiness check.

CMC / GxP Readiness Check

A thorough evaluation of manufacturing, quality and supply-chain compliance from an EU perspective.

- Review of the CMC dossier to identify required modifications prior to submission.
- Assessment of GMP status and qualification needs for API and drug product manufacturers.
- Evaluation of supply-chain dependencies, including the need for audits or pre-submission inspections.
- Analysis of quality management systems, including technical quality agreements (TQAs).
- Planning of post-approval variations in the phase of submission of the MAA.
- Support in identification of service providers such as secondary packaging and distribution (e.g. 3PLs).

Outcome: Assessment report of the dossier, identification of potential issued which may occur during the MAA, manufacturing and quality system compliance with EU GMP and GDP standards, including gap analysis and action plan for alignment with EU requirements.

EU Readiness Assessment Packages

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Clinical Evidence Readiness Check

Confirm your clinical evidence is suitable for EU authorities.

A review of your clinical evidence to determine suitability for EU authority review, including alignment with EMA or national guidance.

- Assessment of clinical datasets against EU guidelines and scientific expectations.
- Identification of evidence gaps and design of potential bridging approaches.
- Considerations for EU legal representation, CTIS submissions and GCP compliance.
- Preparation for national or EMA Scientific Advice.

Outcome: report of clinical data suitability and evidence alignment with EU regulatory expectations, including identification of data gaps and recommendations to achieve submission readiness.

EU Readiness Assessment Packages

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Regulatory Strategy & and Market Access Readiness Check

A comprehensive review of all regulatory and procedural prerequisites for successful EU submissions:

- Analysis and/or support with the EU regulatory strategy including check of procedural options, timelines and submission routes.
- SME status eligibility, procedure and affiliation to an EU based SME (mandatory).
- Evaluation of PIP and ODD requirements (as applicable).
- Pre-submission conditions (central and local).
- ERA preparation.
- Preparation of Module 1 regional documents (including SmPC, PIL, labelling).
- Onboarding for national portal(s) and/or EMA portals (Syncplicity, PLM, IRIS).
- Market Access: Anticipated evidence requirements under the EU HTA Regulation (Joint Clinical Assessment procedure, Joint Clinical Consultation option).

Outcome: Evaluation report of regulatory prerequisites for EU submission, including recommendations on procedure selection, identification of missing documentation and a consolidated overview of required activities and indicative timelines to achieve MAA readiness.

Marketing Authorization Holder (MAH) as a Service and Post Market Activities

Your compliant footprint in Europe without operational overhead.

Beyond Readiness: Establishing Your EU Operational Framework

A successful EU launch requires a compliant and durable presence in Europe.

We provide the frameworks and roles necessary to operate legally and efficiently without requiring you to build infrastructure from scratch.

Our MAH and post-approval services include:

- EU-based MAH function.
- Responsible Person for Wholesaling (GDP).
- QP batch release under our Manufacturing & Importation Authorization (MIA).
- EU QPPV and local pharmacovigilance (PV).
- Scientific Services, Promotional Material Review (including responsible functions like DIO and MIO).
- Variation handling and lifecycle management.

These services provide a stable operational foundation and ensure long-term compliance across the product lifecycle.

https://www.regenold.com

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