



## Regulatory Landscape Assessment Checklist

**Instructions:** A regulatory landscape assessment is a critical first step in preparing for a product registration, as it identifies current guidelines, requirements, and processes for the country of interest. Typically, a landscape assessment is conducted in consultation with personnel from the regulatory authority, either in person or via phone. If this is not an option, a desk-review landscape assessment can be utilized, though it will be most helpful to engage a local consultant for confirmation of your findings online, as some may be outdated. This Regulatory Landscape Assessment checklist will guide you through the essential regulatory information to consider when conducting your own landscape assessment.

### GENERAL REGULATORY TOPICS

Identify the country's regulatory authority and website, if available. Collect published regulations and/or guidelines, if available

Establish points of contact at regulatory authority and collect contact details

Confirm product classification (e.g., pharmaceutical/medicine, medical device, combination, innovator or generic)

Confirm trademark requirements (e.g., country of origin, local, classification, etc.)

Define requirements for the Marketing Authorization Holder (MAH) and/or Local Technical Representative (LTR)

Confirm current product registration and Good Manufacturing Practice (GMP) guidelines

Confirm required dossier format (e.g., ICH CTD or country-specific)

Confirm submission process, including how to submit (e.g., online or hard copy), who must submit (e.g., MAH, LTR, other), and where to submit if hard copy required (e.g., contact person, contact details, address)

Confirm application fees for registration and GMP inspection, including when they should be paid and any other additional costs to expect

Confirm dossier evaluation process and timeline

Confirm if samples are required for registration, including the quantity, condition (e.g., labeling), and to whom they should be shipped and when

Confirm labeling requirements for registration

Confirm requirements for authentication of administrative documents

Confirm language requirements for the dossier

Identify the process for post-marketing changes and request appropriate guidelines

### TECHNICAL REGULATORY TOPICS

Confirm clinical study requirements (e.g., local pharmacokinetics study requirements, Good Clinical Practice requirements, etc.)

Confirm product stability requirements (e.g., climatic zone, minimum data, required batches, etc.)

Confirm product specifications with the local guidelines

Confirm GMP requirements, including if and when an in-person or desktop audit may be required

Identify pharmacovigilance requirements, including data collection and reporting