Preparing for a Regulatory Submission in a Low- or Middle-Income Country Checklist

Instructions: This checklist will guide you through the essential steps when preparing a regulatory submission in a low- or middle-income country.

- ☐ Establish a strategy for your product, which can include critical aspects of the product such as the proposed indication, specification, shelf life, labeling, etc.
- ☐ If working with third-party vendors or partners, establish a working group. Coordinate a kick-off meeting that includes orientation to the product and strategy.
- ☐ Identify country-specific guidelines for medicines or medical devices in the country of interest. Read thoroughly in order to understand the relevant requirements for your product.
- ☐ Determine whether you will need to conduct a regulatory landscape assessment to confirm registration guidelines and requirements. See Regulatory Landscape Assessment checklist in toolkit.
- ☐ Identify sample requirements for registration (e.g., quantity and labeling of samples) and whether an import permit will be required to get the samples into the country.
- ☐ Identify labeling requirements for the product. Draft and/or revise labeling as needed for submission.
- ☐ Identify Good Manufacturing Practice (GMP) inspection requirements and whether a separate GMP application is required. If required, determine the timing and content of the GMP application.
- ☐ If a local technical representative (LTR) is required, identify who it will be early in the process. Begin contracting early, since some submission documentation may be required from them.
- ☐ Conduct a gap assessment between the product dossier and the country-specific guidelines. Determine gaps and resolve them. See Dossier Preparation: Gap Analysis template in toolkit.
- ☐ Identify application fee structure and timing. If fees are required to be paid prior to application submission, ensure this is completed and documented.
- ☐ Identify submission process (e.g., electronic or paper copy) and format (e.g., CTD) and prepare for any in-person travel that may be required for in-person submission.