

3.2.R Regional Information

Any additional drug substance and/or drug product information specific to each region should be provided in section R of the application. Applicants should consult the appropriate regional guidance and/or regulatory authorities for additional guidance. Some examples are as follows:

Executed Batch Records (USA only)

- Number of batches should be discussed with the FDA prior to submission
- Method Validation Package (USA only)
- See 3.2.R.2 Method Validation Package.doc
- Comparability Protocols (USA only)
- Well defined, detailed, written plan for accessing specific CMC changes
- Description of Change
- Specific tests and studies to be performed
- Analytical Procedures
- Acceptance Criteria
- Justification for tests, procedures, and acceptance criteria.
- Number and size of batches to be compared
- Stability studies

Process Validation Scheme for the Drug Product (EU only)

Where validation is still to be completed, a summary of the studies intended to be conducted should be provided.

Medical Device (EU only)