Reliance in pre-market processes

- Reliance is used for class I and II (IIa & IIb) products that have been registered and marketed in recognized countries.

Reliance pathways allow for shorter review time for:
- Market approval (MA)
- Significant changes
- Renewal and non-significant changes - declaration

- The MD validity is registered in accordance with recognized country MA.
- Labeling is approved in accordance with recognized country MA.
Reliance in post-market processes

- In general, reliance is based on requirement for MA holder (MAH) to report of any incidents (e.g., FSN, FSCA, recall) that accord in a recognized country.

- Other PM Information sources:
  - Reporting of local health organizations and patients
  - Public reporting of incidents from recognized countries
  - Specific RFIs from recognized countries
Key considerations with reliance

• Multiple countries -> multiple regulatory schemes
• Requirements from MAH versus manufacturer
• Timing of reporting (initial signal or after full investigation)