DHF, DMR, DHR, DDF, MDF, TD

How and where are they used?

FDA

- **Design History File (DHF) - (21 CFR 820.30)**
  Tracks design development.
- **Device Master Record (DMR) - (21 CFR 820.181)**
  Focuses on manufacturing processes.
- **Device History Record (DHR) - (21 CFR 820.184).**
  Aggregates manufacturing documents for record.

ISO 13485

- **Design & Development File (DDF)**
  Captures design evidence.
- **Medical Device File (MDF)**
  Manufacturing instructions and validation of processes for manufacture.

EU MDR

- **Technical documentation (TD)**
  File for submission including DHF + DMR + Post-market documentation.