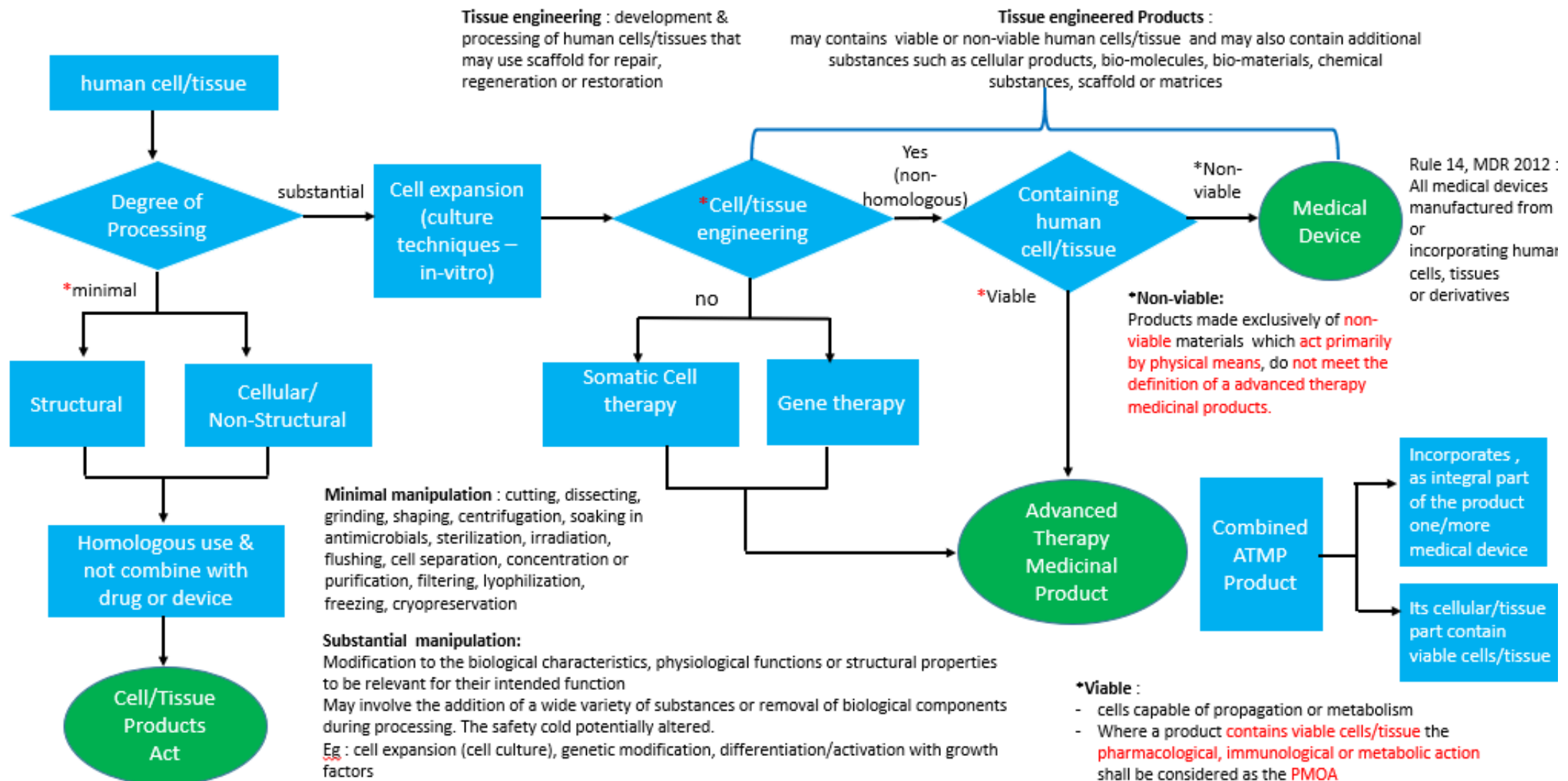


Penentuan Kawalan Terhadap *Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's)*

1. In classifying HCT/P as minimally or substantial manipulated: case by case, review of manufacturing process, review the availability of clinical data to support the intended use.
2. **Degree of processing**
 - 2.1 **Minimal:**
 - In respect of Structural tissue: processing does not alter the original characteristics that are relevant to the claimed utility of the product for reconstruction, repair or replacement)
 - In respect of Cellular/Non-Structural tissue: processing does not alter the relevant biological characteristics that are relevant to their claimed utility (include cell separation techniques: density gradient separation, selective removal of B-cells, T-cells, red blood cells or platelets, cell selection to enrich the product with CD34+ cells and centrifugation, lyophilisation, cryopreservation, freezing)
 - 2.2 **Substantial:**
 - Modification to the biological characteristics, physiological functions or structural properties to be relevant for their intended function
 - May involve the addition of a wide variety of substances or removal of biological components during processing. The safety could potentially altered.
Eg : cell expansion (cell culture), genetic modification, differentiation/activation with growth factors
3. **Type of HCT/P**
 - 3.1 **Structural:** support or serve as a barrier/conduit or connect, cover, cushion
 - 3.2 **Cellular/Non-Structural:** Serve metabolic or other biochemical roles in the body - hematopoietic, immune and endocrine functions)
4. **Original relevant characteristics of structural tissues:** generally, include the properties of that tissue in the donor that contribute to the tissue's function or functions. Relating to the tissue's utility for reconstruction, repair, or replacement
5. **Biological Characteristics (for cellular/non-structural):** The properties of this HCT/P in the donor that contribute to the HCT/Ps function(s).
Eg.: differentiation & activation state, proliferation state, proliferation potential and metabolic activity

Product Classification Determination : Product Contains Human Cell/Tissue



Jurisdiction over Human Cell/Tissue Based Products

USFDA : Sect 351 of PHS Act and/or Food Drug&Cosmetic Act
 HC : Medical Devices Regulations (SOR/98/282), Food & Drugs Act
 EU : Reg EC 1394/2007 (repealing 93/42/EEC)
 HSA : Health Products Act (HPA; Health Products (Medical Devices) Regulations 2010)

