Sneak Peek

Drug-Device Combination Products:

Quality & Regulatory Requirements

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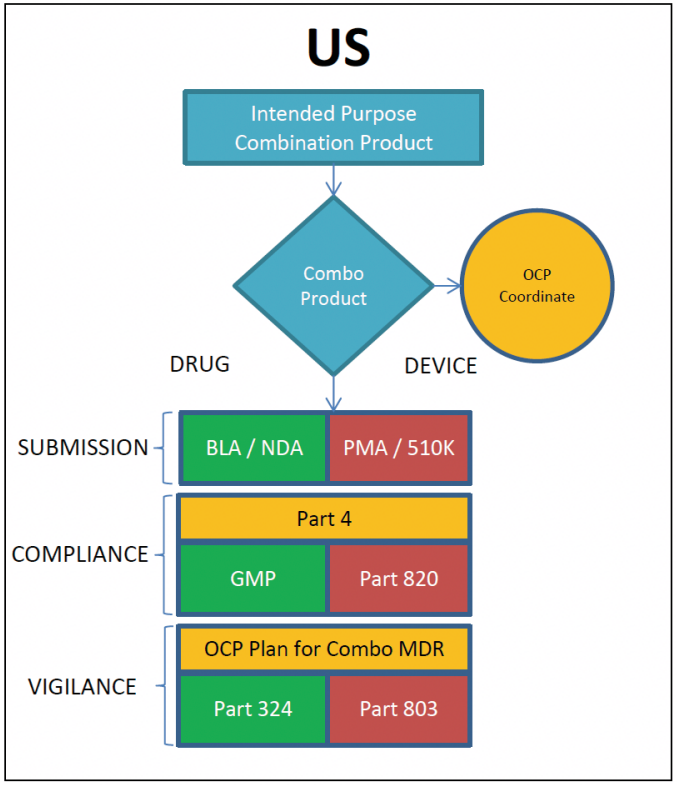
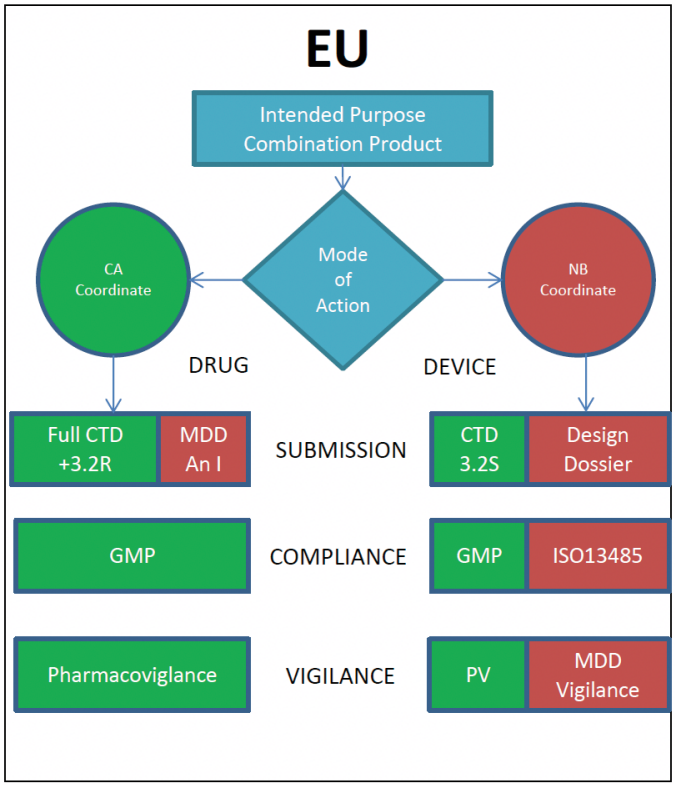
ONLINE
TRAINING

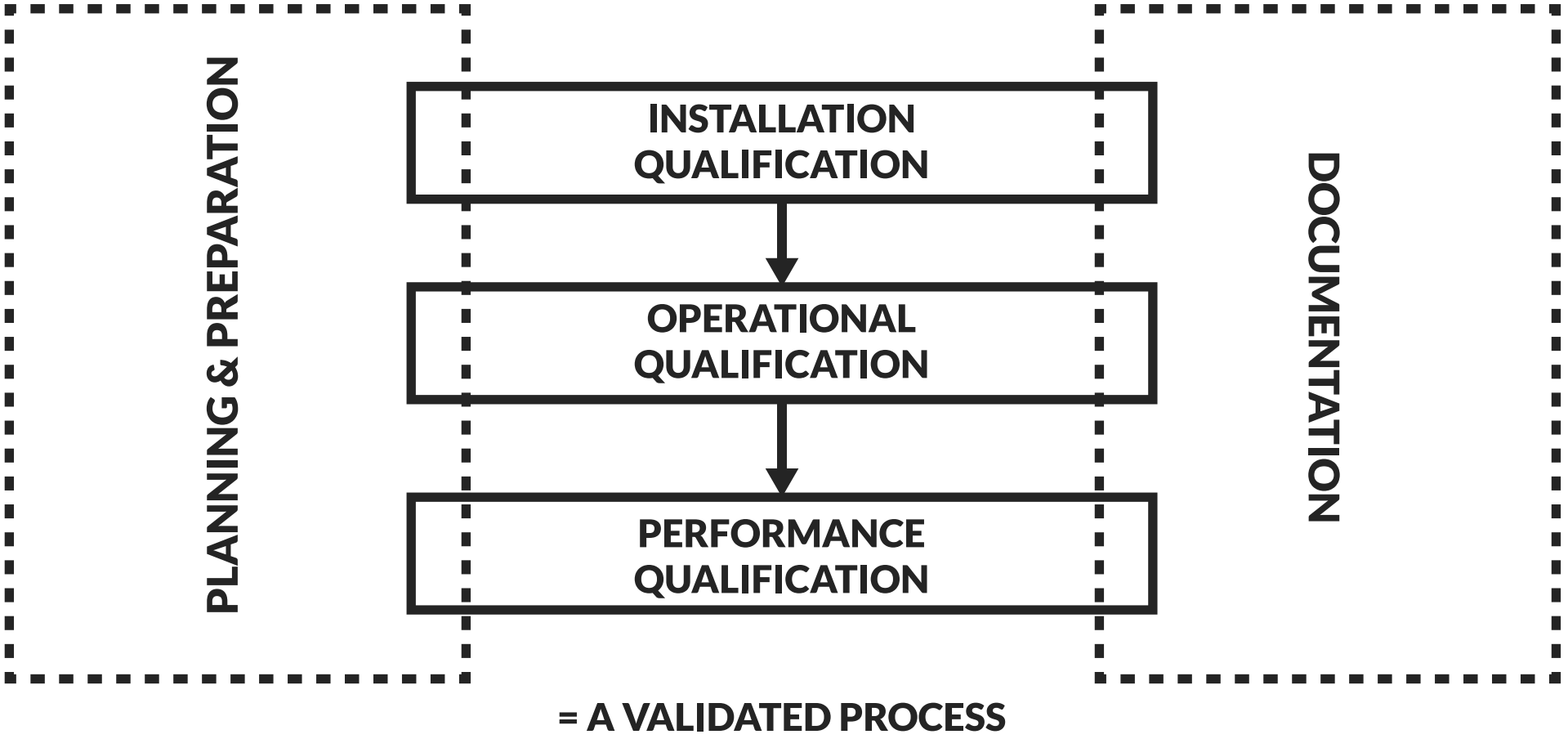
Combination Products and How they are regulated – Graphical Summary





CA = Competent Authority, OCP = Office of Combination Products, NB = Notified Body

Device Process Validation Elements

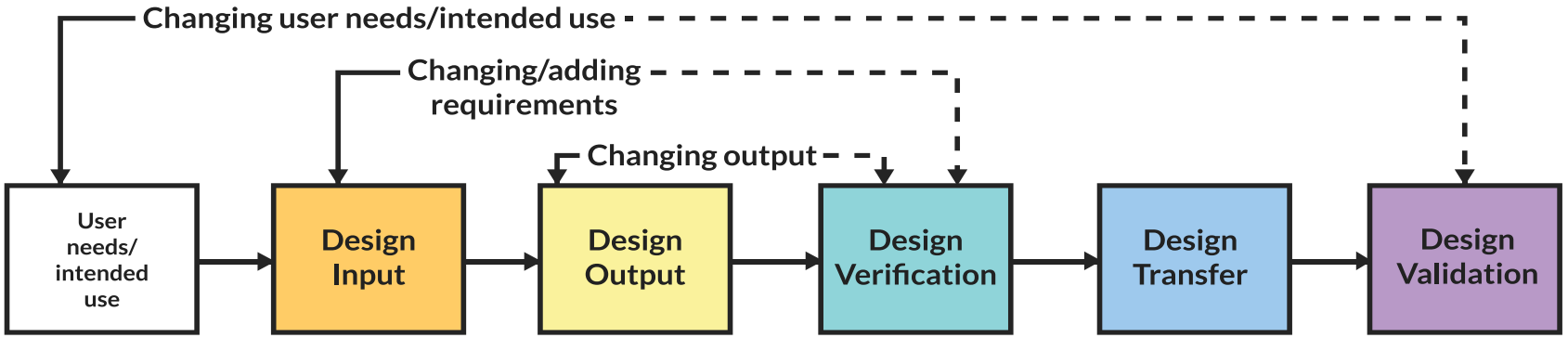


- Applies to Device itself, and to Combination Product

Considering Impact of a Change

Always evaluate …

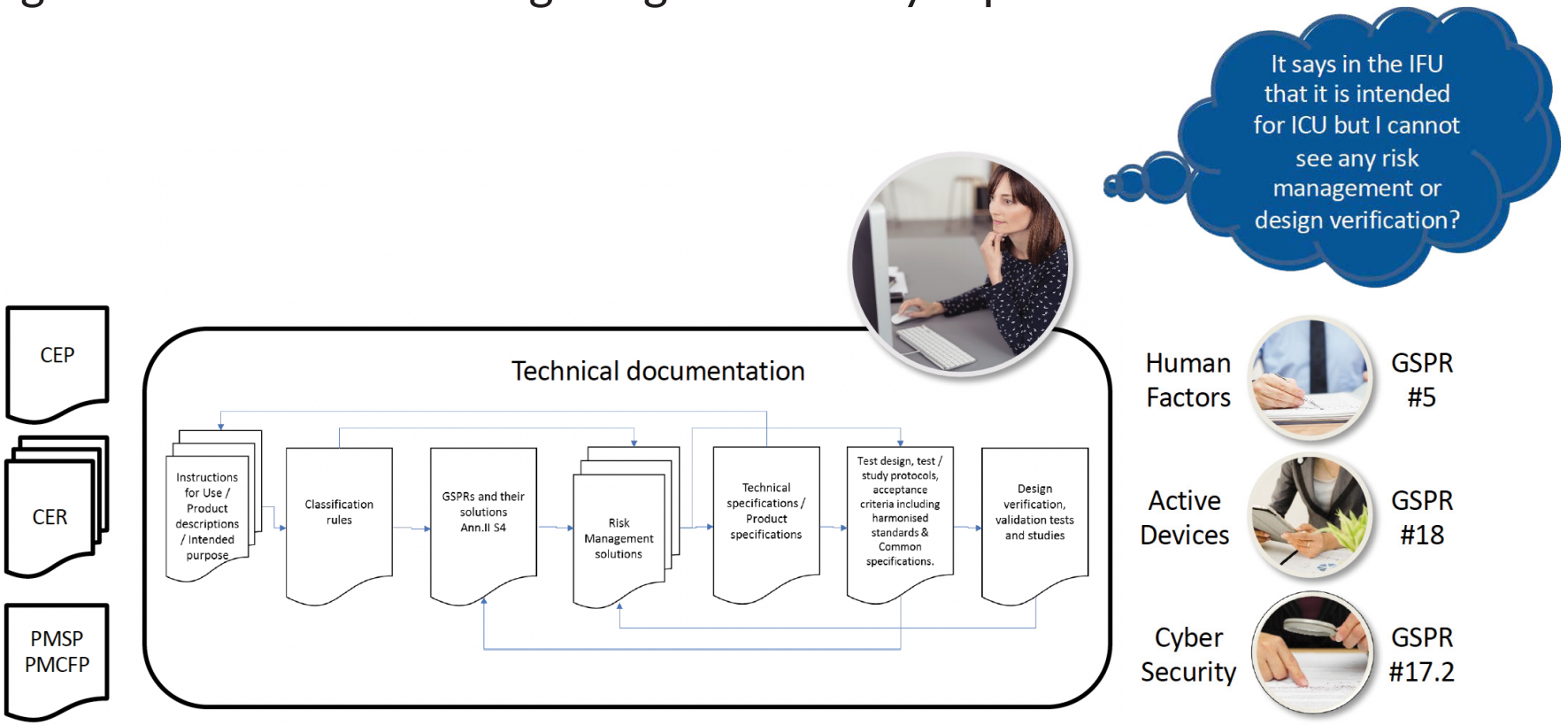
- Impact on risk profile: Increasing? Altering risk control? New hazards?
- Impact on regulatory submissions: BLA amendment? Significant change?
- Impact on other devices/accessories: Interfaces to other products?
- Does change affect essential outputs?
- Does scope imply need to update Design Plan? Conduct Design Review?
- Impact on overall QS: Prod. & Process Controls? Process validation?
- How far back in the Design Control process do we go …



Product Review Process in Europe

Notified body reviewers use ALL tech docs

- Risks identified
- Risk controls iaw State of the Art (SOTA)
- Design Verification iaw Harmonised Standards/Common Specification
- Design Validation achieves high degree of safety & performance



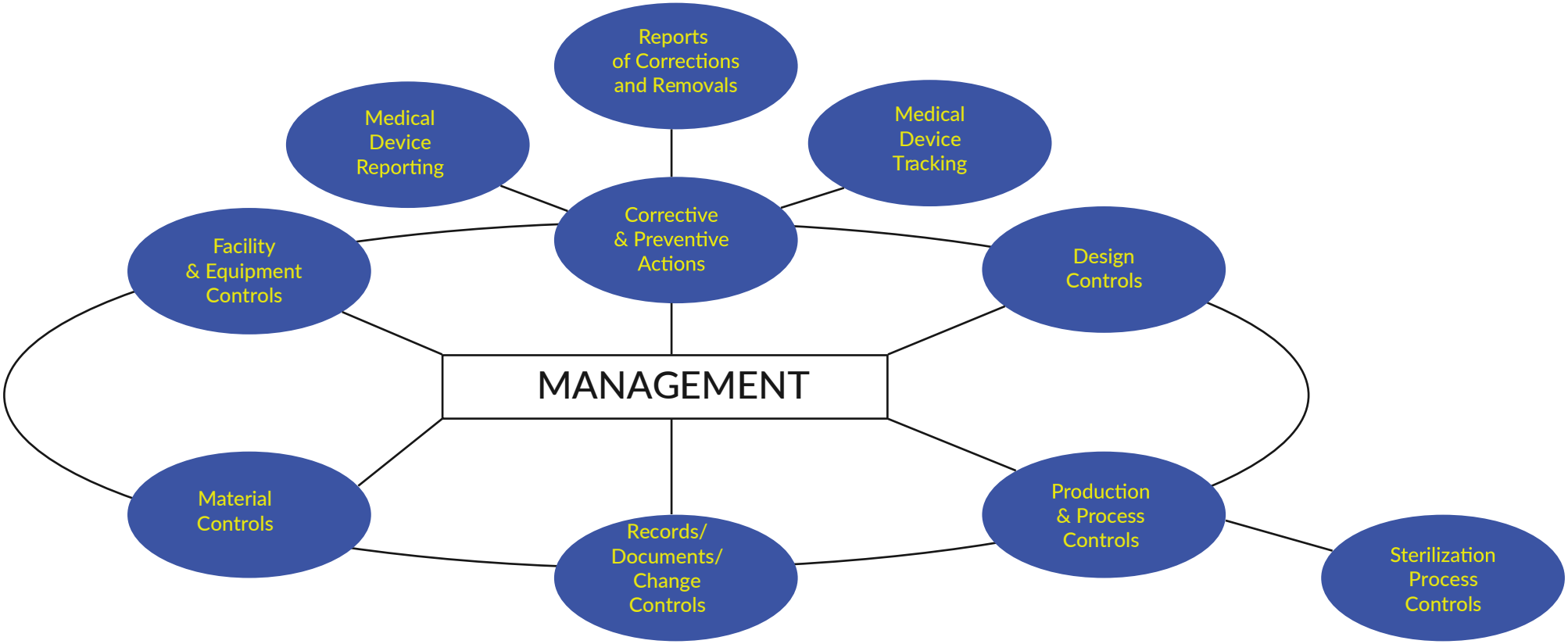
Options for Compliance to cGMPs

Two options for demonstrating compliance with the cGMP requirements applicable to a copackaged or single-entity combination product:

- (1) To demonstrate compliance with the specifics of all CGMP regulations applicable to each of the constituent parts included in the combination product

- To demonstrate compliance with the specifics of either the drug CGMPs or the QS regulation, rather than both, when the combination contains both a drug and a device, under certain conditions

FDA Quality System Inspection Technique (QSIT) Subsystems



Registration

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