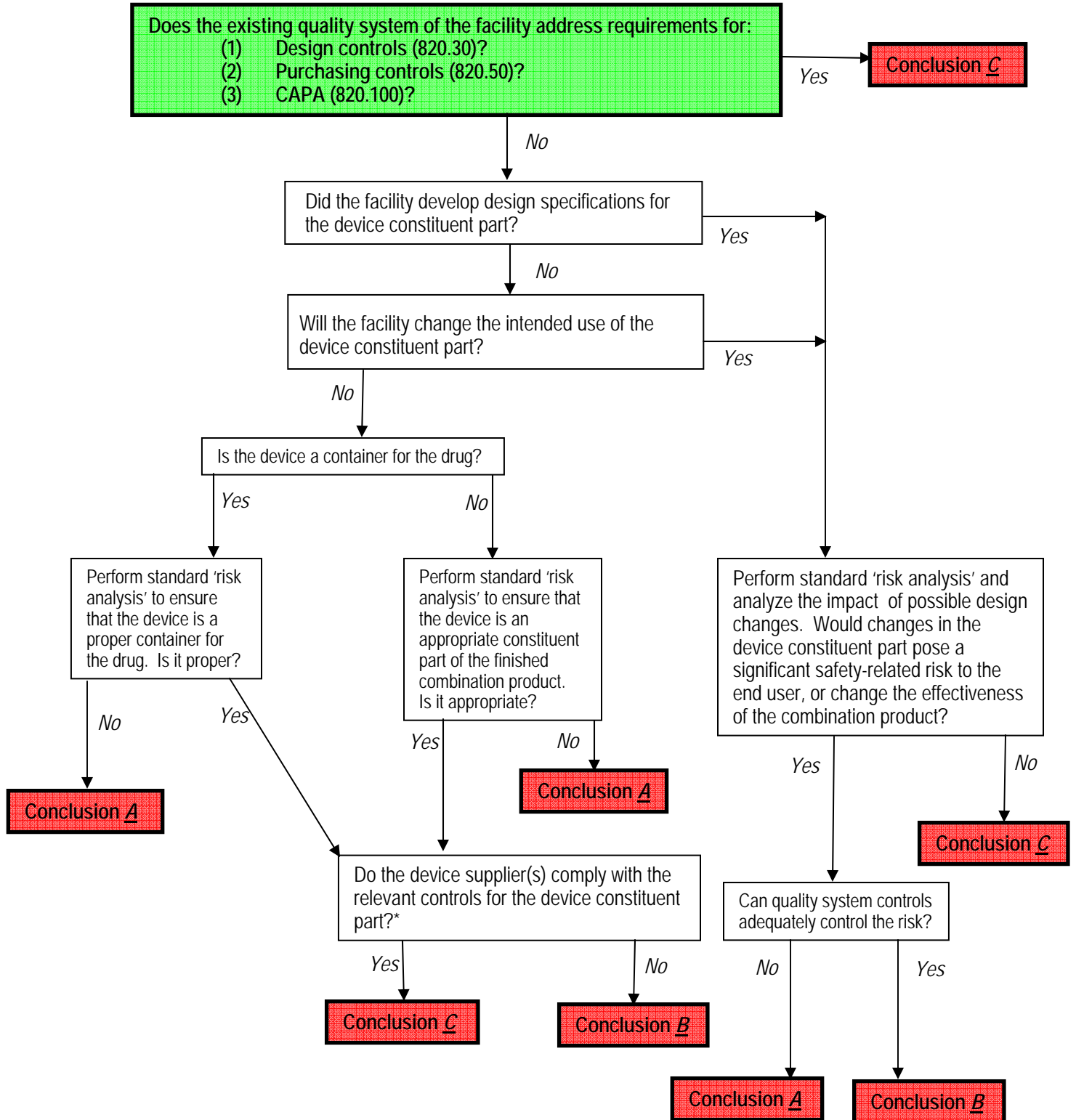


Appendix A: Facility Operating Under Parts 210/211
Adding a Device Constituent Part to a Single Entity Combination Product



**Note: Even if the analysis indicates that the facility does not need to implement purchasing controls, this step of the analysis should be performed in order to ensure appropriate supplier controls.*

Conclusion A:
Device must be re-designed.

Conclusion B: The facility must implement the relevant control to the degree needed to ensure product quality.

Conclusion C: If you are analyzing design controls or purchasing controls, the facility does not have to implement this control. If you are analyzing CAPA, the facility should implement CAPA and/or integrate CAPA requirements with its existing system to the degree needed to ensure product quality.