

Goals/ Definition

Develop a plan for the supply chain and associated logistics to ensure product can be distributed to the appropriate locations for launch.

Turn and move all raw materials to the final combination products and then transfer to customers/users.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> ▪ Supply chain / logistics plan in place 	<ul style="list-style-type: none"> a) Sufficient inventory build up based on demand forecast and management of on-going supply chain b) Transportation design validation reports developed from commercially representative lots c) Verification that incoming, in-process, and final commercial packaging specifications and labeling are in place d) Definition and implementation of tracking capabilities with distributors e) Confirmation of import and export practices meeting local laws and regulations f) Establishment of mechanisms for recalls g) Commercial packs designed and ready for regulatory submission at risk of potential changes by regulators just prior to approval 	