This Work Breakdown Structure (WBS) Checklist is designed to identify key phases and work packages (i.e., documents) typically required for combination product development. Detailed templates and timelines are available by contacting Kymanox at info@kymanox.com.

WBS ID	Task Name	Date Completed
1	**Combination Product Design & Development**	
1.1	**Design Controls**	
1.1.1	**Initiation**	
1.1.1.1	Project Start	
1.1.1.2	Project Kickoff and Management	
1.1.1.3	Project Charter	
1.1.1.4	Project Roster	
1.1.2	**Design Input Phase**	
1.1.2.1	Design and Development Plan	
1.1.2.2	Quality Plan	
1.1.2.3	Project Schedule	
1.1.2.4	User Needs Document	
1.1.2.5	Design Input Requirements	
1.1.2.6	Risk Management Plan	
1.1.2.7	Hazard Analysis	
1.1.2.8	Use Risk Assessment	
1.1.2.9	Design Risk Assessment	
1.1.2.10	Risk Assessment Summary Report	
1.1.2.11	Traceability Matrix	
1.1.2.12	Design Input Phase Review	
1.1.3	**Design Output Phase**	
1.1.3.1	Design Specification	
1.1.3.2	Product Component and Packaging Drawings	
1.1.3.3	Manufacturing Documentation	
1.1.3.4	Artwork and Labeling - Clinical Trial	
1.1.3.5	Instructions for Use	
1.1.3.6	Traceability Matrix	
1.1.3.7	Design Output Phase Review	
1.1.4	**Design Verification and Validation Phase**	
1.1.4.1	Design Verification and Validation Master Plan	
1.1.4.2	Design Verification Protocols	
1.1.4.3	Design Verification Reports	
1.1.4.4	Design Validation Protocols	
1.1.4.5	Design Validation Reports	
1.1.4.6	Design Verification and Validation Summary Report	
1.1.4.7	Design Verification and Validation Phase Review	
1.1.5	**Design Transfer Phase**	
1.1.5.1	Finalize Manufacturing Documentation	
1.1.5.2	Finalize Artwork and Labeling	
1.1.5.3	Process Risk Assessment	
1.1.5.4	Process Validation Protocols	
1.1.5.5	Process Validation Reports	
1.1.5.6	Risk Management Report	

WBS ID	Task Name	Date Completed
1.1.5.7	Design History File Index (DHF Index)	
1.1.5.8	DHF Audit	
1.1.5.9	Design Transfer Phase Review	
1.2	**Clinical Studies and Clinical Supply**	
1.2.1	**Phase 1 Study**	
1.2.1.1	Phase 1 Clinical Product Supply	
1.2.1.1.1	Drug Product Batch Manufacturing	
1.2.1.1.2	Combination Product Assembly and Packaging	
1.2.1.1.3	Finished Goods Distribution	
1.2.1.2	Phase 1 Study Execution	
1.2.1.2.1	Final Protocol Approval (Phase 1)	
1.2.1.2.2	Study Execution (Phase 1)	
1.2.1.2.3	Clinical Study Report (CSR) Approved (Phase 1)	
1.2.2	**Phase 3 Study**	
1.2.2.1	Phase 3 Clinical Product Supply	
1.2.2.1.1	Drug Product Batch Manufacturing	
1.2.2.1.2	Combination Product Assembly and Packaging	
1.2.2.1.3	Finished Goods Distribution	
1.2.2.2	Phase 3 Study Execution	
1.2.2.2.1	Final Protocol Approval (Phase 3)	
1.2.2.2.2	Study Execution (Phase 3)	
1.2.2.2.3	Clinical Study Report (CSR) Approved (Phase 3)	
1.3	**Regulatory Filings**	
1.3.1	**IND Filing**	
1.3.1.1	Determine Need for Pre-IND Type B Meeting	
1.3.1.2	Request Pre-IND Type B Meeting	
1.3.1.3	Hold Pre-IND Type B Meeting	
1.3.1.4	IND Submission	
1.3.1.5	IND Approval	
1.3.2	**IND Amendment** (as needed for Phase 3)	
1.3.2.1	IND Amendment Submission (as needed for Phase 3)	
1.3.2.2	IND Amendment Approval (as needed for Phase 3)	
1.3.3	**NDA Filing**	
1.3.3.1	Request Pre-NDA Type B Meeting	
1.3.3.2	Hold Pre-NDA Type B Meeting	
1.3.3.3	NDA Submission	
1.3.3.4	NDA Approval	
1.4	**Commercial Launch Readiness**	
1.4.1	**Execute Final Labelling Updates**	
1.4.2	**Commercial Manufacturing**	

Things to keep in mind

- Timing of these phases can vary widely depending upon the type of product being developed
- Detailed project plans, Standard Operating Procedures (SOPs), templates, and a MS Word version of this WBS checklist are available by contacting Kymanox at info@kymanox.com.