6 WAYS to Getting the Supply Chain in Sync

	GLOBAL COMPLEXITY	INTEGRITY	REQUIREMENTS GUIDELINES	RESOURCES	FRAGMENTATION	IMPLEMENTATION OF CHANGES
CHALLENGES	Multi-sites: • Manufacturing • Distribution • Testing	• Counterfeit • Theft	Divergent: • Guidelines • Data Requirement	Capacity Issues: • Backlog • Reviews • Inspections • Training to Strengthen Expertise	Mandatory: • Minimum Inventory • Product Specific Monograph (PSM) Adherence • Release Testing	Divergent: • Submission Categories • Review Times
	1	2	3	4	5	6
ENABLERS	• Allow Flexible Multi-site Activities	• Anti-Counterfeit • Secure Supply Chain	Convergent: • Guidelines • Data Requirement	Mutual Recognition: • Reviews • Inspections • WHO Training and Workshops	• Inventory to Meet Needs • PSM not Applicable for Biotech Products • Reduce Redundant Release Testing	• Standard Submission Categories • Standard Defined Review Times

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