Pharmaceutical Product Lifecycle Activities

Do your research, development, and commercial manufacturing of drug products and APIs, biotechnology, and biological products include the critical product lifecycle activities?

- ☐ Pharmaceutical Development
- ☐ Technology Transfer
- ☐ Commercial Manufacturing
- ☐ Product Discontinuation

If your answer is 'YES' to the above activities, please follow the below checklist to check the degree of assurance throughout the pharmaceutical product lifecycle.

Activity Number	Technical Activity	Sub-technical activity	YES or NO	Explanation if answer is 'NO'
1	**Pharmaceutical Development includes**	Drug substance development	☐ YES ☐ NO	
		Formulation development (including container/-closure system)	☐ YES ☐ NO	
		Manufacturing of investigational product	☐ YES ☐ NO	
		Delivery system development (where relevant)	☐ YES ☐ NO	
		Manufacturing process and technical specification development	☐ YES ☐ NO	
		Commercial scale-up and production feasibility	☐ YES ☐ NO	
		Analytical method development	☐ YES ☐ NO	
2	**Technology Transfer**	Transfer product and process knowledge to production	☐ YES ☐ NO	
		Development is converted into production specification and production testing possibilities	☐ YES ☐ NO	
		Transfers are within and between manufacturing and testing sites	☐ YES ☐ NO	
		Process validation is included as a part of technology transfer	☐ YES ☐ NO	
		Continual improvement during manufacturing	☐ YES ☐ NO	

Activity Number	Technical Activity	Sub-technical activity	YES or NO	Explanation if answer is 'NO'
3	**Commercial Manufacturing assures**	Raw material procurement and quality control activities are carried out	☐ YES ☐ NO	
		All relevant facilities, utilities, and equipment are provided	☐ YES ☐ NO	
		Commercial production, packaging, and labeling are done as per specification	☐ YES ☐ NO	
		Quality control plans are established and monitored	☐ YES ☐ NO	
		Quality Assurance is integrated with QMS toward product realization	☐ YES ☐ NO	
		Storage and warehousing are appropriate as per requirements (special storage facilities like cold storage, minus degree storage, etc.. available if required)	☐ YES ☐ NO	
		Product release is a systematic approach and traceable	☐ YES ☐ NO	
		Distribution and supply chain (excluding wholesaler activities)	☐ YES ☐ NO	
4	**Product Discontinuation involves**	Archival and documentation of discontinued products	☐ YES ☐ NO	
		Controlled samples must be archived for a pre-defined period	☐ YES ☐ NO	
		Continued product assessment (complaint handling, feedback, stability) and regulatory reporting, if any.	☐ YES ☐ NO	

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