30 August 2024

ePQS – Matrix of various Product and Application types as they pertain to eCTD submissions

Product Type	FPP	FPP	FVP	APIPQ	APIMF
Product sub-type	ВТР	FPP	No value ¹	No value ¹	No value ¹
Application: Prequalification	PQP	PQP	PQP	PQP	APIMF
Application subtype(s)	Abridged Full	Abridged Full	Abridged Product Extension Standard	Abridged Conversion Parallel Standard	Abridged Standard
Application: EUL	EUL	EUL	EUL		
Application subtype(s)	EUL - Abridged ² EUL - Full	EUL - Abridged ² EUL - Full	None ³ Product Extension		
Application: Post-PQ change	PPQC	PPQC	PPQC		PPQC
Application subtype(s)	AN eCTD-Baseline IN Major Minor SRA-IN	AN eCTD-Baseline IN Major Minor SRA-IN	eCTD-Baseline Type A (Major) Type N (Minor)		AAN AIN Major Minor eCTD-Baseline Update
Application: Requalification	RQAP	RQAP			
Application subtype(s)	None ³	None ³			
Application: Annual Report			AR		
Application subtype(s)			None ³		
Application: Reassessment			REAS		
Application subtype(s)			None ³		

¹ Meaning, no value is expected for these product types

² This value is being introduced in June/July to validator.

³ Meaning a value of "None" should be entered.