Compare Detailed requirements such as manufacturing, trial, and distribution for different countries/entities

Example: You are running a clinical trial for a small molecule in the USA and are looking to also run a trial in China or the Russian Federation. You want to compare manufacturing requirements and note similarities and differences across these countries for the drug substances used in your clinical trials to help with your country selection.

Clarivate

Cort	tellis CMC Intelligence Small Molecu	les Pre-Approval	1. Choose Small Mo		
Home		Il Molecules Biologics re-Approval Post-Approval	2. Choose Pre-App		
etailed etailed Report	3. Click Countries/Territories tab and select USA, Russian Federation and China from the list that appears . Click Apply.	Countries / Territories	Regions Organizations	Member States Clima >	٩
C odates Alerts		elect all / Clear all Taiwan Thailand Turkey Ukraine Venezuela	 Tajikistan Togo USA United Arab Emirates Vietnam 	 Tanzania Tunisia Uganda United Kingdom Yemen 	
ortellis		Zambia	Zanzibar	Zimbabwe	Apply
	Small Molecules Biologics Pre-Approval	anizations Member States Cli >	Explore and se both official re requirements	egulatory	
	Countries / Territories Selected (3) China Russian Federation USA Go to:	Clear all	practices orga	nized into eCTD iently linked to	

© 2024 Clarivate. Clarivate and its logo, as well as all other trademarks used herein are trademarks of their respective owners and used under license



In the left-hand column, select the requirements you'd like to compare. For our example we'll

focus on manufacturing requirements for clinical trials.

¢ Clarivate								
Cort	tellis CMC Intelligence	Small Molecules Pre-Approval						
(S) Home	> My selection (3) 👔	Manufacturing Requirements	Г					
Summary	Filter Menu	Select Clinical Trial		regulator	y authori	cial Regulation ty and the Loca dditional guidar	l Practice	
Ê Detailed	Detailed Requirement Clinical Trial	① 幸 Filters		consultan	its.			
	Requirements	China 🏠	Russian Federation		\$	USA	۲۵ ۲۵	
Report	 ✓ Administrative Requirements Clinical Trial 	Official Regulations IMP ^	Official Regulations	IMP	~	Official Regulations	IMP ^	
C Updates	Application Procedure Content of the	Per the China GCP Revision 2020	Local Practice		^	Click the arr	ows to open and	
Alerts	Clinical Trial Application	Article 44: The investigational product shall be manufactured, packaged, labelled and coded in accordance with the following requirements:	All local manufactur manufacturers shou			close the co		
	✓ Manufacturing and Authorisations	Additional requirements to manufacture the IMP	CT were produced a	anufacturing license and the drug sam I were produced according with GMP co		register with FDA except when the drug product is used in research, teaching, or chemical analysis and not for sale.		
Cortellis	Manufacturing Requirements	Select Manufacturing Requirements	 IND drug samples sh conditions defined b 			Manufacturing of an investigational drug		
	✓ GCP compliance	Requirements		roduct Type: IMP Submission Type: New Drug Drug Type: Drug Substance, Drug Product		Investigational drugs for use in a Phase 1 study are not subject of current good manufacturing practice		
	Import of IMP	product shall be marked; the investigational product				regulations and are exem	pt also from compliance with	
	Export of IMP	shall be packaged and labelled in a manner that protects the blinding for blinded trials.	Drug Type: Drug Substanc				ood Manufacturing Practice als. The exemption does not	
	 Marketing Authorization Requirements 	2. The sponsor shall explicitly specify, for the investigational product, storage temperatures,	tigational product, storage temperatures, portation conditions (e.g., protection from light), ze times, reconstitution fluids preparation			apply to an investigational drug for use in a phase 1 study once the investigational drug has been made available for use by or for the sponsor in a phase 2 or		
	> CMC Requirements – Drug Substance	transportation conditions (e.g., protection from light), storage times, reconstitution fluids preparation			03-Nov-2016			
	 CMC Requirements – Drug Product 	methods and procedures, and requirements for product infusion devices. The sponsor shall inform all involved parties (e.g., monitors, investigators,	SourceID: <u>190, 4613, 4614, 46</u>	Decision No. 79 on Approval of the Rules of Good Clinical Practice of t		d Clinical Practice of the	In the phase 1 study must	
	> CMC Requirements -			IDRAC Number: 24/331				
	Click the links to view the Sou							
			s and click the links to access		Get PDF 🛓	Go to Website 🗹		
		from the pop-up.					_	

Filters allow you to narrow down the data. For example, let's filter the table

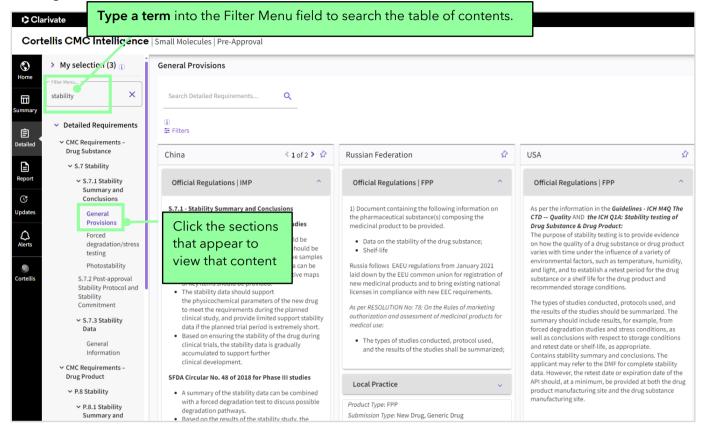
to data just pertaining to new drugs:

Click Filters	1	Apply Filters				
	≢ Filters	Product Type				
		IMP				
		FPP				
		Submission Type				
	Select New Drug	Vew Drug				
		Generic Drug				
		Hybrid Application	Hybrid Application			
		Drug Master File Drug Type				
						Drug Substance
				Drug Product		
		Pharmaceutical Form	Click Apply			
logo, as well as all other trademarks used herein			Cancel Apply			



Cortellis CMC Intelligence

Filtering the Menus



Searching Detailed Requirements

Clarivate						
Cor	tellis CMC Intelligenc	Type a term into into the box	and click the search icon.			
(S) Home	> My selection (3) (j					
Gummary	Filter Menu	Search Detailed Real rements C. Search applied				
Ê	 Detailed Requirements Clinical Trial 	① 莘 Filters				
	Requirements	China 🕹 1 of 2 🔰 🏠	Russian Federation			
Report	 Manufacturing and Authorisations Manufacturing 	Official Regulations IMP ^	Official Regulations FPP	Official Regulations FPP		
C Updates	Manufacturing Requirements > Marketing Authorization Requirements	Dosage form and product composition: SFDA Circular No. 16 of 2018 for Phase I studies	 Document containing the following information of the medicinal product for medical use to be provide 	ded. CTD – Quality:		
ک Alerts	 CMC Requirements – Drug Substance 	 Applicant shall list describes the formulation and dosage prescription form, but with the final 	Description and composition of the drug for medical use.	A description of the drug product and its composition should be provided. The information provided should include, for example:		
S.5 Reference Standa or Materials Cotallis CMC Requirements – Drug Product		remean of the components should also be listed. • Th : excipients in the preparations should meet the mean mean requirements; for the new excipients that have not been used in domestic our overgan preparations, the relevant declaration should be med.	Russia follows EAEU regulations from January 2021 laid down by the EEU common union for registration new medicinal products and to bring existing nation licenses in compliance with new EEC requirements. As per RESOLUTION No: 78: On the Rules of marketing	on of diluent(s) should be provided in a separate part onal "P", as appropriate) of the dosage form; s. Composition, i.e., list of all components of the		
	P.1 Description and Composition of the Drug Product	Click the sections that appear in the table of	a uthorization and assessment of medicinal products medical use: A description of the finished medicinal product and composition shall be provided.	ts for (including overages, if any) the function of the components, and a reference to their quality		
	General Information	contents to find the content with the search	 The information shall include the description the pharmaceutical form and composition wi all the constituents of the finished medicinal 	with • Type of container and closure used for the dosage		
	 P.2.1 Components of Drug Product 	of Drug Product	product, their amount on a per-unit basis, the function of the constituents of: - the active substance	form and accompanying reconstitution diluent, if applicable. (Source ID- 6717 for injectables): FDA recommends that		
	P.2.1.1 Drug Substance	Detailed Requirements	- the constituent(s) of the excipients whatever their nature or the quantity used, including			

For more information contact Customer Service at LS Product Support.

© 2024 Clarivate. Clarivate and its logo, as well as all other trademarks used herein are trademarks of their respective owners and used under license