FACULTY: RITUPARNA CHAKI GHOSH

PROGRAM: M. PHARM

Course Code: MPT1064
Course Name: REGULATORY AFFAIR

Suggested Books for the Course (with links):

Sl. No.	*Book Name, Ed., Vol*	*Authors*	*Weblink(s)*
1.	*GUIDEBOOK FOR DRUG REGULATORY SUBMISSIONS*	*Sandy Weinberg*	
2.			
3.			

Supplementary Materials for Reference and Self Study:

Date	*Module (as per Lesson Plan)*	*Topic*	*Live Recording Link*	*Powerpoint Presentation Link*	*Supplementary Notes / Resources*
06/11/2020	*-*	*History of drug regulation*	*CLICK HERE*	*CLICK HERE*	*Click here*
07/11/2020	*-*	*Significance of regulatory affairs and its role*	*CLICK HERE*	*Click here*	
13/11/2020	*1.a.*	*Master formula record DMF (Drug Master File)*	*CLICK HERE*	*CLICK HERE*	*CLICK HERE* *CLICK HERE*
21/11/2020	*1.a.*	*Distribution records Generic drugs product development: Introduction*	*https://youtu.be/PY0djl2eHAE*	*CLICK HERE* *CLICK HERE*	

	1.a.	Hatch-Waxman act and amendments		CLICK HERE	
	1.a.	CFR (CODE OF FEDERAL REGULATION)		CLICK HERE	
18.12.2020	1.a.	in-vitro Drug product performance/ in –vivo BE and drug product assessment	CLICK HERE	CLICK HERE	
18.12.2020	1.a.	ANDA regulatory approval process	CLICK HERE	CLICK HERE	
18.12.2020	1.a.	NDA approval process	CLICK HERE CLICK HERE	CLICK HERE	
19.12.2020	1.a.	Scale Up Process Approval Changes (SUPAC)		CLICK HERE	
19.12.2020	1.a.	Post marketing surveillance (PMS)		CLICK HERE	
22.01.2021	1.a.	Outsourcing BA and BE to CRO	CLICK HERE	CLICK HERE	
22.01.2021	1.b.	Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways	CLICK HERE	CLICK HERE CLICK HERE CLICK HERE	
22.01.2021	1.b.	Means of US registration for foreign drugs	CLICK HERE	CLICK HERE	
29.01.2021	2.	CMC, post approval regulatory affairs	CLICK HERE	CLICK HERE	

05.02.2021	*2.*	*Regulation for combination products and medical devices*	*CLICK HERE*	CLICK HERE	
05.02.2021	*2.*	*CTD and ECTD format*	*CLICK HERE*	CLICK HERE	
06.02.2021	*2.*	*Industry and FDA liaison* *ICH GUIDELINES*		CLICK HERE CLICKHERE	
13.02.2021	*2*	*ICH GUIDELINES* *Regulatory requirements of EU, MHRA, TGA and ROW countries.*	*CLICK HERE*	CLICK HERE CLICK HERE	
19.02.2021	*3*	*Non clinical drug development*	*CLICK HERE*	CLICK HERE	
20.02.2021	*3*	*Global submission of IND* *Investigation of medicinal products dossier (IMPD)* *Investigator brochure (IB)*		IND IMPD IB	*IB*
26.02.2021	*4*	*Institutional review board/ independent ethics committee: Formulation and working procedures*		CLICK HERE	
27.02.2021	*4*	*Informed Consent process and procedures.*		CLICK HERE	
05.03.2021	*4*	*HIPAA- new requirement to clinical study process*		CLICK HERE	

06.03.2021	*4*	*Pharmacovigilance: safety monitoring in clinical trials*		CLICK HERE	*CLICK HERE LINK 2*
06.03.2021	*4*	*Developing clinical trial protocols.*		CLICK HERE	