



TEMPLATE FOR VIDEO & SUPPLEMENTARY MATERIAL POSTING

FACULTY: MR. SAPTARSHI DUTTA

PROGRAM: B. PHARM

Course Code:

PT-716A

Course Name:

INDUSTRIAL PHARMACY-II

Suggested Books for the Course (with links):

Sl. No.	Book Name, Ed., Vol	Authors	Weblink(s)
1.	<i>FDA Regulatory Affairs (2013, CRC Press) (3RD EITION)</i>	<i>Pisano, Douglas J.[EDITED BY]</i>	https://drive.google.com/file/d/1fBGd5azJzHb420t1CETNsKamkNOJyds_/view?usp=sharing
2.	<i>FDA Regulatory Affairs_ A Guide for Prescription Drugs, Medical Devices, and Biologics (2003, Informa Healthcare)</i>	<i>Pisano, Douglas J.[EDITED BY]</i>	https://drive.google.com/file/d/12yfanYd2WiYNu1hc2L9t0sW7umQ2GbhH/view?usp=sharing
3.			



Supplementary Materials for Reference and Self Study:

Date	Module (as per Lesson Plan)	Topic	Live Recording Link	Power point Presentation Link	Supplementary Notes / Resources	Remarks, if any
22-07-2020	*****	INTRODUCTION TO PILOT PLANT, RA AND QMS	https://youtu.be/4KH59KubDrs	https://drive.google.com/file/d/1iEF90x0p7RUyrh75LBLWeJCzxBfN50dX/view?usp=sharing		
23-07-2020	UNIT-3	RA-INTRODUCTION AND HISTORY OVERVIEW	https://youtu.be/QMGVGqGiNaE	https://drive.google.com/file/d/1BVHRsnFoEJW1ymvDVC3svMxRFE21m3/view?usp=sharing		
29-07-2020	UNIT-3	RA-INTRODUCTION AND HISTORY OVERVIEW AND ROLE OF RA	https://youtu.be/L0mj6iJEso_c	https://drive.google.com/file/d/1e2vJNwO8oNUAuJu87cxVSr9Js		
30-07-2020	UNIT-3	REGULATORY AUTHORITIES AND RESPONSIBILITY OF REGULATORY AFFAIRS PROFESSIONALS	https://youtu.be/KioiYP6t4rA	https://drive.google.com/file/d/1e2vJNwO8oNUAuJu87cxVSr9JsFKJmQzpv/view?usp=sharing		



05-08-2020	UNIT-3	REGULATORY REQUIREMENTS FOR DRUG APPROVAL AND DRUG DEVELOPMENT TEAM	https://youtu.be/AuE7MVjwYMo	https://drive.google.com/file/d/1nllmag9GG5a7OhGnDxdN-NJQlk3JzjgJ/view?usp=sharing		
06-08-2020	UNIT-3	DRUG DEVELOPMENT AND DISCOVERY PHASE NON-CLINICAL DRUG DEVELOPMENT	https://youtu.be/w6B8spIFsY	https://drive.google.com/file/d/1TBDtRD4ZU9JDdvZ7iy4qSuAywHKeykF/view?usp=sharing		
12-08-2020	UNIT-3	NON-CLINICAL DRUG DEVELOPMENT E-CTD IND-INTRODUCTION	https://youtu.be/1L1HnEJc30g	https://drive.google.com/file/d/1RAvAwfif48fk2J48TF97_vRFkF/WZWvsv/view?usp=sharing		
13-08-2020	UNIT-3	INVESTIGATIONAL NEW DRUG (IND) APPLICATION	https://youtu.be/JFf4EqHbp38	https://drive.google.com/file/d/1YaH5jj0gxbHaWro_2MWrt_PzFd2MRNR/view?usp=sharing	https://drive.google.com/file/d/1a66_RYIEsz47v9jF4WQ0Rwqa8fTbUDqi/view?usp=sharing	



19-08-2020	UNIT-3	IND EXEMPTION CRITERIA, INVESTIGATOR'S BROCHURE (IB) and NDA-INTRODUCTION	https://youtu.be/e/-uDGYOiOQWA	https://drive.google.com/file/d/1yESkQkGth4gKB9SXYkP8Eb8caPZFxuM5/viiew?usp=sharing	https://drive.google.com/file/d/1N1sOH15lP20mM5QcSugQo0laYAGyEGtn/view?usp=sharing	
20-08-2020	UNIT-3	NDA-OBJECTIVES, FAR, CONTENTS AND ASSEMBLING APPLICATIONS FOR SUBMISSION	https://youtu.be/ny1Zi0ki7i8	https://drive.google.com/file/d/1hPOhgBOW5BQXKz6JpOXOhcRNiDzbOjeS/view?usp=sharing	https://drive.google.com/file/d/1ra86K1IDgU1iYgae0k-ZpzKSibl-l2XX/view?usp=sharing	
26-08-2020	UNIT-3	NDA –APPROVAL PROCESS AND BE STUDIES INTRODUCTION	https://youtu.be/e/-YXM OGXl6vc	https://drive.google.com/file/d/1E7M UqOGM7upy2OsZIN9qP-7D48bKk5d/view?usp=sharing		



27-08-2020	UNIT-3	BE STUDIES	https://youtu.be/e/3cy1fbmjQw	https://drive.google.com/file/d/1XqW5JjOLbfVKfZYevqq7Th3Ofb9KxNY4/view?usp=sharing		
02-09-2020	UNIT-3	DESIGN OF BIOEQUVALENCE STUDY AND CLINICAL RESEARCH PROTOCOL-INTRODUCTION	https://youtu.be/e/EWNtJoNFTLU	https://drive.google.com/file/d/1hg-82DrZwYiGsbOcGwju65bdF0rrBE7/view?usp=sharing		
03-09-2020	UNIT-3	CLINICAL RESEARCH PROTOCOL	https://youtu.be/e/6i1aXSH6kZA	https://drive.google.com/file/d/14tzEsZiHc92yYplhvx3LrLYCbH1mr-Bn/view?usp=sharing		
09-09-2020	UNIT-3	CLINICAL RESEARCH PROTOCOL AND DATA PRESENTATION FOR FDA SUBMISSION	https://youtu.be/e/tjdEA0JLyCQ	https://drive.google.com/file/d/1lPKRax8GG3s9rmDoEtFP8FrA1BQV0QjU/view?usp=sharing		
10-09-2020	UNIT-3	DATA PRESENTATION FOR FDA SUBMISSION AND CTMS (MANAGEMENT OF CLINICAL	https://youtu.be/e/wZqCwlQiXTk	https://drive.google.com/file/d/1lPKRax8GG3s9rmDoEtFP8FrA1BQV0QjU/v		



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16-09-2020/19-09-2020	UNIT-5	INDIAN REGULATORY REQUIREMENT-INTRODUCTION, FUNCTION AND ORGANIZATION	https://youtu.be/e-xtlbjVd6qA	https://drive.google.com/file/d/1tYi7HoDKGmaylaWiD7OrWWE8qKS9NAzr/view?usp=sharing		
17-09-2020	HOLIDAY					
30-09-2020	UNIT-5	COPP	https://youtu.be/e/vbg3Nmr8i4w	https://drive.google.com/file/d/1ZPbfcW291PJ3aRalQp2YwpT-tf-sfim4/view?usp=sharing		
02-12-2020	UNIT-5	REGULATORY REQUIREMENTS AND APPROVAL PROCESS FOR NEW DRUG	https://youtu.be/g0jeuu7qdXTA	https://drive.google.com/file/d/1xsnlhPV0Ng_uBCB_VwiXePraeWtKLdoQO/view?usp=sharing		
03-12-2020	UNIT-5	REGULATORY REQUIREMENTS AND APPROVAL PROCESS FOR NEW DRUG	https://youtu.be/zikLAZy1DcY	https://drive.google.com/file/d/1xsnlhPV0Ng_uBCB_VwiXePraeWtKLdoQO/view?usp=sharing		