



# TEMPLATE FOR VIDEO & SUPPLEMENTARY MATERIAL POSTING

FACULTY: MR. SAPTARSHI DUTTA

**PROGRAM: B. PHARM**

**Course Code:**

7.2.T

**Course Name:**

INTRODUCTION TO PILOT PLANT, RA AND QMS

**Suggested Books for the Course (with links):**

Sl. No.	Book Name, Ed., Vol	Authors	Weblink(s)
1.	<i>FDA Regulatory Affairs (2013, CRC Press) (3<sup>RD</sup> EITION)</i>	<i>Pisano, Douglas J.[EDITED BY]</i>	<a href="https://drive.google.com/file/d/1fBGd5azJzHb420t1CETNsKamkNOJyds_/view?usp=sharing">https://drive.google.com/file/d/1fBGd5azJzHb420t1CETNsKamkNOJyds_/view?usp=sharing</a>
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>	<a href="https://drive.google.com/file/d/12yfanYd2WiYNu1hc2L9t0sW7umQ2GbhH/view?usp=sharing">https://drive.google.com/file/d/12yfanYd2WiYNu1hc2L9t0sW7umQ2GbhH/view?usp=sharing</a>
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	<a href="https://youtu.be/4KH59KubDrs">https://youtu.be/4KH59KubDrs</a>	<a href="https://drive.google.com/file/d/1EF90x0p7RUyRh75LBLWeJCzxBfN50dX/view?usp=sharing">https://drive.google.com/file/d/1EF90x0p7RUyRh75LBLWeJCzxBfN50dX/view?usp=sharing</a>		
23-07-2020	UNIT-3	RA-INTRODUCTION AND HISTORY OVERVIEW	<a href="https://youtu.be/QMGV GqG iNaE">https://youtu.be/QMGV GqG iNaE</a>	<a href="https://drive.google.com/file/d/1BVHRsnFoEJW1ymvDVC_3svMxRFEn21m3/view?usp=sharing">https://drive.google.com/file/d/1BVHRsnFoEJW1ymvDVC_3svMxRFEn21m3/view?usp=sharing</a>		
29-07-2020	UNIT-3	RA-INTRODUCTION AND HISTORY OVERVIEW AND ROLE OF RA	<a href="https://youtu.be/L0mj6iJEsoC">https://youtu.be/L0mj6iJEsoC</a>	<a href="https://drive.google.com/file/d/1e2vJNwO8oNUAuJu87cxVSr9Js">https://drive.google.com/file/d/1e2vJNwO8oNUAuJu87cxVSr9Js</a>		
30-07-2020	UNIT-3	REGULATORY AUTHORITIES AND RESPONSIBILITY OF REGULATORY AFFAIRS	<a href="https://youtu.be/KioiYP6">https://youtu.be/KioiYP6</a>	<a href="https://drive.google.com/file/d/1e2vJNwO8oNUAuJu8">https://drive.google.com/file/d/1e2vJNwO8oNUAuJu8</a>		



		PROFESSIONALS	<a href="#">t4rA</a>	<a href="#">7cxVSr9JsFKJmQzp/view?usp=sharing</a>		
05-08-2020	UNIT-3	REGULATORY REQUIREMENTS FOR DRUG APPROVAL AND DRUG DEVELOPMENT TEAM	<a href="https://youtu.be/AuE7MVJwYMo">https://youtu.be/AuE7MVJwYMo</a>	<a href="https://drive.google.com/file/d/1nllmag9GG5a7OhGnDxdN-NJQIk3JzjgJ/view?usp=sharing">https://drive.google.com/file/d/1nllmag9GG5a7OhGnDxdN-NJQIk3JzjgJ/view?usp=sharing</a>		
06-08-2020	UNIT-3	DRUG DEVELOPMENT AND DISCOVERY PHASE  NON-CLINICAL DRUG DEVELOPMENT	<a href="https://youtu.be/w6B8spIFs_Y">https://youtu.be/w6B8spIFs_Y</a>	<a href="https://drive.google.com/file/d/1TBDtRD4ZU9JDdvZ7iy4qSuAywHKeYkF/view?usp=sharing">https://drive.google.com/file/d/1TBDtRD4ZU9JDdvZ7iy4qSuAywHKeYkF/view?usp=sharing</a>		
12-08-2020	UNIT-3	NON-CLINICAL DRUG DEVELOPMENT  E-CTD  IND-INTRODUCTION	<a href="https://youtu.be/1L1HnEJc30g">https://youtu.be/1L1HnEJc30g</a>	<a href="https://drive.google.com/file/d/1RAvAwfif48fk2J48TF97_vRFkFWZWvsv/view?usp=sharing">https://drive.google.com/file/d/1RAvAwfif48fk2J48TF97_vRFkFWZWvsv/view?usp=sharing</a>		
13-08-2020	UNIT-3	INVESTIGATIONAL NEW DRUG (IND) APPLICATION	<a href="https://youtu.be/JFf4EqHbp38">https://youtu.be/JFf4EqHbp38</a>	<a href="https://drive.google.com/file/d/1YaH5jj0gxbHaWro_2MWrt_PzFd2MRNR/vi">https://drive.google.com/file/d/1YaH5jj0gxbHaWro_2MWrt_PzFd2MRNR/vi</a>	<a href="https://drive.google.com/file/d/1a66_RYIEsz47v9jF4WQ0Rwqa8fTbUDqi/vie">https://drive.google.com/file/d/1a66_RYIEsz47v9jF4WQ0Rwqa8fTbUDqi/vie</a>	



				<a href="#">ew?usp=sharing</a>	<a href="#">w?usp=sharing</a>	
19-08-2020	UNIT-3	IND EXEMPTION CRITERIA, INVESTIGATOR'S BROCHURE (IB) and NDA-INTRODUCTION	<a href="https://youtu.be/-uDGYOiOQWA">https://youtu.be/-uDGYOiOQWA</a>	<a href="https://drive.google.com/file/d/1yESkQkGth4gKB9SXykP8Eb8caPZFxuM5/view?usp=sharing">https://drive.google.com/file/d/1yESkQkGth4gKB9SXykP8Eb8caPZFxuM5/view?usp=sharing</a>	<a href="https://drive.google.com/file/d/1N1sOH15LP20mM5QcSugQo0laYAGyEGtn/view?usp=sharing">https://drive.google.com/file/d/1N1sOH15LP20mM5QcSugQo0laYAGyEGtn/view?usp=sharing</a>	
20-08-2020	UNIT-3	NDA-OBJECTIVES, FAR, CONTENTS AND ASSEMBLING APPLICATIONS FOR SUBMISSION	<a href="https://youtu.be/ny1Zi0ki7i8">https://youtu.be/ny1Zi0ki7i8</a>	<a href="https://drive.google.com/file/d/1hPOhgBOW5BQXKz6JpOXOchrNiDzbOjeS/view?usp=sharing">https://drive.google.com/file/d/1hPOhgBOW5BQXKz6JpOXOchrNiDzbOjeS/view?usp=sharing</a>	<a href="https://drive.google.com/file/d/1ra86K1IDgU1iYqae0k-ZpzKSib-l-2XX/view?usp=sharing">https://drive.google.com/file/d/1ra86K1IDgU1iYqae0k-ZpzKSib-l-2XX/view?usp=sharing</a>	
26-08-2020	UNIT-3	NDA –APPROVAL PROCESS AND BE	<a href="https://youtu">https://youtu</a>	<a href="https://drive.google.c">https://drive.google.c</a>		



		STUDIES INTRODUCTION	<a href="https://youtu.be/XMOGXl6vc">utu.be/-YXMOGXl6vc</a>	<a href="https://drive.google.com/file/d/1E7M_UqOGM7upy2OsZIN9qP-7D48bKk5d/view?usp=sharing">om/file/d/1E7M_UqOGM7upy2OsZIN9qP-7D48bKk5d/view?usp=sharing</a>		
27-08-2020	UNIT-3	BE STUDIES	<a href="https://youtu.be/e/3cy1fbImjQw">https://youtu.be/e/3cy1fbImjQw</a>	<a href="https://drive.google.com/file/d/1XgW5JjOLbfVKfZYevqq7Th3Ofb9KxNY4/view?usp=sharing">https://drive.google.com/file/d/1XgW5JjOLbfVKfZYevqq7Th3Ofb9KxNY4/view?usp=sharing</a>		
02-09-2020	UNIT-3	DESIGN OF BIOEQUVALENCE STUDY AND CLINICAL RESEARCH PROTOCOL-INTRO DUCTION	<a href="https://youtu.be/e/EWNtJoNFTLU">https://youtu.be/e/EWNtJoNFTLU</a>	<a href="https://drive.google.com/file/d/1hg-82DrZwYIGsbOc-Gwju65bdF0rrBE7/view?usp=sharing">https://drive.google.com/file/d/1hg-82DrZwYIGsbOc-Gwju65bdF0rrBE7/view?usp=sharing</a>		
03-09-2020	UNIT-3	CLINICAL RESEARCH PROTOCOL	<a href="https://youtu.be/e/6i1aXSH6kZA">https://youtu.be/e/6i1aXSH6kZA</a>	<a href="https://drive.google.com/file/d/14tzEsZiHc92yYpIhvx3LrLYCbH1mr-Bn/view">https://drive.google.com/file/d/14tzEsZiHc92yYpIhvx3LrLYCbH1mr-Bn/view</a>		



				<a href="#">?usp=sharing</a>		
09-09-2020	UNIT-3	CLINICAL RESEARCH PROTOCOL AND DATA PRESENTATION FOR FDA SUBMISSION	<a href="https://youtu.be/tjdEA0JLyCQ">https://youtu.be/tjdEA0JLyCQ</a>	<a href="https://drive.google.com/file/d/1PKRax8GG3s9rmDoEtFP8FrA1BQV0QjU/view?usp=sharing">https://drive.google.com/file/d/1PKRax8GG3s9rmDoEtFP8FrA1BQV0QjU/view?usp=sharing</a>		
10-09-2020	UNIT-3	DATA PRESENTATION FOR FDA SUBMISSION AND CTMS (MANAGEMENT OF CLINICAL STUDIES)	<a href="https://youtu.be/wZqCwlQiXTk">https://youtu.be/wZqCwlQiXTk</a>	<a href="https://drive.google.com/file/d/1PKRax8GG3s9rmDoEtFP8FrA1BQV0QjU/view?usp=sharing">https://drive.google.com/file/d/1PKRax8GG3s9rmDoEtFP8FrA1BQV0QjU/view?usp=sharing</a>		
16-09-2020 /19-09-2020	UNIT-5	INDIAN REGULATORY REQUIREMENT-INTRODUCTION, FUNCTION AND ORGANIZATION	<a href="https://youtu.be/bjVd6gA">https://youtu.be/bjVd6gA</a>	<a href="https://drive.google.com/file/d/1tYi7HoDKGmaylaWiD7OrWWE8qKS9NAzr/view?usp=sharing">https://drive.google.com/file/d/1tYi7HoDKGmaylaWiD7OrWWE8qKS9NAzr/view?usp=sharing</a>		
17-09-2020	<b>HOLIDAY</b>					
30-09-2020	UNIT-5	COPP	<a href="https://youtu.be/vbg3Nmr8j4w">https://youtu.be/vbg3Nmr8j4w</a>	<a href="https://drive.google.com/file/d/1ZPbfcW291PJ3aRalQp2YwpT-tf-sfjm4/view?usp=sharing">https://drive.google.com/file/d/1ZPbfcW291PJ3aRalQp2YwpT-tf-sfjm4/view?usp=sharing</a>		

