BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, Pilani
Pilani Campus

INSTRUCTION DIVISION
SECOND SEMESTER 2016-2017
Course Handout (Part II)

Date: 02/08/2016

In addition to part-I (General Handout for all courses appended to the time table) this portion gives further specific details regarding the course.

Course No. : **PHAF413**
Course Title : **Pharmaceutical Management and Quality Control**
Instructor-in-charge : **SUNIL KUMAR DUBEY**

1. **Scope & Objective of the Course**: It is a course intended to give the students an idea of various aspects of pharmaceutical management with emphasis on latest trends in current good manufacturing practices and international certification. This course also deals with process validation, quality control, pilot plant and scale up operations, drug regulatory affairs, production management, pharmaceutical marketing, management of materials and finance and management information systems.

2. **Text Book**: i. Khanna O.P : Industrial Engg. & Mgt, Dhanpat Rai, Rev. Ed, 1999.
ii. Willing, H.Sidney, Tuckerman, M. Murray, Hitchings IV, S. William: Good Manufacturing practices for Pharmaceuticals, Marcel Dekker, 4th ed.

3. **Ref. Book**: The students should refer to the following Books & Literatures for further knowledge.
   i. Lachmann, Liebermann & Kanig: the Theory & Practice of Industrial, Pharmacy, K.M. Varghese, Third Edition, 1990. New Delhi.
   ii. Raja, B. Smarta : Strategic Pharmaceutical Marketing, Wheeler Pub.
   iii. Sekhar Mukhopadhyay: Pharmaceutical Selling, Sterling Pub.
   iv. International Organisation for Standardization Geneva: 1S80 9000 Quality Management Systems 2nd Ed. Pub. By International Trade Center Geneva.
   v. Bernard. T. Loftus, Robert A. Nash: Pharmacentical Process Validation, Marcel Dekker.

4. Course Plan :

Lecture No	Learning objective	Topics to be covered	Reference Chap/Sec
1	Scope & objective of course	Introduction	
2-3	WHO GMP guidelines	CGMP	2(ii) ch 3
4-5	Design & features of cGMP unit	Buildings & facility requirements	2(ii) ch 4
6	Equipment design & features	Equipment requirements	2(ii) ch 5
7	Air control systems	Heat, Ventilation & air control	2(ii) ch 5
8-9	Process control requirements for cGMP unit	Process control	2(ii) ch 7
10	Record maintenance	Records	2(ii) ch 11
11	Packaging & labeling requirements	Packaging & labeling	2(ii) ch 8
12	Validation-basics & methodology	Process validation introduction	3(v) intro
13-14	Guidelines for validation of solid dosage forms	Validation of solid dosage forms	3 (v) ch 5,6
15	Ability to conduct prospective validation	Prospective validation	3 (v) ch 7
16	Ability to conduct retrospective validation	Retrospective validation	3 (v) ch 8
17	Ability to conduct sterile product validation	Sterile product validation	3 (v) ch 4
18	Knowledge of costing procedures	Product costing	2(i) ch 27
19-20	Quality by Design (QbD) in pharma development	QbD Approach	Class notes
21	Financial analysis for decision making	Break even analysis	2(i) ch 27
22	Variance analysis for decision making	Variance analysis	2(i) ch 27
23	Preparation of budget	Budgeting	2(i) ch 28

24	Knowledge of functions of Materials Management	Materials Management	2(i) ch 13
25-26	Knowledge of inventory analysis & management	Inventory control	2(i) ch 24
27-28	Requirements of Pilot Plant	Pilot plant & scale up operations	2(i) ch 23
29-31	Statistical analysis for decision making	Statistical applications in pharmaceuticals	3(i) ch 10
32-33	Quality control tools	Quality Control & Assurance	3(i) ch 27
34-35	Salient features of ISO	ISO Introduction	3(i) ch 1,2
36-37	Interpretation of various clauses of ISO	ISO requirements	3(i) ch 3-25
38	Control of production schedules	Production management	2(i) ch 7
39	Knowledge of functions of Marketing Management	Pharmaceutical marketing	2(i) ch 31
40	Various aspects of Pharmaceutical selling	Detailing	3(iii) ch 4-7

5. Evaluation Scheme:

Component	Duration	Weightage (%)	Date & Time	Venue	Remarks
Test	90 mts.	30	3/10 2:00 - 3:30 PM		CB
Surprise Quiz #	10 mts.	10			CB
Seminar / Assignment		20			
Compre Exam	3 hrs.	40	2/12 FN		CB

3 **quizzes** will be conducted during the lecture hours and the best 2 will be taken for the final total.

6. Mid-Semester Evaluation: The Mid- Semester evaluation would be based on Test (30%), and Assignment (10%)

7. Make-up Policy:
The facility of make-up test is meant to take care of 'Unavoidable' absence from scheduled tests. It is expected that the students will "keep faith" in this respect and avoid any misuse of

this useful feature. There will be no insistence on "certificate" but all decisions to give or not to give make-up tests would be based on mutual faith and trust.

8. **Chamber Consultation Hour**: To be announced in the class

9. **Notices**: Notices, if any, concerning the course will be displayed on the Notice Board of Pharmacy Group Only

Instructor In-Charge
PHAF413