IIHMR UNIVERSITY

School of Pharmaceutical Management

MBA Pharmaceutical Management

Batch-09th (2017-2019)

First Year

Regulatory Environment for Pharma Business

Term Examination

Time - 3 Hour **MM-70**

The question paper contains 01 of 01 printed page.

Attempt any 5 questions, all questions carry equal 14 marks

Q. 1. Discuss the Generic Drug User Fee Amendments (GDUFA) and its procedure with benefits to generic drugs manufactures?

Q. 2. The company Polar Pharmaceuticals perform certain changes in its approved medicine under the brand name Flu-chip (Fluconazole) tablets, these changes are pertaining to composition and additional new API sources of brand product Flu-chip. Discuss the category of changes takes place with applicant responsibility to provide relevant documentation?

Q. 3. If you are designated as a Regulatory manager in Pharmaceutical companies then what type of document management is required to perform the pharmaceutical industry operations, discuss in detail?

Q. 4. Elaborate the pharmaceutical regulatory process pertaining to marketing authorization for the new pharmaceutical product development?

Q. 5. The generic manufacturer wants to get marketing authorization for his drug product Diclofenac+ Serratiopeptidase, kindly assist the applicant so that manufacturer get the marketing authorization under USFDA.

Q. 6. Write Short notes on (Any 2)

a. CTD
b. Biosimilars
C. DMF
D. ICH