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[LJ 825] OCTOBER 2016 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Discuss in detail the overview of regulatory environment in Europe and USA.
2. What is informed consent? Explain content of informed consent as per regulatory authorities in clinical trials.
3. What are the different methods of post marketing surveillance?
4. Discuss the importance of safety monitoring in clinical trials.

II. Write notes on: **(6 x 5 = 30)**

1. Briefly write on Case Report Form.
2. Role and responsibility of clinical research co-ordinator.
3. Write note on Impartial witness.
4. Purpose of an audit in clinical trial.
5. Investigational new drug application.
6. Why randomization is important in clinical research?

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