Total No. of Pages : 2

Register Number : **7647**

Name of the Candidate :

P.G. DIPLOMA EXAMINATION DECEMBER 2013.

130 — DATA MANAGEMENT, PHARMACOVIGILANCE AND AUDITS

Time : Three hours Maximum : 100 marks

SECTION A

Answer any TWO questions. (2 × 20 = 40)

All questions carry equal marks.

1. What is Pharmacovigilance? List out the various methodology and importance and need for pharmacovigilance in present scenario?

2. Write down in detail the sources of clinical data and effective data management.

3. Discuss the steps in clinical data management and list out the data validation process.

SECTION B

Answer any SIX questions. (6 × 10 = 60)

All questions carry equal marks.

4. DRUG Registries.

5. Write down the unexpected SAE reporting Timelines in India.

6. Write a brief

   (a) Periodic Safety Update Reporting (PSUR)

   (b) Periodic safety reporting.

7. Describe causality assessment scale.

8. Compare and contract audits and inspection. Write in brief about the out come of USFDA inspection.

9. Role of National Pharmacovigilance Advisory Committee (NPAC).

10. Brief the data clarification form.

11. How are clinical trials audited?

12. Signal detection programe.

13. Write down the individual case safety reporting.

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