**UNIT-III: Regulatory Affairs & Drug Approval Requirements**

**Elaborate Questions (10 Marks):**

1. Discuss the **general considerations of an Investigational New Drug (IND) application**, outlining its purpose and key components [3, 11, 14].

2. What are the **regulatory requirements and approval procedures for new drugs**? Explain in detail, including non-clinical and clinical drug development phases [3, 11, 12].

3. Discuss **New Drug Application (NDA)** and **Investigational New Drug Application (IND)**, highlighting their key differences and purposes [3, 9].

**Notes Questions (5 Marks):**

1. Write a note on the **organizational structure of regulatory affairs** [5, 11].

2. Discuss the **role and responsibility of regulatory affairs** professionals/department [3, 7, 9, 11].

3. Write a short note on **Investigator's Brochure (IB)** [3, 7, 9].

4. Discuss **biostatistics in Pharmaceutical product development** [3, 5, 8, 13].

5. Describe the **clinical trial protocol** [3, 5].

6. Explain **non-clinical drug development** in brief [3, 11, 13].

7. Write a note on the **management of clinical studies** [3, 7].

8. Discuss the **NDA regulatory approval process** with suitable examples [3, 7].

9. Describe the **historical overview of Regulatory Affairs** [3, 11].

**Short Answer Questions (2 Marks):**

1. Define **Investigational New Drug (IND)** [11].

2. What is the purpose of **pre-clinical testing**? [10]

3. Define **clinical research** [8, 10].

4. What are the **types of Clinical Research**? [8, 9]

5. What are **BE & BA studies**? [10]

6. State the **regulatory requirement of bioequivalence studies** [5].

7. What is an **Abbreviated New Drug Application (ANDA)**? [8, 10]