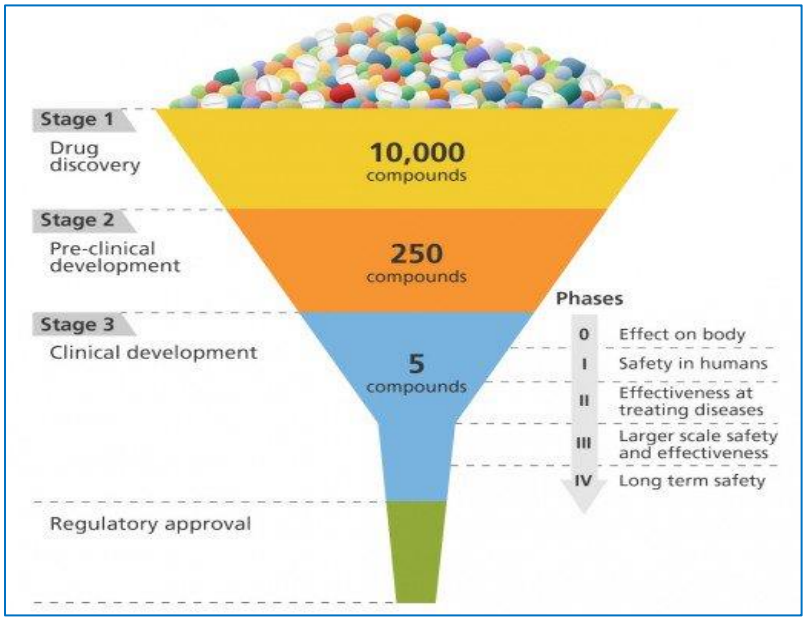

AL107:
The Drug Development Process from Concept to Market

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Training Description:

The drug development process involves a series of lengthy steps that determine the degree of success for every drug brought to the market. Decisions made throughout the process affect every aspect of future development and impact heavily on commercialization strategies. Included in the course content is an overview of the regulatory and premarketing steps that occur to ensure a successful launch. The course also covers sales planning and the commercialization decisions that affect the development of the drug.

The course will discuss:

- Basic concepts of drug discovery and testing
- Scientific, regulatory, and management framework for modern pharmaceutical development
- Pre-clinical study requirements and how information gathered is used for human clinical studies
- The four major clinical phases (1-4) in the drug development process and the rationale for each and an introduction to the special problems of each phase
- The economics of drug development
- Cost/benefit issues in clinical development
- Discovery and development milestones
- The IND Process
- The NDA Process
- FDA Interactions – Application review and approval process
- Patents and exclusivity

Training Objectives:

By the end of the training, participants will be able to:

- ✓ Have an in-depth understanding of the interrelated activities throughout the drug development cycle and is designed for R&D, operations and/or marketing and sales management
- ✓ Understand the drug development process
- ✓ Familiarize with the steps involved in developing a drug from discovery to commercialization. The address specific organizational, departmental or functional issues

Training Designed for:

This course is intended for those employees who need an understanding of the drug development process, this course provides a detailed picture of the complex and highly interrelated activities of the development cycle for drugs and biologics, from discovery to a successful commercialization. The training will be beneficial for anyone involved in the R&D process. It can also be customized for Marketing & Sales Personnel who need to understand that actions taken during the development process have a significant effect on sales and marketing strategies. Typical participants include Research & Development Scientists, Clinical Monitors and Research Associates, Medical and Clinical Investigators and Study Coordinators, Physicians & Medical Liaisons, Statisticians & Data Management Professionals, CMC/Pharmaceutical Research Professionals, Regulatory Affairs professionals, Project Managers, Financial Managers, Brand Team Personnel, Senior Sales Managers and Strategic Planners.

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Training Program:

FIVE DAYS:

- PRE-TEST
- Introduction
- Drug Discovery
  - Regulatory Definition of A "Drug"
  - Types of Drugs & How They Are Produced
  - Approaches to Drug Discovery
  - Patents
  - Exercise # 1 Drug Discovery
- Drug Development
  - Challenges in Drug Development
  - Drug Development Lifecycle
  - Industry Perspective
  - Non-Clinical Studies
    - GLP
  - Clinical Studies
    - The IND/IMPD
    - CDP
    - Phase I-IV
  - Exercise # 2 Drug Development
- Good Clinical Practices
  - Purpose & Principals
  - The IRB/IEC
  - Exercise # 3 GCP
- Components of a Clinical Study
  - Regulatory Requirements
    - History & Role
  - Key Players
    - Roles & Responsibilities
  - Documentation
  - Monitoring
  - Data Processing
  - Exercise # 4 Clinical Study
- The NDA/CTD
  - Definition & Contents
  - Process
    - Submission, Review & Approval
  - Exercise # 5 NDA/CTD
- Post Approval
  - Sales Training
  - Role of Marketing

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- Marketing Strategy
- Promotional Advertising
- Post Marketing Compliance
  - AE Reporting
- Exercise # 6 Post Approval

❖ GMP
- Impact
- Commercial Manufacture
- GMP Controls
- Scale-up Issues
- Process Validation
- Exercise # 7 GMP

❖ DDP Workshop
- Break into Working Groups
- Present Findings

❖ Course Conclusion
❖ POST-TEST and EVALUATION

Training Requirement:

"**Hand's on practical sessions, equipment** and **software** will be applied during the course if required and as per the client's request."

Please note that the above topics can be amended as per client's learning needs and objectives. Further, it should be forwarded to us a month prior to the course dates.

Training Methodology:

This interactive training course includes the following training methodologies as a percentage of the total tuition hours:

- 30% Lectures, Concepts, Role Play
- 70% Workshops & Work Presentations, Techniques, Based on Case Studies & Practical Exercises, Software & General Discussions
- Pre and Post Test

Training Certificate(s):

Internationally recognized certificate(s) will be issued to each participant who completed the course.

Training Fees:

As per the course location - This rate includes participant's manual, hand-outs, buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

Note: The 5% VAT (Value Added Tax), will be effective starting 01st of January 2018 as per the new regulation from the UAE Government. The VAT applies for all quotation both for local and abroad.

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Training Timings:

Daily Timings:

07:45 - 08:00	Morning Coffee / Tea
08:00 - 10:00	First Session
10:00 - 10:20	Recess (Coffee/Tea/Snacks)
10:20 - 12:20	Second Session
12:20 - 13:30	Recess (Prayer Break & Lunch)
13:30 - 15:00	Last Session

For training registrations or in-house enquiries, please contact:

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Training & Career Development Department