



# Pharma Excipient Essentials...For the Non-Technical Professional

## From FDA to Formula™

### o Who should attend?

- Any employee who is peripherally or directly involved with pharmaceutical technical or regulatory tasks, departments, colleagues, or functions BUT:
- Does not have a technical / regulatory background him/herself;
- Wants the technical / regulatory basics of the pharmaceutical industry, especially excipients, fast;
- Wants a refresher of the technical / regulatory basics of pharmaceutical industry, especially excipients, fast;
- Is new to the pharmaceutical industry

#### Examples:

- Purchasing / Procurement professionals
- New Commercial Hires (Non-technical )
- Sales professionals
- Customer service professionals
- Commercial operations professionals
- Mid- to Senior Level Non-technical Managers

### o What will I learn?

- Day One – Industry Basics
  - Background and functions of the main industry regulatory and guidance organizations (FDA and IPEC)
  - Key regulations and guidance affecting the industry
  - Key pharmaceutical compendia – what they contain and why they are important
  - The various drug approval processes within FDA guidelines, including clinical trials
  - Excipients and their supply chain, including an introduction to IPEC & its functions
- Day Two – Excipients for Oral – OR - Topical Dosage Forms
  - Excipients types and definitions for each dosage form
  - Formulation basics for each dosage form
  - The “bigger picture” of excipient supply
  - Factors to consider in choosing excipient suppliers
  - Factors to consider in choosing excipient distributors

### o Why this course?

- Taught by professional trainers with years of industry and training experience.
- Group exercises interspersed throughout the course to verify and reinforce learning!
- Specially designed for those without background in the physical or life sciences.

### o Logistics

- Taught at your facility
- 2 days
- 12 – 20 people per class