

# Short Course

# Solubility & Dissolution Behavior of Small Molecules and Proteins

Presented by HTD Biosystems

## Course background and objectives

This course provides basic and advanced knowledge about solubility and dissolution rate of sparingly soluble drugs as well as biomolecules such as proteins.

## Who should attend?

This course is useful for all scientists working with drug development, preformulation and formulation of small molecules, protein formulation, development of biotech drugs and nanoparticles. It provides a general and in-depth knowledge in the field of dissolution.

## Course instructor

### **Mitra Mosharraf, PhD**

Dr. Mosharraf received her Ph.D. degree from Uppsala University (Sweden) in Pharmaceutics. She was Sr. Scientist at Pharmacia Corp. and Principal Scientist at Pfizer, working with product development before joining HTD Biosystems Inc. as Chief Scientific Officer in 2005. Dr. Mosharraf has published several scientific articles and given numerous lectures on the solubility and dissolution rate topics.

## Contact

For more information please contact:

Mitra Mosharraf , Tel. (510) 734 -4812

Email: [mitra.mosharraf@htdcorp.com](mailto:mitra.mosharraf@htdcorp.com)

HTD Web site: [www.htdcorp.com](http://www.htdcorp.com)



BIOSYSTEMS INC.

## Course outline

### **Morning Session**

#### DISSOLUTION RATE OF SPARINGLY SOLUBLE DRUGS

- **Definitions and theoretical models of dissolution**
- **The diffusion layer model-important factors**
  - Hydrodynamic and diffusion boundary layers
  - The effect of agitation intensity
  - The effect of particle size
  - The effect of temperature
  - The effect of viscosity
- **Interfacial dissolution surface area**
  - The effect of particle size
  - The effect of wetting
  - The effect of formulation
- **Solubility**
  - Definitions and terminology
  - Theoretical models of solubility

#### FACTORS AFFECTING SOLUBILITY

- The effect of temperature
- Complexation
- Co-solvents
- Micellar interactions and self association
- pH
- Electrolytes and ionic interaction
- Particle size
- Solid state structure

#### SOLUBILITY ENHANCEMENT STRATEGIES

### **Afternoon Session**

#### PROTEIN SOLUBILITY & DISSOLUTION RATE

- **Important parameters for protein solubility**
  - Interactions
  - Water structure
  - Molecular structure
  - Solid-state structure
- **Strategies to improve solubility of proteins**
  - Chemical Modifications
  - Formulation; buffers, salts, solubilizers, polymers, preservatives
- **Dissolution of lyophilized formulation**
- **Dissolution in high dose protein formulations**
  - The effect of viscosity
  - The effect of cake porosity and specific surface area
  - The effect of fill volume of pre-lyo solution
  - Reconstitution approaches
- **Dissolution in dual chamber syringes**
- **Strategies to improve dissolution rate of proteins**