

# HSIEN-HSIN TUNG

## EDUCATION

- Postdoctoral Research Fellow, Department of Chemical Engineering** **1984 - 1986**  
California Institute of Technology, Pasadena, CA  
Postdoc advisor: Professor Manfred Morari
- Ph.D. and M.S., Department of Chemical Engineering, GPA 4.0/4.0** **1979 - 1985**  
Northwestern University, Evanston, IL  
Ph.D. advisor: Professor Richard S.H. Mah
- B.S., Department of Chemistry, GPA 3.7/4.0** **1972 - 1976**  
National Taiwan University, Taiwan, R.O.C.

## RELEVANT PROFESSIONAL EXPERIENCE

- ABBOTT LABORATORIES** **2009 - present**  
**Volwiler Research Fellow, Process R&D, Global Pharmaceutical R & D**
- Direct and mentor scientists in supporting late-stage development efforts of multiple drug candidates, including oversea outsourcing & starting material strategy, QbD-based process development & control justification, supply for formulation and clinical trials, oversea commercial technical transfer & process validation, and regulatory CMC section
  - Lead multiple technical initiatives and construct technical excellence in Process R&D area, including crystallization platform, continuous processing, best practice for unit operations, and Process Analytical Technology (PAT)
  - Collaborate with Drug Product division, pioneer dimer dissolution screening and in-silico hot melt extrusion (HME) technology development for enabling formulation of water-insoluble compounds
  - Collaborate with Purdue Univ. (Prof. Ramkrishna), investigate fundamental mechanisms affecting polymorph formation and crystal morphology domain
- MERCK RESEARCH LABORATORIES** **1986 - 2008**  
**Senior Investigator, Pharm R&D & Chem Eng R&D, Merck Research Laboratories (2001-2008)**
- Mentored scientists on enabling formulation technologies - spray drying, nano-precipitation and nano-milling for enhancing oral bioavailability, aerosol for pulmonary delivery, and liposomes for RNAi delivery
  - Founded the 1<sup>ST</sup> Crystallization Laboratory in the pharmaceutical industry; established crystallization platform; supported crystallization development of all small molecule APIs.
  - Collaborated with Princeton Uni. (Prof. Prud'homme), investigated nanoparticle precipitation for oral and parental deliveries
  - Collaborated with Uni. of Illinois (Prof. Braatz, now MIT), pioneered crystal kinetic parameter estimation and feedback control via Process Analytical Technology (PAT)
  - Collaborated with AspenTech (Dr. C-H Chen), pioneered NRTL-SAC solubility prediction for small molecule APIs
- Senior Research Fellow, Chem Eng R&D, Merck Research Laboratories (1996 - 2000)**
- Re-defined and established new Unit Operation Lab. to support API process development and scale-up:
    - ◇ crystallization (fluidized bed, semi-continuous/continuous operation, impinging jet)
    - ◇ reaction with various mixing configurations (vortex, mixing elbow, impinging jet)
    - ◇ drying (humid drying, lyophilization, agitated filter/dryer, conic screw dryer)
    - ◇ milling (pin, air-jet, rotor-stator, cavitation, sonication, & media milling)
    - ◇ cross-flow filtration, distillation, counter-current extractor and solid bowl centrifuge
- Research Associate / Research Fellow, Chem. Eng. R&D, Merck Research laboratories (1986-1995)**

## SELECTED PUBLICATIONS & BOOK

**Tung, Hsien-Hsin**, "Industrial Perspectives of Pharmaceutical Crystallization", *Organic Process R&D*, 445-454, 17(3) (2013).

**Tung, Hsien-Hsin**, Edward Paul, Michael Midler, James McCauley, "*Crystallization of Organic Compounds, An Industrial Perspective*", John Wiley & Sons (2009)

**Tung, Hsien-Hsin**, J. Tabora, N. Variakaval, Chauchyun Chen, "Prediction of Pharmaceuticals Solubility via NRTL-SAC and Cosmo-SAC", *Journal of Pharmaceutical Science*, 97, 1813-1820 (2007)

T. Togkalidou, **H.-H. Tung**, Y. Sun, A. Andrews, and R. Braatz, "Parameter Estimation and Optimization of a Loosely-Bound Aggregating Pharmaceutical Crystallization Using In-Situ Infrared and Laser Backscattering Measurements", *Ind. Eng. Chem. Res.* **43**, 6168-6181 (2004)

## SELECTED PATENTS

"Nanoparticle Formation via Rapid Precipitation", US 20110053927, WO2009/131930

"Method of Generating Amorphous Solids for Water-Insoluble Pharmaceuticals", US 20090111997, WO2007/061849

"Process and Apparatus for the Production of Crystalline Organic Microparticle Compositions by Micro-milling and Crystallization on Micro-Seed and Their Use", US 20090087492, EP1993513, WO/2007/106768

## SYNERGISTIC ACTIVITIES - INVITED SPEAKER

"Crystallization of Pharmaceuticals – An Industrial Perspective", Asymchem Symposium, Tianjin, China (2011)

"Mixing and Crystallization", Process System Engineering consortium, University of Mass, Amherst, MASS (2011)

"Solubility in Process and Product Development of Pharmaceuticals", AspenTech Pharmaceutical Seminar Series, Princeton, NJ (2007)

"Crystallization Development of Pure Bulk Pharmaceuticals", Banyu Pharmaceuticals, Japan (2005).

"Crystallization Development of Pure Bulk", 4<sup>th</sup> International Symposium Polymorphism and Crystallization, Scientific Update Conferences, England (2003).