

Tzu-chi “Rob” Ju, Ph.D.

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Summary of Professional Experiences

A technical leader with global perspectives and connection from 15 years working in three pharmaceutical/biotech organizations. Experiences include management in mature organizations, growing a young organization, contract manufacturing, overall product development from bench to commercial scales, new technology development, assessment of external opportunities, design and construction of manufacturing facility, and project management. Recognized expertise with track record accomplishment in the areas of controlled release technologies and bioavailability enhancement.

Professional Experiences

- 1/09 - **Scientific and Education Advisory Council, National Institute of Pharmaceutical Technology Education**
- 1/08 – present **Member of PQRI QbD Committees**
- Proposed and reviewed study proposals in support of revising regulatory guidance related to QbD.
- August 2006 **Associate Research Fellow, Group Leader, the Volwiler Society, Abbott**
- Recognized one of the top scientists in modified release and polymer science
 - Conceptualized, developed, and commercialized a novel modified release technology based on mini-tablets capable of achieving no food effects (Trilipix™ approval 4Q08).
 - Conceptualized, developed, and commercialize a combination product (Tricerad) of Trilipix™ and Crestor® using a novel encapsulation machine (NDA expected 2Q09).
 - President Awards, a prestigious award in Abbott for top performance.
 - Developed training program for formulators.
 - Pediatric formulations and task masking
 - Innovation Awards of Life Cycle Management
- 1/05 – present **Member of PQRI Biopharmaceutics Committees**
- Proposed and reviewed study proposals in support of revising regulatory guidance related to Biopharmaceutics.
 - Identified and helped monitor a study related to BCS Class III compounds and a case study of QbD.
- 7/02 – present **Group Leader, Global Pharmaceutical R&D, Abbott Laboratories**
- Innovation Awards in Life Cycle Management
 - Management and development of staff members.
 - Strategic planning, budgeting, infrastructure improvement, and talent retention.
 - New technology evaluation and development.
 - Product development, life cycle management, and project management
 - Co-advisor of a Ph.D. student.
- 9/99 – 7/02 **Head, Formulation of Small Molecule Pharmaceuticals, Amgen**
- Grew the Small Molecule Formulation Group; budgeting, talent retention, creation of infrastructure and information management systems.
 - Design and construction of a state-of-art pilot plant.
 - Management of 3rd party contract manufacturing.
 - Conceptualized, developed, and commercialized an immediate release formulation of a BCS Class II compounds using high shear granulation (Sensipar® approved in 2004)
 - Member of the Drug Delivery Technology Team.
- 4/99 – 9/99 **Group Leader, Non-conventional Dosage Forms, Pharmacia and Upjohn**

- Drug delivery systems for water insoluble compounds, especially using polymer mediated supersaturation.
 - Supervision and development of personnel.
- 6/98– 9/99 **CMC Project Leader, Pharmaceutical Development, Pharmacia and Upjohn**
- Project management of CMC activities; member of corporate project teams.
- 4/95 – 4/99 **Research Scientist, Drug Delivery R&D, Upjohn Company**
- Extended release (ER) formulations for five new chemical entities.
 - Formulation development, tech transfer, NDA filing, and PAI readiness.
 - Oral (solution and tablet) and IV formulation development.
 - Member of Drug Delivery Working Group.
 - Developed a training program for new formulators.
- 12/93 - 4/95 **Project leader, the Supersaturating Project: led a group of three scientists and two associates in identifying formulations for poorly soluble compounds.**
- 12/93 - 4/95 **Postdoctoral Research Scientist; the Upjohn Company, Drug Delivery R&D, MI.**
- Developed a “spaghetti” model which predicted polymer and drug release from hydrophilic matrices; formulation capable of pH-independent release.

Education:

- 12/93 **Ph.D. in Chemical Engineering, Stanford University, CA**
- 6/90 **M.S. in Chemical Engineering, Stanford University, CA**
- 8/86 - 5/88 **Ph.D. candidate in Chemical Engineering, University of Houston, TX (transferred to Stanford University)**
- 6/84 **B.S. in Chemical Engineering, National Taiwan University, Taiwan**

Other Leadership Experiences

- 6/04 ~ **Board Member**, Drug for AIDS and HIVS Patients (DAHP), a faith-based organization dedicated to the AIDS/HIV epidemic in Nigeria. Programs include procurement of drug supplies and testing kits, development and manufacture of cocktail formulations, and education.
- 2003 to present **Coordinator** of Midwest Thanksgiving Conference: coordinate centralized annual and regional conferences across US that involved approximately 1,000 participants
- 6/98 ~ 3/99 **Chairperson** of Greater Kalamazoo Chinese Association: led a group of 12 elected board members in organizing activities for the Kalamazoo community, especially for the local Chinese community.
- 6/87 - 8/88 **Vice president**, Graduate Student Association, University of Houston: Assisted in organizing an annual graduate student research conference where most of the 50 invited attendants came from corporations.

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Patents (granted and pending)

1. US8423, “Pharmaceutical compositions”, TR Ju, Huailiang Wu, Gao Yi, **2007**.
2. Ju, Tzuchi R.; Davila, Claudia M.; Gao, Yi; Gustavson, Linda E.; Leblond, David; Zhu, Tong. Pharmaceutical formulations. U.S. Pat. Appl. Publ. (**2007**), Cont.-in-part of U.S. Ser. No. 399,964.
3. Ju, Tzuchi R.; Davila, Claudia M.; Engh, Kevin R.; Gao, Yi; Gustavson, Linda E.; Jayaraman, Shyamala C.; Leblond, David; Lee, Dennis Y.; Zhu, Tong. Composition comprising 2-[4-(4-chlorobenzoyl)phenoxy]-2-methyl-propanoic acid. U.S. Pat. Appl. Publ. (**2007**).
4. Ju, Tzuchi R.; Engh, Kevin R.; Gao, Yi; Jayaraman, Shyamala C.; Lee, Dennis Y. Composition comprising 2-[4-(4-chlorobenzoyl)phenoxy]-2-methyl-propanoic acid. U.S. Pat. Appl. Publ. (**2007**).
5. Lipari, John M.; Lefebvre, Didier R.; Ju, Tzuchi R.; Marsh, Kennan C.; Zhang, Geoff; Jayanth, Jayanth; Pujara, Chetan P.; Cheskin, Howard S.; Vucenovic, Vitomir; Tong, Ping. Formulation comprising drug of low water solubility and phospholipid. PCT Int. Appl. (**2007**).
6. Ju, Tzuchi R.; Davila, Claudia M.; Gao, Yi; Gustavson, Linda E.; Leblond, David; Zhu, Tong. Oral pharmaceutical formulations of 2-[4-(4-chlorobenzoyl)phenoxy]-2-methylpropanoic acid. U.S. Pat. Appl. Publ. (**2006**).
7. EP 1017391B1, “sustained release tablet formulation to treat parkinson disease”, **2005**, Ju, Tzuchi, Robert.
8. EP1280521B1, “Vaccine Composition, Method Of Preparing The Same, And Method Of Vaccinating Vertebrates”, **2005**, Bowersock, Terry, L.; Guimond, Paul; Ju, Tzu-Chi, R.; Kidane, Argaw.
9. US20050147669A1, “Rapid dissolution formulation of a calcium receptor-active compound”, **2005**, Glen Lawrence, Gary; Alvarez, Francisco, Homer Lin, Tzuchi R Ju, patent pending.
10. US20040138200A1, “Pharmaceutical compositions for treatment of Parkinson’s disease”, **2004**, M Hawley, M Bergren, PR Nixon, GW Hasstead, RS Chao, and TR Ju, patent pending.
11. US20040071727A1, “Method Of Vaccinating Vertebrates”, **2004**, Bowersock, Terry, L.; Guimond, Paul; Ju, Tzu-Chi, R.; Kidane, Argaw, patent pending.
12. US6656470B2, “Vaccine Composition, Method of Preparing Same, and Method of Vaccinating Vertebrates”, **2003**, TJ Bowersock, P Guimond, TR Ju, and A Kidane.
13. US 6197339 B1, “Sustained Release Tablet Formulation to Treat Parkinson’s Disease”, **2001**, TR Ju.

Keynote Speeches

1. “Role of controlled release: current status and future trends” SMi Conference on Controlled Release”, February 14-15, **2005**, London. (in preparation)
2. Pharmaceutical Development annual Enz Awards meeting, Pharmacia and Upjohn, October 19, **1998**. (Enz Awards meeting brings top senior graduate students and faculty from six selected Pharmaceutics schools and internal scientists together for a two-day information exchange.)

Invited Speeches

1. Dissolution Enhancement For Formulations Containing Salt of a Poorly Soluble Compound, **2005** AAPS Annual Meeting, Nashville.
2. “The Effects of Formulation and Dosage Form Designs on IVIVC”, AAPS/FIP/CPA Joint Symposium on Pharmaceutics Sciences, June 7-9, **2004**, Nanjing, China.

3. Dissolution Enhancement For Formulations Containing Salt of a Poorly Soluble Compound, **2005** AAPS Annual Meeting, Nashville.
4. "The Effects of Formulation and Dosage Form Designs on IVIVC", AAPS Short Course "Drug Property, Formulation Design and Dissolution Considerations in Developing In Vitro-In Vivo Correlation (IVIVC) for Oral MR Products", October 26, **2003**, Utah.
5. "Physicochemical Characterization of Drug and Dosage Forms in IVIVC Development", D Law, Y Qiu and TR Ju, AAPS Short Course "Drug Property, Formulation Design and Dissolution Considerations in Developing In Vitro-In Vivo Correlation (IVIVC) for Oral MR Products", October 26, **2003**, Utah.
6. "Oral Polymeric Drug Delivery and Recent Development", SMi Conference on Controlled Release", February 12-13, **2003**, London.
7. Emerging Oral Controlled Release Technologies, Jiang Nan University, February **2002**.
8. "Formulation Factors That May Alter In Vivo Response to IVIVC", In Vitro – In Vivo Correlation Symposium 2001: Methods, Applications, & Future Directions, Baltimore, September 10-11, **2001**
9. "Emerging Oral Controlled Release Technologies", lecture in AAPS Workshop on State of the Art in Designing Controlled Release Solid Oral Dosage Forms, June **2001**, Tucson, AZ.
10. "Formulating Matrix Controlled Release System I", lecture in AAPS Workshop on State of the Art in Designing Controlled Release Solid Oral Dosage Forms, June, **2001**, Tucson, AZ.
11. "Formulating Matrix Controlled Release System II", lecture in AAPS Workshop on State of the Art in Designing Controlled Release Solid Oral Dosage Forms, June, **2001**, Tucson, AZ.
12. "Oral Vaccination of Mice with outer membrane proteins and one-shot antigens of Mannheimia haemolytica encapsulated in alginate microspheres", A Kidane, T Ju, P Guimond, M Sanchez, J Gibson, T Bowersock, **2001** Controlled Release Society annual Meeting, San Diego.
13. "Drug Release from Hydrophilic Matrices – the Spaghetti Theory", Department of Pharmaceutics, University of Iowa, November **2000**.
14. "Drug Release from Hydrophilic Matrices: The Science Behind Accelerated Product Development", Department of Pharmaceutics, University of Michigan, March **1999**.
15. "Performance of Extended Release Matrices and Multiparticulates: Principles and Case Studies", 38th Annual Eastern Pharmaceutical Technology Meeting, October 16, **1998**, Whippany, NJ.
16. "Drug Release from Hydrophilic Matrices: Using Good Science and Teamwork to Speed Formulation Development", Department of Industrial Pharmacy, Purdue University, September 15, **1998**.
17. "Stability of Particulate Systems: Effects of Polymer, Hydrophobic Interaction, pH and Ionic Strength", Seminar of Department of Industrial Pharmacy, Purdue University, February **1996**.
18. "Flocculation of Silica Particles by Hydrophobically Modified Polymers: Dynamic Light Scattering and Fluorescence Studies", the Symposium on Polymer/Colloidal Science and Engineering, **1995** annual Fine Particle Society Meeting, Chicago, IL.
19. "*Polymer-Particle Interaction in Aqueous Suspensions*", December **1993**, Hua-Cheng Pharmaceutical Company, Hsing-Tsu, Taiwan.

20. "Polymer-Particle Interaction in Aqueous Suspensions", December 1993, National Taiwan University, Taipei, Taiwan.
21. "Polymer-Particle Interaction in Aqueous Suspensions", December 1993, National Cheng-Kuan University, Tainan, Taiwan.
22. "Polymer-Particle Interaction in Aqueous Suspensions", December 1993, National Ching-Hui University, Hsing-Tsu, Taiwan.
23. "Polymer-Particle Interaction in Aqueous Suspensions", December 1993, Young-Ming Medical School, Taipei, Taiwan.

Book Chapters

1. P. Liu, T. R. Ju and Y. Qiu, Diffusion Controlled Systems in Design of Controlled Drug Delivery Systems. Edited by X. Li and B. R. Jasti. McGraw-Hill, 2006.
2. TR Ju, "Polyvinyl Alcohol", in Handbook of Pharmaceutical Excipients, ed., A H Kibbe, American Pharmaceutical Association, 2000, Washington, D.C., pp 424-25
3. KS Alexander, TR Ju, "Corn Oils", in Handbook of Pharmaceutical Excipients, ed., A H Kibbe, American Pharmaceutical Association, 2000, Washington, D.C., pp 154-55.

Manuscript Publications

1. Lan Xiao, Joe Robinson, and TR Ju, "Probing Gel Strengths using Texture Analyzer (I) Method, Model Development, and Insight into Formulation Design (I), under preparation.
2. Lan Xiao, Joe Robinson, and TR Ju, "Probing Gel Strengths using Texture Analyzer (II) Gel Structure of a Swelling Tablet, under preparation.
3. Wu-Wong, J. R.; Nakane, M.; Ma, J.; Ju, T. R., "Statins do not directly activate vitamin D receptor. Journal of Thrombosis and Haemostasis", 2007, 5(2), 415-416.
4. Kidane Argaw; Guimond Paul; Rob Ju Tzu-chi; Sanchez Margaret; Gibson Janet; North Adam; HogenEsch Harm; Bowersock Terry L "Effects of cellulose derivatives and poly(ethylene oxide)-poly(propylene oxide) tri-block copolymers (Pluronic)surfactants) on the properties of alginate based microspheres and their interactions with phagocytic cells", JOURNAL OF CONTROLLED RELEASE, 2002, 85(1-3), 181-9.
5. Kidane-A. Guimond-P. Ju-TC Rob. Sanchez-M. Gibson-J. Bowersock-TL, "The efficacy of oral vaccination of mice with alginate encapsulated outer membrane proteins of Pasteurella haemolytica and One-Shot(R)", Vaccine, 19, 2001, 2637-2646.
6. Kidane A.; Ju, T. R.; Guimond, P.; Sanchez, M.; Gibson, J.; Bowersock, T. L. Oral vaccination of mice with outer membrane proteins and One-Shot antigens of Mannheimia haemolytica encapsulated in alginate microparticles. Proceedings - 28th International Symposium on Controlled Release of Bioactive Materials and 4th Consumer & Diversified Products Conference, San Diego, CA, June 23-27, 2001, pages 1251-1252.
7. Robert T.C. Ju, Phillip R. Nixon, Mahesh V. Patel, "Diffusion Coefficients of Polymer Chains in the Diffusion Layer Adjacent to a Swollen Hydrophilic Matrix," Journal of Pharmaceutical Sciences, 86(11), 1997, 1293-1298.
8. Jeff D. Lewis, Robert T. C. Ju, Alexandra I. Kim, Steven L. Nail, "Kinetics of Low pH Induced Aggregation of Equine IgG" J. of Colloid Interface Sci., 196, 1997, 170-76.
9. KC Sung, PR Nixon, JW Skoug, TR Ju, P Gao, EM Topp, and MV Patel, "Effect of Formulation Variables on Drug and Polymer Release from HPMC-Based Matrix Tablets," Int. J. Pharm., 142, 1996, 53-60.

10. P. Gao, J.W. Skoug, P.R. Nixon, T.C.R. Ju, N. L. Stemm, K.C. Sung, 'Swelling of HPMC Matrix Tablets II: Mechanistic Study of the Influence of Formulation Variables on Drug Release Kinetics', J. Pharm. Sci., 85, 732-740, **1996**.
11. Ju, T.C.R., Nixon, P.R., Patel, M.V. 'Drug Release From Hydrophilic Matrices: (I). New Scaling Laws for Predicting Polymer and Drug Release Based on the Polymer Disentanglement Concentration and the Diffusion Layer', J. Pharm. Sci., 84, 1455-1463, **1995**.
12. Ju, T.C.R.; Nixon, P.R., Patel, M.V.; Tong, D.M. 'Drug Release From Hydrophilic Matrices (II). A Mechanistic Model Based on the Polymer Disentanglement and the Diffusion Layer', J. Pharm. Sci., 84, 1464-77, **1995**.
13. Ju, Robert T. C.; Nixon, Phillip R.; Patel, Mahesh V. New scaling laws for polymer and drug release from hydrophilic matrixes. Proceedings of the International Symposium on Controlled Release of Bioactive Materials (**1995**), 22nd 344-5.
14. Robert T.C. Ju, Curtis W. Frank and Alice P. Gast, 'CONTIN Analysis of Colloidal Aggregates', Langmuir, vol. 8, No. 9, p2165, **1992**.
15. Tzu-chi Robert Ju, 'Polymer-Particle Interaction in Aqueous Suspensions', Ph.D. Thesis, Stanford University, **1993**.
16. Robert T.C. Ju and Lii-ping Leu, 'Solution of the Graetz Problem of Power Law Fluids with Viscous Dissipation by Orthogonal Collocation - Constant Wall Temperature', J. Chinese Inst. of Chem. Eng., vol. 17, No.1, p17, **1986**.
17. Robert T.C. Ju and Lii-ping Leu, "Solution of the Graetz Problem of Power-Law Fluids with Viscous Dissipation by Orthogonal Collocation - Constant Wall Heat Flux", Proceedings of Symposium of Transport Phenomena and Application, Taipei, Taiwan, p102, **1984**.
18. Lan Xiao, Joe Robinson, and TR Ju, "Probing Gel Strengths using Texture Analyzer (I) Method, Model Development, and Insight into Formulation Design (I), under preparation.
19. Lan Xiao, Joe Robinson, and TR Ju, "Probing Gel Strengths using Texture Analyzer (II) Gel Structure of a Swelling Tablet, under preparation.

Conference Presentations:

1. Dissolution Enhancement For Formulations Containing Salt of a Poorly Soluble Compound (I), Huailiang Wu, Tzuchi R. Ju, Geoff G.Z. Zhang, **2005** AAPS Annual Meeting, Nashville.
2. Dissolution Enhancement For Formulations Containing Salt of a Poorly Soluble Compound (II), Huailiang Wu, Tzuchi R. Ju, Geoff G.Z. Zhang, **2005** AAPS Annual Meeting, Nashville.
3. Kim, D. K., Ju, T. R., Quan, B. P, "Characterization of Non-Disintegrating Granules: Relationship Between Water Level and Granule Structure", Poster Presented at AAPS Annual Meeting and Exposition, Toronto. Canada, **2002**.
4. Mark Menning, T R Ju, D Kim "Monitoring In-Process Particle Behavior during High-Shear Granulation with the Lasentec D600L FBRM" **2001** AAPS Annual Meeting, Denver, CO.
5. M Menning, M Cheng, TR Ju, "FBRM in the Formulation Development Laboratory: Part A: A Study of Particle Behavior During Dissolution", **2001** Lasentec User Conference, Barcelona, Spain.
6. M Menning, M Cheng, TR Ju, "FBRM in the Formulation Development Laboratory: Part B: Particle Behavior during Granulation", **2001** Lasentec User Conference, Barcelona, Spain.
7. Rob T.C. Ju, Phillip R. Nixon, John W. Skoug, E. John Lee, Ping Gao, Rena R. Schaller, Michael S. Hemenway, "HPMC-based extended-release matrices

- containing poorly-soluble compounds: a mechanistic study of the effects of key formulation variables on drug and polymer release.”, **1998** AAPS annual meeting, San Francisco, CA.
8. Skoug, J.W.; Gao, P.; Nixon, P.R.; Ju, T.C. '*Kinetics of Solute Release from Hydrophilic Matrix Extended Release Dosage Forms*'; **1995** Spring ACS National Meeting, Anaheim, CA.
 9. T.C. R. Ju, P.R. Nixon and M.V. Patel '*A New Scaling Law for Soluble Drug Release from Hydrophilic Matrices Based on the Polymer Disentanglement Concentration and the Diffusion Layer*', **1995** Controlled Release Society Meeting, Seattle, WA.
 10. T.C. R. Ju, P.R. Nixon, M.V. Patel and D. M. Tong '*A Mechanistic Model for Predicting Soluble Drug Release from Hydrophilic Matrices Based Upon the Microscopic Structure of Swollen Matrices*', **1995** Controlled Release Society Meeting, Seattle, WA.
 11. Ju, T.C.R.; Cooper, A.M.; Gauri, V.; Patel, M.V. '*pH Controlled Release Oral Drug Delivery: Effects of Bulk and Internal pH*', Paper No. PDD 7491 presented in the **1994** AAPS Annual Meeting, San Diego.
 12. Ju, T.C.R.; Nixon, P.R., Patel, M.V.; Sung, K.C. '*Swelling and Erosion of A Polymer Matrix: The Case of Hydroxypropylmethylcellulose (HPMC) in Water*', Paper No. PDD 7538, **1994** AAPS annual meeting, San Diego.
 13. Sung, K.C.; Nixon, P.R.; Skoug, J.W.; Patel, M.V.; Ju, T.C.R.; Gao, P.; Topp, E.M. '*Effect of HPMC Concentration and Viscosity Grade on the Swelling Kinetics and Drug Release of HPMC-Based, Matrix Extended-release Tablets*', Paper No. PDD 7490, **1994** AAPS Annual Meeting, San Diego.
 14. Robert T.C. Ju, Curtis W. Frank and Alice P. Gast, '*Structural Evolution of Colloidal Aggregates*', A.I.Ch.E **1991** annual meeting, Los Angeles, CA.