Metin Çelik, Ph.D.

22 Durham Road, Skillman, New Jersey 08558, USA Voice: + 1 908-864 0555 ; +90 548 853 0550 e-mail: <u>Metin.Celik@pt-int.com</u> metin.celik@neu.edu.tr

CURRICULUM VITAE

Current/Recent Position(s) and Affiliation(s):

9/97 - present:President, Pharmaceutical Technologies International, Inc. (PTI), Skillman, NJ.08/08 - presentPart-time faculty member, Department of Pharmaceutical Technology, Faculty of
Pharmacy, Near East University, Nicosia, Turkish Republic of Northern Cyprus

Fields and Areas of Specialization:

Dr. Çelik's recent areas of interests include:

- QbD and PAT;
- Development of solid dosage formulation and processing (including milling, mixing, granulation, tabletting, and film coating) using SUPAC guidelines, QbD and PAT approach
- Process assessment of pharmaceutical manufacturing process for solid dosage forms
- Evaluation of novel drug delivery technologies;
- Development of artificial intelligence based pharmaceutical expert systems, excipient databases (for tableting, spray drying, film coating, and novel dosage forms), and management tools for FDA inspection preparations (PAI, API, Validation, Technology Transfer, etc)
- Utilization of compaction simulators in the product development; pharmaceutical compaction; excipient functionality;

Education:

B.S. (Hons.): Faculty of Pharmacy, Hacettepe University, Ankara, Turkey (1979).

Ph.D.: Department of Pharmaceutical Technology, School of Pharmacy, De Montfort University (formerly known as Leicester Polytechnic), UK (1984).

Previous Positions Held:

1/04 – 08/08	Faculty, Department of Industrial & Systems Engineering, Rutgers University, Piscataway, NJ	
	1/04 – 9/04	Part-time Faculty
	9/05 — 5/08	(Visiting) Research Professor of Pharmaceutical Processing
9/1988 - 7/1997: Assistant Professor of Pharmaceutics, and Director of Pharmaceutical Compaction Research		
Labora	tory & Information	Center, College of Pharmacy, Rutgers University, Piscataway, NJ.
6/1986 - 9/1988: Post Doctoral Scientist, Pharmaceutical Research & Technologies, SK & F Labs, Swedeland, PA.		
11/1985 - 3/1986: Military Service.		
5/1985 - 10/1985: Development Coordinator, Galenical R & D, Sandoz, Istanbul, Turkey.		
7/1984 - 5/1985: Special Trainee, Galenical R & D, Sandoz Ltd., Basel, Switzerland.		

Professional Licensure:

Pharmacy License (Turkey)

Honors, Awards, Promotions, and Recognitions:

Faculty Academic Service Increment Program Award (1991, 1993, 1994) Who is who in science and engineering (1995) Commission of Science & Technology of New Jersey Award (1996).

THE PORTFOLIO OF ACCOMPLISHMENTS

1. Publications:

<u>Book</u>:

M. Çelik "Pharmaceutical Powder Compaction Technology", 2nd Edition, Informa Healthcare (2011).

Book Chapters:

M. Çelik*, M. Mollan and N. Chang, "The reworkability of microcrystalline cellulose formulations" in "Tableting technology Volume 2 (Compression), Edited by J.I. Wells and M.H. Rubinstein, Ellis Horwood, Chapter 5, 44-61 (1993).

M. Çelik, "Compaction of multiparticulate oral dosage forms", in "Multiparticulate oral drug delivery" (Edited by I. Ghebre-Sellassie), Marcel Dekker, Inc., Chapter 9, 181-216 (1994).

M. Çelik* and L. Maganti, "An overview of the compaction of microspheres" in "Minutes: 9th Int. Symposium on Microencapsulation", 157-168, Edited by S. Kal and A.A. Hincal, Editions de Santé, Paris (1994).

M.J. Mollan, Jr. and M. Çelik*, "Maltodextrin", in "Analytical profiles of drug substances and excipients", Edited by H.G. Brittain, Vol. 24, Chapter 8, 307-350, Academic Press (1996).

M. Çelik and S.C. Wendel "Spray drying", in "Handbook of Granulation Technology", Edited by Dilip Parikh, 2nd Edition, Taylor & Francis, Chapter 5, 129-157 (2005).

M. Çelik and S.C. Wendel "Spray drying and pharmaceutical applications", in "Handbook of Granulation Technology", Edited by Dilip Parikh, 3nd Edition, Informa Healthcare, Chapter 5, 98-126 (2009).

M. Çelik and S.C. Wendel "Expert systems and their pharmaceutical applications", in "Handbook of Granulation Technology", Edited by Dilip Parikh, 3nd Edition, Informa Healthcare, Chapter 5, 579-597 (2009).

C. Ruegger and M. Çelik, "Advanced compaction research equipment, Compaction simulators", in Pharmaceutical Powder Technology, Edited by M. Çelik, 2nd Edition, Informa Healthcare, Chapter 6, (2011).

M. Çelik, "Expert systems and their use in pharmaceutical applications", in Pharmaceutical Powder Technology, Edited by M. Çelik, 2nd Edition, Informa Healthcare, Chapter 13, (2011).

Refereed Journal Articles:

D.N. Travers*, M. Çelik and T.C. Buttery, "A computer aided investigation on strain movements in compacts under constant stress within the die", Drug Dev. & Ind. Pharm., 9, 139 - 157 (1983).

M. Çelik, D.N. Travers* and T.C. Buttery, "Computer logged changes of strain movements in compacts of direct compression bases and granules produced by wet massing techniques", Labo-Pharma, 32, 22 - 27 (1984).

M. Çelik and D.N. Travers*, "The use of an elastic recovery index as a criterion of compactional behavior of some direct compression bases", Drug Dev. & Ind. Pharm., 11, 299 - 314 (1985).

M. Çelik and K. Marshall, "Use of a compaction simulator system in tabletting research, I. Introduction to and initial experiments with the system", Drug Dev. & Ind. Pharm., 15(5), 759 - 800 (1989).

M. Çelik* and N. G. Lordi, "The Pharmaceutical Compaction Research Laboratory & Information Center", Pharm. Technol., 15(3), 112 - 116 (1991).

M. Çelik, "Overview of compaction data analysis techniques", Drug Dev. & Ind. Pharm., 18(6&7) 767 - 810 (1992).

L. Maganti and M. Çelik* "Compaction studies on pellets Part I: Uncoated pellets", Int. J. Pharmaceutics, 95, 29 - 42 (1993).

M. Çelik* and C.E. Driscoll, "An overview of the effects of some physico-chemical and mechanical characteristics of particulates on the compaction and post-compaction properties of compacts", Drug Dev. & Ind Pharm., <u>19(17-18)</u>, 2119 - 2141 (1993).

M. Çelik* and E. Okutgen, "A feasibility study for the development of a perspective compaction functionality testing and the establishment of a compaction data bank", Drug Dev. & Ind Pharm., 19(17-18), 2309 - 2334 (1993).

M.J. Mollan, Jr. and M. Çelik*, "Characterization of directly compressible maltodextrins manufactured by three different processes", Drug Dev. & Ind Pharm., 19(17-18), 2335 - 2358 (1993).

L. Maganti and M. Çelik*, "Compaction studies on pellets Part II: Coated pellets", Int. J. Pharmaceutics, 103, 55 - 67 (1994).

M.J. Mollan, Jr., and M. Çelik*, "Tabletability of maltodextrins and acetaminophen mixtures", Drug Dev. & Ind. Pharm. 20(20), 3139 - 3149 (1994).

M. Çelik* and L. Maganti, "Formulation and compaction of microspheres", Drug Dev. & Ind. Pharm., 20(20), 3151 - 3173 (1994).

M.J. Mollan, Jr., and M. Çelik*, "The effects of humidity and storage time on the behavior of maltodextrins for direct compression", Int. J. Pharmaceutics, 114(1), 23-32 (1995).

M.J. Mollan, Jr., N. Chang and M. Çelik*, "The effect of reworking on post-compaction properties of microcrystalline cellulose formulations", Pharm. Technol. 19(10), 2-14 (1995).

M. Çelik, "The past, present and future of tableting technology", Drug Dev. & Ind. Pharm., 22(1), 1-10 (1996).

M. Çelik* and M.E. Aulton, "The viscoelastic deformation of some tableting materials as assessed by indentation rheology", Drug Dev. & Ind. Pharm., 22(1), 67-75, (1996).

M. Çelik*, J.T.H. Ong, Z.T. Chowhan and G.J. Samuels, "Compaction simulator studies of a new drug substance: Effect of particle size and shape, and its binary mixtures with microcrystalline cellulose", Pharmaceutical Development & Technology, 1(2), 119-126 (1996).

M. Çelik* and C.E. Ruegger, "An overview of tableting technology - Part I: Tablet presses and instrumentation", Pharm. Technol., Vol. 20, Suppl. 20-39(1996).

M.J. Mollan, Jr. and M. Çelik*, "The effects of lubrication on the compaction and post-compaction properties of directly compressible maltodextrins". Int. J. Pharmaceutics, 144(1), 1-9 (1996).

S. A. Sharpe, H. G. Brittain*, A. W. Newman, and M. Çelik, "Physical characterization of the polymorphic variations of magnesium stearate and magnesium palmitate species". Structural Chemistry, 8, 73-84 (1997).

S.C. Wendel & M. Çelik*, "An overview of spray drying applications", Pharm. Technol., 21(10), 124-156 (1997).

C. E. Ruegger & M. Çelik*, "The effect of compression and decompression speed on the mechanical strength of the compacts", Pharmaceutical Development & Technology, 5(4), 485-494 (2000).

C. E. Ruegger & M. Çelik*, "The influence of varying pre- & main compaction profile parameters on the mechanical strength of the compacts", Pharmaceutical Development & Technology, 5(4), 495-505 (2000).

R. Sirihorachai, S.C. Wendel & M. Çelik*, "Evaluation of a novel portable instrumented punch system", stp Pharma Pratiques, (10) 27-31, 2000

M. Çelik, "Catching up with Expert Systems", Pharm. Technol., 25(7), 122-124 (2001)

M. Çelik, "Excipient selection: Practical advice on using SUPAC", Tablets & Capsules, 6(6), PP. , 2008

M. Çelik, Eye on Excipients: "Compactability testing of excipients", Tablets & Capsules, 7(3), 37-40, 2009

M. Çelik, Eye on excipients: "Compactability testing of excipients, Part 2", Tablets & Capsules 7(4), 33-37, 2009

M. Çelik, Eye on Excipients: "Tools for risk-based product development", Tablets & Capsules, 7(6), 55-59, 2009

Non-Refereed Journal Articles:

M. Çelik, "A new method for characterizing the compression process", IPP (Information for Pharmaceutical Production), 2(March), 23 - 29 (1985).

Book Reviews:

M. Çelik, "Excipient and delivery systems for pharmaceutical formulations", Journal of American Chemical Society, 118(21), 5160 (1996).

Abstracts:

M. Çelik and D.N. Travers, "Tablet compression studies using a 5 channel computer linked data processor", Pharm. Research, 4(2), S69 (1987).

E. Okutgen, P. Wray and M. Çelik, "The effect of crystal surface history on post- compaction properties of sodium chloride tablets", Pharm. Research, 9(10), S115 (1992).

M. Çelik, D. Goldman, E. Okutgen, R. Pinal and A.W. Malick, "Simulation of an F-3 single station press using an integrated compaction research system", Pharm. Research, 9(10), S134 (1992).

M.J. Mollan, Jr. and M. Çelik, "Direct compression of maltodextrins and acetaminophen", Pharm. Research, 9(10), S134 (1992).

M. Çelik, E. Okutgen and C. Driscoll, "Compaction functionality testing", Pharm. Research, 10(10), S138 (1993).

E. Okutgen, C. Driscoll and M. Çelik, "Introduction to a compaction data bank", Pharm. Research, 10(10), S138 (1993).

M.J. Mollan, Jr. and M. Çelik, "Lubrication effects on the properties of maltodextrins", Pharm. Research, 10(10), S146 (1993).

M.J. Mollan, Jr. and M. Çelik, "The effect of humidity on the properties of maltodextrins", Pharm. Research, 10(10), S146 (1993).

M. Çelik and M.E. Aulton, "The viscoelastic deformation of some tableting materials as assessed by indentation rheology", Pharm. Research, 11(10), S131 (1994).

C.E. Driscoll, E. Okutgen and M. Çelik, "A new approach to the use of pre- & main compaction cycles", Pharm. Research, 11(10), S132 (1994).

A. Ayman, M. Çelik, H. Brittain, A. Newman and G. Young, "Physicochemical properties of the pure magnesium stearate pseudopolymorphs", Pharm. Research, 11(10), S152 (1994).

C. Driscoll-Ruegger and M. Çelik, "The effect of compression and decompression speed on the mechanical strength of compacts", Pharm. Research, 12(9), S179 (1995).

M. Çelik, "The use of Force-Time Curves to evaluate the compaction behavior of pharmaceutical materials", Pharm. Research, 12(9), S185 (1995).

M. Çelik and E. Okutgen, "An electronic tablet compaction data bank - I: Microcrystalline cellulose", Pharm. Research, 12(9), S185 (1995).

M. Çelik and E. Okutgen, "An electronic tablet compaction data bank - I: Microcrystalline cellulose", European Journal of Pharmaceutics and Biopharmaceutics, Suppl. 5S (1996).

M. Çelik, A.W. Newman, R. Mueller, C. Kiesnowski, I. Vitez, S.A. Sharpe, R.C. Moreton, "Pre-compaction and lubrication properties of Pruv", Pharm. Research, 13(9), S200 (1996).

M. Çelik, R.C. Moreton, B.E. Sherwood, J.D. Cobb, D.J. Schaible, and J.A. Zeleznik, "The effects of moisture content and particle size on the functional properties of microcrystalline cellulose for use in direct compression", Pharm. Research, 13(9), S209 (1996).

C. Driscoll-Ruegger, M. Çelik and S.D. Bateman, "Simulation of an instrumented manesty betapress using an integrated compaction research system", Pharm. Research, 13(9), S209 (1996).

M. Çelik and R.L. Schmitt, "A Study on the compaction properties of three water soluble polymers", Pharm. Research, 14(11), 1 (1997).

S. Wendel and M. Çelik, "Limitations of applying artificial neural networks to a small spray drying data set and methods for overcoming limitations", Pharm. Research, 14(11), 88 (1997).

J. Engelhart and M. Çelik, "Feasibility of predicting lyophilization endpoint using artificial neural networks", Pharm. Research, 14(11), 88 (1997).

M. Çelik, R. Sirihorachai, and F. Spadaccini, "Artificial neural networks aided study on the comparison of the models 193 and 197 of the quadro-comil milling equipment", Pharm. Research, 14(11), 92 (1997).

2. **Presentations**:

Invited Presentations/Plenary Lectures at Scientific Meetings:

"Compaction simulators - A historical perspective", New Jersey Pharmaceutical Discussion Group Meeting, New Brunswick, NJ (October 1988).

"Potential applications of the compaction simulators in advanced tableting technology", AAPS-Eastern Regional Meeting, East Brunswick, NJ (June 1989).

"The role of the integrated tablet research systems in the drug development", Johnson & Johnson's Annual Symposium on Drug Delivery, New Brunswick, NJ (October 1990).

"Integrated tablet research systems: A case study", 26th Annual Arden House Conference, Harriman, NY (January 1991).

"Overview of compaction data analysis techniques", The First Symposium of the PCRL & IC on the physics of tablet compaction, Piscataway, NJ (March 1991).

"Instrumented tablet machines and compaction simulators: What they are & what they can do?", Pharm. Tech. Conference, New Brunswick, NJ (September 1991).

"A Case Study: Compaction behavior of the pellets", Pharm. Tech. Conference, New Brunswick, NJ (September 1991).

"The role of compaction studies on the design and development of tablet formulations", Pharmaceutical & Cosmetic Engineering World Conference, Philadelphia, PA (October 1991).

"The effects of physico-mechanical characteristics of particulates on the compaction and post-compaction properties of compacts", The Second Symposium of the PCRL & IC on the compaction behavior of pharmaceutical materials, Piscataway, NJ (March 1992).

"Integrated Compaction Research Systems: "Compaction Simulators", Philadelphia Pharmaceutical Forum, Philadelphia, PA (September 1992).

"Compaction functionality testing of tableting excipients and introduction to a compaction data bank", The Third Symposium of the PCRL & IC on the application of compaction techniques as prospective functionality tests for tablet excipients, Piscataway, NJ (March 1993).

"Functionality testing for tableting excipients", AAPS-Eastern Regional Meeting, New Brunswick, NJ (June 1993).

<u>Plenary Lecture:</u> "Fundamentals of compaction", Symposium on the Pharmaceutical Solid Technology at the First International Conference on Pharmaceutical Science and Technology in Conjunction with the 24th Annual Meeting of the Fine Particle Society, Chicago, IL (August 1993). <u>Plenary Lecture:</u> "A functionality testing for tableting excipients and introduction to a compaction data bank", FIP Post-Satellite Symposium'93 Seoul: Pharmaceutical Excipients, Seoul, Korea (September 1993).

<u>Plenary Lecture:</u> "Compaction of microspheres and microcapsules", 9th International Symposium on Microencapsulation, Ankara, Turkey (September, 1993).

"Critical aspects to consider in the formulation and compaction of microspheres", The Fourth Symposium of the PCRL & IC on the tabletability of multiparticulates: A new technology, Piscataway, NJ (March 1994).

"Microcrystalline cellulose in tableting", Mendell Symposium, Cedar Rapids, IO (April 1994).

"Formulation and compaction of coated and uncoated microspheres", Rhône-Poulenc Symposium on Biodegradability and Formulation, Research Triangle Park, NC (October 1994).

"The past, present and future of tableting technology", The Fifth Symposium of the PCRL & IC on tableting technology in the year 2001, Piscataway, NJ (March 1995).

<u>Plenary Lecture:</u> "The past, present and future of tableting technology", Symposium on the Pharmaceutical Solid Technology at the International Conference on Pharmaceutical Science and Technology in Conjunction with the 26th Annual Meeting of the Fine Particle Society, Chicago, IL (August 1995).

"Functionality testing and batch to batch consistency of pharmaceutical excipients", AAPS Process Development Focus Group Meeting, 10th Annual AAPS Meeting, Miami, FL (November 1995).

"Is there an electronic database in your future? What you should and need to know", Pharm. Tech. Conference, Philadelphia, PA (September 1997).

"An overview of pharmaceutical expert systems", 12th Annual AAPS Meeting, Boston, MA (November 1997).

"How expert systems can enhance pharmaceutical process and development", IIR Meeting on Pharmaceutical Dosage Forms, Orlando, FL (December 1997).

"Pharmaceutical expert systems and databases", 1998 Conference on Pharmaceutical Science & Technology, Dallas, TX (April 1998).

<u>Plenary lecture (Speaker of the month):</u> "Formulation and processing expert systems", NJPhAST Meeting, Somerset, NJ (April 1998).

"Pharmaceutical Expert Systems", Tablet Manufacturing Technology, Atlantic City, NJ (April 1998).

"Use of compaction simulators in tableting technology", Recent Advances in Pharmaceutical Tableting Technology, Las Vegas, NE (May 1998).

"Pharmaceutical (formulation & process) expert systems", Recent Advances in Pharmaceutical Tableting Technology, Las Vegas, NE (May 1998).

"How expert systems can enhance pharmaceutical process and development", IIR Meeting on Pharmaceutical Dosage Forms, Princeton, NJ (May 1998).

"Application of artificial neural networks in pharmaceutical processing", AAPS Eastern Regional Meeting, Parsippany, NJ (June 1998).

"Pharmaceutical formulation and processes expert systems", Pharm. Tech. Puerto Rico Conference, Rio Grande, PR (June 1998).

"Pharmaceutical formulation and processing expert systems and databases", Second International Meeting on Pharmacy & Pharmaceutical Sciences, Istanbul, Turkey (September 1998).

"The rational choice of excipients: Preformulation databases", Pharm. Tech. Europe Conference, Dusseldorf, Germany (October 1998).

"Pharmaceutical expert systems", Tablet Manufacturing CANADA'98, Richmond Hill, Ontario, Canada (October 1998).

"Expert systems: The future of formulation & process development", 13th AAPS Annual Meeting, San Francisco, CA (Nov 1998).

"Integrated compaction research systems: Compaction Simulators", 34th Annual Pharmaceutical Technologies Section Conference at Arden House, Harriman, NY (January 1999)

"Use of instrumented tablet presses in formulation studies", 34th Annual Pharmaceutical Technologies Section Conference at Arden House, Harriman, NY (January 1999)

"How to make most of the compaction simulators", Arden House 4th European Conference, Cambridge, UK (February-March 1999).

"Use of expert systems & databases in the development of pharmaceutical formulation & processes", 12th Powrex Symposium, Tokyo, Japan (July 1999).

"Utilization of expert systems technology to troubleshoot pharmaceutical processes", Troubleshooting'99, Atlantic City, NJ (October 1999).

"Expert Systems: Use of predictive science in pharmaceutical applications", Tablet Manufacturing Technology'2000 Atlantic City, NJ (April 2000).

"Theory and Practice of Compaction", Formulations Forum 2000, Orlando, FL (September 2000)

<u>Plenary Lecture:</u> "The use of expert systems in pharmaceutical applications", Second workshop on physical characterization of pharmaceutical solids", Lancaster, PA (September 2000).

"Theory and practice of compaction", Second workshop on physical characterization of pharmaceutical solids", Lancaster, PA (September 2000).

<u>Plenary Lecture:</u> "Use of Artificial Intelligence in the preparation of FDA inspections: PAI, QSIT, API, Solid Dosage Form Validation", NJPhAST Meeting, Mahwah, NJ (October 2001).

"Compaction Simulator: Its role in characterizing pharmaceutical solids", AAPS Drug Delivery Conference 2002, Arlington, VA (April 2002).

"The rational choice of excipients utilizing a preformulation database", Barnett International's 2nd Pharmaceutical Excipients Conference, Philadelphia, PA (June 2002).

"The rational choice of excipients utilizing a preformulation database", Barnett International's Raw Materials Conference, Philadelphia, PA (October 2002).

"Critical Overview of the Proposed USP Compaction Functionality Test", 17th AAPS Annual Meeting, Toronto, Ontario, Canada (November 2002).

"Use of AI in Formulation & Process Development and FDA Inspection Preparations", AAPS – PT Section Conference, Advances in Pharmaceutical Processing, Parsippany, NJ (June 2003).

"Practical and Regulatory Considerations for Utilizing a Preformulation Database in the Characterization of Excipients", Pharmaceutical Excipients Conference, Philadelphia, PA (June 2003).

"Tools for Knowledge Management: Neural Networks and Expert Systems", 39th Arden House Conference on "Quality by Design in Pharmaceutical Development and Manufacturing: Principles, Applications and Scientific Risk-Based Regulatory Decisions", Harriman, NY (January 2004).

"Theory and practice of compaction", Advanced Practices in pharmaceutical tablet and capsule technology", Las Vegas, NE (May 2004).

"Practical and regulatory considerations for utilizing a preformulation database in the characterization of excipients", Barnett International's 4th Annual Pharmaceutical Excipients Conference" Philadelphia, PA (May 2004).

"What does PAT mean for the formulation scientist?", 1st Annual Symposium on Process Analytical Technology (PAT), Piscataway, NJ (March 2005): Acted the program co-chair and a speaker.

"Theory and practice of compaction", Advanced Practices in pharmaceutical tablet and capsule technology", Las Vegas, NE (May 2005).

"Practical and regulatory considerations for utilizing a preformulation database in the characterization of excipients", Barnett International's 5th Annual Pharmaceutical Excipients Conference" Philadelphia, PA (June 2005).

"Selecting Optimal Excipients for Direct Compression: Considering the SUPAC and PAT Guidelines", Advances in Direct Compression" Philadelphia, PA (June 2005).

"The use of Artificial Intelligence 'Expert Systems' as formulation and process tools to overcome the PAT challenges", 18th Powrex Symposium, Osaka, Japan (July 2005).

"The use of Artificial Intelligence 'Expert Systems' as formulation and process tools to overcome the PAT challenges", 3rd Annual Garnet E. Peck Symposium in Industrial Pharmacy, Lafayette, IN (October 2005).

"FDA's Process Analytical Technology (PA) initiative and formulation & processing related challenges" Las Vegas, NE (May 2006).

"Theory and practice of compaction", Advanced Practices in pharmaceutical tablet and capsule technology" Las Vegas, NE (May 2006).

"Use of new technologies/tools in the development and manufacturing of novel dosage forms", ISPE Washington Conference, Arlington, VA (June 2006).

"Turning the results of preformulation studies into robust formulation and process development", PharmTech

Conference, Somerset, NJ (June 2006).

"FDA's Process Analytical Technology (PA) initiative and formulation & processing related challenges", Las Vegas, NE (May 2007).

"Theory and practice of compaction", Advanced practices in pharmaceutical tablet and capsule technology", Las Vegas, NE (May 2007).

"Use of artificial intelligence [expert systems]in pharmaceutical applications", Pharmaceutical Technology Seminar 2011 – "Advances in Tablet Production", Singapore, Singapore (May 2011).

"Theory and Practice of pharmaceutical compaction I", Pharmaceutical Technology Seminar 2011 – "Advances in Tablet Production", Singapore, Singapore (May 2011).

"Theory and Practice of pharmaceutical compaction II", Pharmaceutical Technology Seminar 2011 - Pharmaceutical Technology Seminar 2011, Singapore, Singapore (May 2011)

"Use of artificial intelligence [expert systems]in pharmaceutical applications", Pharmaceutical Technology Seminar 2011 – "Advances in Tablet Production", Ho Chi Minh City, Vietnam (May 2011).

"Theory and Practice of pharmaceutical compaction I", Pharmaceutical Technology Seminar 2011 – "Advances in Tablet Production", Ho Chi Minh City, Vietnam (May 2011).

"Theory and Practice of pharmaceutical compaction II", Pharmaceutical Technology Seminar 2011 - Pharmaceutical Technology Seminar 2011, Ho Chi Minh City, Vietnam (May 2011).

"Use of artificial intelligence [expert systems]in pharmaceutical applications", Pharmaceutical Technology Seminar 2011 – "Advances in Tablet Production", Suwon, South Korea (June 2011).

"Theory and Practice of pharmaceutical compaction I", Pharmaceutical Technology Seminar 2011 – "Advances in Tablet Production", Ho Chi Minh City, Suwon, South Korea (June 2011).

<u>Plenary Lecture</u>: "Theory and Practice of pharmaceutical compaction", XIII Argentinean Congress of Industrial Pharmacy and Biochemistry and II Latin American Congress of Industrial Pharmacy and Biochemistry, Buenos Aires, Argentine (November 2011).

<u>Plenary Lecture</u>: "Advanced formulation development strategies and expert systems", XIII Argentinean Congress of Industrial Pharmacy and Biochemistry and II Latin American Congress of Industrial Pharmacy and Biochemistry, Buenos Aires, Argentine (November 2011).

<u>Plenary Lecture</u>: "Impact of pharmaceutical science for the pharmaceutical industry", Asian Federation for Pharmaceutical Sciences Conference, Kuala Lumpur, Malaysia (December 2011).

<u>Plenary Lecture</u>: "Intelligent and Risk-based approaches to formulation and process development", Asian Federation for Pharmaceutical Sciences Conference, Kuala Lumpur, Malaysia (December 2011).

<u>Plenary Lecture</u>: "The past, present and the future of pharmaceutical industry: Impact of Pharmaceutical Sciences", Conference on Recent Advances in Pharmaceutical Science: Transferring Knowledge From Education To Sceince, Kathmandu, Nepal (February 2012).

Plenary Lecture: "The PAT challenge for the formulation and process development scientist", Symposium on

"Simulator Aided Tablet Formulation Development Technique", Nicosia, (May 2012).

"Introduction to tableting", GEA-NUS Pharmaceutical Processing Research Laboratory, Pharmaceutical Tablet Technology Seminar & "Hands-on" Workshop, Singapore (December 2013).

"Physics of compaction", GEA-NUS Pharmaceutical Processing Research Laboratory, Pharmaceutical Tablet Technology Seminar & "Hands-on" Workshop , Singapore (December 2013).

"Theory and practice of compaction, Part I, and Part II", GEA-NUS Pharmaceutical Processing Research Laboratory, Pharmaceutical Tablet Technology Seminar & "Hands-on" Workshop, Singapore (December 2013).

"Tablet simulators", GEA-NUS Pharmaceutical Processing Research Laboratory, Pharmaceutical Tablet Technology Seminar & "Hands-on" Workshop, Singapore (December 2013).

"Use of artificial intelligence in pharmaceutical applications: Expert Systems", GEA-NUS Pharmaceutical Processing Research Laboratory, Pharmaceutical Tablet Technology Seminar & "Hands-on" Workshop, Singapore (December 2013).

Presentations/Invited Lectures at Scientific Short Courses:

"Theory and practice of compaction", Tablet Technology Update, College of Pharmacy, Rutgers University, Piscataway, NJ (March 1989).

"Computer technology in pharmaceutical manufacturing", FDA Course in Industrial Pharmacy, St. John's University, Jamaica, NY (June 1990).

"Theory and practice of compaction", Tablet Technology Update, College of Pharmacy, Rutgers University, Piscataway, NJ (September 1990).

"Theory and practice of compaction", Merck Sharp & Dohme, West Point, PA (December 1990).

"Theory and practice of compaction", Takeda Tablet Technology Update, Toronto, Canada, (February, 1991).

"Formulation aspects of solid dosage forms", Advanced courses for FDA inspectors, North Brunswick, NJ (November 1991).

"Tablet and capsule machine instrumentation A, The Institute for Applied Pharmaceutical Sciences, East Brunswick, NJ (July 1992).

"Compaction, functionality testing and compaction data bank", 1st Tablet technology update symposium: Tableting technology in the year 2000, Istanbul, Turkey (April 1994).

"Dissolution and bioavailability", 1st Tablet technology update symposium: Tableting technology in the year 2000, Istanbul, Turkey (April 1994).

"Contract research: Pros & cons", 1st Tablet technology update symposium: Tableting technology in the year 2000, Istanbul, Turkey (April 1994).

"Tableting technology", FDA Field Investigators Short Course in Pharmaceutical Science, Rutgers University, Piscataway, NJ (June 1995).

"The rational choice of Excipients", PTI's 1st Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2004).

"Theory and practice of pharmaceutical compaction", PTI's 1st Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2004).

"Evaluation and critical parameter of spray-drying and their impact on the stability of the resulting products", PTI's 1st Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2004).

"The rational choice of Excipients", PTI's 2nd Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2005).

"Theory and practice of pharmaceutical compaction", PTI's 2nd Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2005).

"Current challenges and suggested solutions in formulation & process development", PTI's 3rd Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2006).

"Use of AI based expert systems as PAT tools", PTI's 3rd Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2006).

"Theory and practice of pharmaceutical compaction", PTI's 3rd Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2006).

"Current challenges and suggested solutions in formulation & process development", PTI's 4rd Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2007).

"Use of AI based expert systems as PAT tools", PTI's 4rd Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2007).

"Theory and practice of pharmaceutical compaction", PTI's 4rd Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April 2007).

"Current challenges and suggested solutions in formulation & process development", PTI's 5th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April-May 2008).

"Use of AI based expert systems as PAT tools", PTI's 5th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April-May 2008).

"Theory and practice of pharmaceutical compaction", PTI's 5th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April-May 2008).

"Current challenges and suggested solutions in formulation & process development", PTI's 6th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April-May 2009).

"Use of AI based expert systems as PAT tools", PTI's 6th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April-May 2009).

"Theory and practice of pharmaceutical compaction", PTI's 6th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (April-May 2009).

"Current challenges and suggested solutions in formulation & process development", PTI's 7th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (August-September 2010).

"Use of AI based expert systems as PAT tools", PTI's 7th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (August-September 2010).

"Theory and practice of pharmaceutical compaction", PTI's 7th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (August-September 2010).

"Current challenges and suggested solutions in formulation & process development", PTI's 7th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (August 2011).

"Use of AI based expert systems as PAT tools", PTI's 7th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (August 2011).

"Theory and practice of pharmaceutical compaction", PTI's 7th Training Program on the formulation and process development for oral dosage forms, Nassau Inn, Princeton, NJ (August 2011).

"Is there s preformulation/compaction database in your future?" and "Use of AI Tools in Pharmaceutical Applications [Expert Systems]", Symposium on Compaction Technologies, Paris (October 2011)

"Introduction to tabletting", GEA-NUS Pharmaceutical Technology Workshop, Singapore, Singapore (December 2011).

"Tablet design: SUPAC Guidelines", GEA-NUS Pharmaceutical Technology Workshop, Singapore, Singapore (December 2011).

"Physics of compaction", GEA-NUS Pharmaceutical Technology Workshop, Singapore, Singapore (December 2011).

"The practical applications of tablet press instrumentation", GEA-NUS Pharmaceutical Technology Workshop, Singapore, Singapore (December 2011).

"Trouble shooting in tabletting", GEA-NUS Pharmaceutical Technology Workshop, Singapore, Singapore (December 2011).

Invited Seminars for Academia/Industry:

"Tablet compression studies", Sandoz Ltd., Basle, Switzerland (December 1983).

"A new method for characterizing the compression process", Pharm. Institute, University of Basle, Basle, Switzerland, (January 1985).

"Fundamentals of the tablet compression process", Sandoz Ltd., Istanbul, Turkey (June 1985).

"A new technique for characterizing the compression process", College of Pharmacy, The University of Illinois at Chicago, IL (May 1987).

"A new technique for characterizing the compression process", Smith Kline & French Labs., Swedeland, PA (July

1987).

"Compaction simulator aided studies on tablet compression process", College of Pharmacy, Rutgers-The State University of New Jersey, Piscataway, NJ (December 1987).

"Use of the compaction simulators in tabletting research", American Cyanamid Company (Lederle Laboratories), Pearl River, NY (August 1988).

"Use of the compaction simulators in tabletting research", Schering-Plough Corporation, Kenilworth, NJ (November 1988).

"Use of the compaction simulators in tabletting research", Johnson & Johnson, New Brunswick, NJ (December 1988).

"Potential applications of the compaction simulators in advanced tabletting technology", Ciba-Geigy, Summit, NJ (March 1989).

"Potential applications of the compaction simulators in advanced tabletting technology", Hoffman-LaRoche, Nutley, NJ (April 1989).

"Potential applications of the compaction simulators in advanced tabletting technology", Glaxo Inc., Research Triangle Park, NC (April 1989).

"Potential applications of the compaction simulators in advanced tabletting technology", Sandoz Research Inst., East Hanover, NJ (September 1989).

"Potential applications of the compaction simulators in advanced tabletting technology", ICI Americas Inc., Wilmington, DE (October 1989).

"Introduction to the advanced Rutgers compaction simulator", Compaction Simulator Users Group Meeting, Hull, United Kingdom (October 1990).

"An overview of compaction research at Rutgers", Pharm. Research Lab. and Information Center Dedication Day, Rutgers University, Piscataway, NJ (November 1990).

"An overview of the integrated tablet compaction research systems", Merck Sharp & Dohme, West Point, PA (December 1990).

"Fundamentals of tablet press instrumentation", Nicolet Instruments Corporation, Madison, WI (January 1991).

"The role of compaction studies on the design and development of tablet formulations", St. John's University, Jamaica, NY (April 1992).

"How to make most of the Integrated Compaction Research Systems", Sandoz Research Inst., East Hanover, NJ (July 1992).

"The reworkability of micro-crystalline cellulose formulations", Mendell, Cedar Rapids, Iowa (September 1992).

"Compaction studies on the Surelease coated pellets", Mendell, Cedar Rapids, Iowa (September 1992).

"How to make most of the Integrated Compaction Research Systems", Burroughs Wellcome Co., Research Triangle Park, N.C. (May 1993).

"Compaction functionality testing of tableting excipients and introduction to a compaction data bank", Mendell, Patterson, N.Y. (August 1993).

"How to make most of the Integrated Compaction Research Systems", G.D. Searle & Co., Chicago, IL (November 1993).

"Tabletability of microspheres", St. John's University, Jamaica, NY (October 1994).

"Theory and practise of compaction", Fundamentals of solid dosage formulations and processing, Pittsburg, PA (May 1997).

"Pharmaceutical Formulation & Process Expert Systems", Bayer, Morristown, NJ (February 1998).

"Pharmaceutical Formulation & Process Expert Systems: Is there an expert system and electronic database in your future?", Elan Pharmaceutical Technologies, Dublin, Ireland (March 1998).

"Pharmaceutical Formulation & Process Expert Systems", RWJ-PRI, Raritan, NJ (August 1999).

"Pharmaceutical Formulation & Process Expert Systems", Pfizer, Sandwich, UK (December 1999).

"Pharmaceutical Formulation & Process Expert Systems", Merck, Sharp & Dhome, UK (December 1999).

"Pharmaceutical Formulation & Process Expert Systems", Merck, Sharp & Dhome, West Point (January 2000).

"Expert Systems and Tableting", Janssen Ortho LLC, San Juan, Puerto Rico (November 2000).

"Expert Systems in Pharmaceutical Applications", College of Engineering, University of Michigan, Ann Arbor, MI (March 2001).

"Expert Manager and PAI expert system", Tap Pharmaceuticals, Lake Forest, IL (July 2001).

"Overview of expert systems with case studies" Tap Pharmaceuticals, Lake Forest, IL (July 2001).

"Use of expert systems in pharmaceutical applications" Abbott Laboratories, North Chicago, IL (July 2001).

"Use of expert systems in pharmaceutical applications: PAI and Technology Transfer" Hoffman-La Roche, Nutley, NJ (July 2001).

"Use of expert systems in pharmaceutical applications: PAI and Technology Transfer" Pfizer, Ann Arbor, MI (December 2001).

"Use of artificial intelligence in the preperation of the FDA inspections: PAI, API, QSIT, GMP" Pfizer, Ann Arbor, MI (December 2001).

"Use of expert systems and databases in pharmaceutical applications" Merck, West Point, PA (August 2002).

"Mechanical properties of materials" Ridgefield, Connecticut (December 2009)

"Tablet compaction physics" Ridgefield, Connecticut (December 2009)

"Analysis of tablet compaction data", Ridgefield, Connecticut (December 2009)

"USP compactability Test", Ridgefield, Connecticut (December 2009)

"Use of compaction simulators for formulation development" Ridgefield, Connecticut (December 2009)

"Informex Database", Boehringer-Ingelheim, Ridgefield, Connecticut (July 2010)

"Formulation changes supporting BG12 fewer smaller project: Characterization of tableting properties", Biogen Idec, Massachusetts (April 2011)

"Theory & Practice of Compaction", BASF, Istanbul, Turkey (May 2014).

Contributed Papers/Presentations at Scientific Conferences (* denotes presenter):

D.N. Travers, M. Çelik* and T.C. Buttery, "A computer aided investigation on strain movements in compacts under constant stress within the die", 3rd British Pharmaceutical Technology Conference, London, 1982.

M. Çelik*, D.N. Travers and T.C. Buttery, "Computer logged changes of strain movements in compacts of direct compression bases and granules produced by wet massing techniques", 3rd International Conference on Pharmaceutical Technology, Paris, 1983.

M. Çelik*, D.N. Travers, P. Wright and D. Porter, "The logging and manipulation of tablet compression data using a microcomputer", British Pharmaceutical Conference, London, 1983.

M.E. Aulton, M. Çelik* and D.N. Travers, "A comparative evaluation of the visco-elastic deformation of tabletting materials", 4th Pharmaceutical Technology Conference, Edinburgh, 1984.

M. Çelik* and D.N. Travers, "The use of an elastic recovery index as a criterion of compactional behavior of some direct compression bases", 4th Pharmaceutical Technology Conference, Edinburgh, 1984.

M. Çelik* and K. Marshall, "Initial experiences with a high speed tablet press simulator", 6th Wisconsin Update Conference "Tabletting", Madison, 1987.

M. Çelik* and D.N. Travers, "Tablet compression studies using a 5 channel computer linked data processor", AAPS 2nd National Meeting and Exposition, Boston, 1987.

M. Çelik*, M.J. Mollan Jr. and N. Chang, "The reworkability of microcrystalline cellulose formulations", 10th Pharmaceutical Technology Conference, Bologna, Italy, 1991.

L. Maganti and M. Çelik*, "Compaction studies on pellets", 10th Pharmaceutical Technology Conference, Bologna, Italy, 1991.

L. Maganti and M. Çelik*, "Compaction studies on surelease coated pellets", 6th International Conference on Pharmaceutical Technology, Paris, 1992.

M. Çelik*, D. Goldman, E. Okutgen, R. Pinal and A.W. Malick, "Simulation of an F-3 single station press using an integrated compaction research system", (Poster) 7th Annual AAPS Meeting, San Antonio, TX, 1992.

M.J. Mollan, Jr*. And M. Çelik, "Direct compression of maltodextrins and acetaminophen", (Poster) 7th Annual AAPS

Meeting, San Antonio, TX, 1992.

E. Okutgen*, P.E. Wray and M. Çelik, "The effect of crystal surface history on post-compaction properties of sodium chloride tablets", 7th Annual AAPS Meeting, San Antonio, TX, 1992.

M.J. Mollan, Jr. and M. Çelik*, "Compaction behavior of maltodextrins for direct compression", 12th Pharmaceutical Technology Conference, Elsinore, Denmark, 1993.

M. Çelik, "Functionality testing for tableting excipients", 12th Pharmaceutical Technology Conference, Elsinore, Denmark, 1993.

M. Çelik*, E. Okutgen and C.E. Driscoll, "Compaction functionality testing", (Poster) 8th Annual AAPS Meeting, Orlando, FL, 1993.

E. Okutgen, M. Çelik*, and C.E. Driscoll, "Introduction to a compaction data bank", (Poster) 8th Annual AAPS Meeting, Orlando, FL, 1993.

M.J. Mollan, Jr.*, and M. Çelik, "Lubrication effects on the properties of maltodextrins", (Poster) 8th Annual AAPS Meeting, Orlando, FL, 1993.

M.J. Mollan, Jr.*, and M. Çelik, "The effect of humidity on the properties of maltodextrins", (Poster) 8th Annual AAPS Meeting, Orlando, FL, 1993.

A. Ayman, M. Çelik*, H. Brittain, A. Newman and G. Young, "Pre-compaction properties of magnesium stearate", 13th Pharmaceutical Technology Conference, Strasbourg, France, 1994.

M. Çelik* and M.E. Aulton, "The viscoelastic deformation of some tableting materials as assessed by indentation rheology", 9th Annual AAPS Meeting, San Diego, CA, 1994.

C.E. Driscoll*, E. Okutgen and M. Çelik, "A new approach to the use of pre- & main compaction cycles", 9th Annual AAPS Meeting, San Diego, CA, 1994.

A. Ayman, M. Çelik*, H. Brittain, A. Newman and G. Young, "Physicochemical properties of the pure magnesium stearate pseudopolymorphs", (Poster) 9th Annual AAPS Meeting, San Diego, CA, 1994.

M. Çelik* and M.E. Aulton, "The viscoelastic deformation of some tableting materials as assessed by indentation rheology", 14th Pharmaceutical Technology Conference, Barcelona, Spain, 1995.

M. Çelik* and E. Okutgen, "Compaction Data Bank - I: Batch to batch, plant to plant, manufacture to manufacture consistency of microcrystalline cellulose and dicalcium phosphate", 1st World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Budapest, Hungary, 1995.

C. Driscoll-Ruegger* and M. Çelik, "The effect of compression and decompression speed on the mechanical strength of compacts", 10th Annual AAPS Meeting, Miami, FL, 1995.

M. Çelik, "The use of F-t Curves to evaluate the compaction behavior of pharmaceutical materials", (Poster) 10th Annual AAPS Meeting, Miami, FL, 1995.

M. Çelik* and E. Okutgen, "An electronic tablet compaction data bank - I: Microcrystalline cellulose", (Poster) 10th Annual AAPS Meeting, Miami, FL, 1995.

M. Çelik*, R.C. Moreton, B.E. Sherwood, J.D. Cobb, D.J. Schaible and J.A. Zeleznik, "The effects of moisture content and particle size on the functional properties of microcrystalline cellulose for use in direct compression", 17th Pharmaceutical Technology Conference, Oxford, England, 1996.

M. Çelik* and E. Okutgen, "An electronic tablet compaction data bank - I: Microcrystalline cellulose", European Journal of Pharmaceutics and Biopharmaceutics", 42nd Annual Congress of the International Association for Pharmaceutical Technology (APV), Mainz, Germany (March 1996).

M. Çelik*, A.W. Newman, R. Mueller, C. Kiesnowski, I. Vitez, S.A. Sharpe, R. C. Moreton, "Pre-compaction and lubrication properties of Pruv", (Poster) 11th Annual AAPS Meeting, Seattle, WA, 1996.

M. Çelik*, R.C. Moreton, B.E. Sherwood, J.D. Cobb, D.J. Schaible, and J.A. Zeleznik, "The effects of moisture content and particle size on the functional properties of microcrystalline cellulose for use in direct compression", 11th Annual AAPS Meeting, Seattle, WA, 1996.

C. Driscoll-Ruegger*, M. Çelik and S.D. Bateman, "Simulation of an instrumented manesty betapress using an integrated compaction research system", 11th Annual AAPS Meeting, Seattle, WA, 1996.

M. Çelik and R.L. Schmitt^{*}, "A Study on the compaction properties of three water soluble polymers", 12th Annual AAPS Meeting, Boston, MA, 1997.

S. Wendel* and M. Çelik, "Limitations of applying artificial neural networks to a small spray drying data set and methods for overcoming limitations", 12th Annual AAPS Meeting, Boston, MA, 1997.

J. Engelhart* and M. Çelik, "Feasibility of predicting lyophilzation endpoint using artificial neural networks", 12th Annual AAPS Meeting, Boston, MA, 1997.

M. Çelik, R. Sirihorachai*, and F. Spadaccini, "Artificial neural networks aided study on the comparison of the models 193 and 197 of the quadro-comil milling equipment", 12th Annual AAPS Meeting, Boston, MA, 1997.

P.E. Wray* and M. Çelik, "Compaction and lubrication functionality issues", 12th Annual AAPS Meeting, Boston, MA, 1997.

B.A. Lang* and M. Çelik, "An electronic database", 12th Annual AAPS Meeting, Boston, MA, 1997.

S. Erdil*, Y. Ozalp and M. Çelik, "The Effect of Fluidized Bed Systems on Granule Flowability and Compaction Properties", FIP Congress Istanbul, 2009.

3. Service As a Editorial Board Member and Referee:

Member of Editorial Advisory Board:

Pharm. Development & Technology (1995-present)

Pharmaceutical Technology (1996-present)

Tablets & Capsules (2008 - present)

European Journal of Pharmaceutical Sciences (1998-2002)

Reviewer:

Pharmaceutical Research (1989)

Journal of Pharmaceutical Science (1993-2007)

International Journal of Pharmaceutics (1994-2007)

European Journal of Pharmaceutics and Biopharmaceutics (1996)

European Journal of Pharmaceutical Sciences (1998-2006)

AAPS PharmSciTech.(2000-2006)

Pharm. Development & Technology (1995-present)

Pharmaceutical Technology (1996-present)

Book Reviewer, Marcel & Dekker (1994).

Book Reviewer, Journal of American Chemical Society (1996).

Drug Development and Industrial Pharmacy (2001 – 2005)

4. Organization of Symposia & Short Courses:

Symposia:

Takeda Tablet Technology Update, Piscataway, NJ (March 1989): Acted as a program committee member.

Takeda Tablet Technology Update, Piscataway, NJ (September 1990): Acted as a program committee member.

The First Symposium of the PCRL & IC on the physics of tablet compaction, Piscataway, NJ (March 1991): Acted as the symposium chair.

Pharmaceutical Technology Conference, New Brunswick, NJ (September 1991): Acted as the session co-director.

The Second Symposium of the PCRL & IC on the compaction behavior of pharmaceutical materials, Piscataway, NJ (March 1992): Acted as the symposium chair.

Centennial Pharmaceutics Conference, Edison, NJ (October, 1992): Acted as the moderator.

The Third Symposium of the PCRL & IC on the application of compaction techniques as prospective functionality tests for tablet excipients, Piscataway, NJ (March 1993): Acted as the symposium chair.

AAPS Eastern Regional Meeting and Exhibition, New Brunswick, NJ (June 1993): Acted as a program committee member.

A symposium on the "Pharmaceutical solid technology" at the First International Conference on Pharmaceutical Science and Technology in Conjunction with the 24th Annual Meeting of the Fine Particle Society, Chicago, IL (August 1993): Acted as the symposium chair.

The Fourth Symposium of the PCRL & IC on the tabletability of multiparticulates: A new technology, Piscataway, NJ (March 1994): Acted as the symposium chair.

1st Tablet Technology Update: Tableting Technology in the year 2000, Istanbul, Turkey (April 1994): Acted as the symposium chair.

AAPS Eastern Regional Meeting and Exhibition, New Brunswick, NJ (June 1994): Acted as a program committee member.

The Fifth Symposium of the PCRL & IC on tableting technology in the year 2001, Piscataway, NJ (March 1995): Acted as the program committee chair.

1st World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Budapest, Hungary, (May 1995): Acted as a session co-moderator.

AAPS Eastern Regional Meeting and Exhibition, New Brunswick, NJ (June 1995): Acted as a program committee member.

A symposium on the "Pharmaceutical solid technology" at the Third International Conference on Pharmaceutical Science and Technology in Conjunction with the 26th Annual Meeting of the Fine Particle Society, Chicago, IL (August 1995): Acted as the symposium chair.

Second Pharmaceutics Conference, Piscataway, NJ (October, 1995): Acted as a program committee member, session moderator and the poster session coordinator.

AAPS Eastern Regional Meeting and Exhibition, New Brunswick, NJ (June 1996): Acted as a program committee member.

A Round Table Discussion on "Research in support of SUPAC guidance", 11th Annual AAPS Meeting, Seattle, WA (October 1996): Acted as the program chair.

A symposium on the "Excipient functionality and the regulatory process", 12th Annual AAPS Meeting, Boston, MA (November 1997): Acted as the symposium chair.

A Round Table Discussion on the "Expert Systems for pharmaceutical formulations and processes", 12th Annual AAPS Meeting, Boston, (November 1997): Acted as the program committee chair.

A symposium on the ARecent advances in solid dosage forms" in conjunction with the 1998 Conference on Pharmaceutical Science & Technology, Dallas, Texas.(April 1998): Acted as the symposium chair.

A symposium on the ARecent advances in the pharmaceutical tableting technology", University of Wisconsin, Pharmaceutical Engineering and Technology Series, Las Vegas, NE (May 1998): Acted as the program chair.

A symposium on the ARecent advances in pharmaceutical technology", Second International Meeting on Pharmacy & Pharmaceutical Sciences, Istanbul, Turkey (September 1998): Acted as the symposium chair.

A symposium on the "Expert systems: the future of formulation & process development", 13th Annual AAPS Meeting, San Francisco, CA (November 1998): Acted as the program chair.

A symposium on the "Polymorphism issues and process development", 14th Annual AAPS Meeting, New Orleans, LA (November 1999): Acted as the program co-chair.

A symposium on the "Process control of solid dosage form unit", 16th Annual AAPS Meeting, Denver, CO (October 2001): Acted as the program co-chair.

A symposium on the "Excipient Functionality and Harmonization Update", 17th Annual AAPS Meeting, Toronto, Ontario, Canada (November 2002): Acted as the program chair.

A symposium on "Use of Artificial Intelligence from Formulation and Process Developemnt to FDA Inspection Preparations", AAPS – PT Section Conference, Advances in Pharmaceutical Processing, Parsippany, NJ (June 2003): Acted as a moderator and speaker

1st Annual Symposium on Process Analytical Technology (PAT), Piscataway, NJ (March 2005): Acted the program co-chair and a speaker.

Short Courses:

"Tablet and capsule machine instrumentation", East Brunswick, NJ (July 1992): Acted as the course co-director and lecturer.

"Fundamentals of solid dosage forms: Formula & process development", 13th Annual AAPS Meeting, San Francisco, CA (November 1998): Acted as the course director and lecturer.

"Pharmaceutical tableting technology", Orlando, FL (September 1998): Acted as the course director and lecturer.

"Pharmaceutical tableting technology", Budapest, Hungary (May 1999): Acted as the course director and lecturer.

"Recent advances in film coating formulation & process development", Istanbul, Turkey (September 1999): Acted as the course director and lecturer.

"Expert Systems & Artificial Neural Networks", 14th Annual AAPS Meeting, New Orleans, LA (November 1999): Acted as the course director and lecturer.

"Modern BA/BE/Dissolution and disintegration requirements", 15th Annual AAPS Meeting, Indianapolis, IN (October-November 2000): Acted as the course director.

"Pharmaceutical tableting technology", Orlando, Florida (May 2000): Acted as the course director and lecturer.

"Tableting technology excellence", Chicago, IL (July 2001): Acted as the course director and lecturer.

"Trouble shooting tableting process and application of expert systems", Chicago, IL (July 2001): Acted as the course director and lecturer.

"Tableting technology excellence", Las Vegas, NV (September 2001): Acted as the course director and lecturer.

"Trouble shooting tableting process and application of expert systems", Las Vegas, NV (September 2001): Acted as the course director and lecturer.

"Tableting technology excellence", Philadelphia, PA (November 2001): Acted as the course director and lecturer.

"Trouble shooting tableting process and application of expert systems", Philadelphia, PA (November 2001): Acted as the course director and lecturer.

"Formulation & Process Development For Oral Solid Dosage Forms", Princeton, NJ (April 2004). Acted as the program co-director, moderator, and lecturer.

2nd Annual Training Program on "Formulation & Process Development For Oral Solid Dosage Forms", Princeton, NJ (April 2005). Acted as the program co-director, moderator, and lecturer.

Advances in Direct Compression" Philadelphia, PA (June 2005): Acted as the program co-chair.

3rd Annual Training Program on "Formulation & Process Development For Oral Solid Dosage Forms", Princeton, NJ (April 2006). Acted as the program co-director, moderator, and lecturer.

4th Annual Training Program on "Formulation & Process Development For Oral Solid Dosage Forms", Princeton, NJ (April 2007). Acted as the program director, moderator, and lecturer.

5th Annual Training Program on "Formulation & Process Development For Oral Solid Dosage Forms", Princeton, NJ (April – May 2008). Acted as the program director, moderator, and lecturer.

Formulation & Process Development & Troubleshooting, Istanbul, Turkey (June 2008). Acted as the program director, moderator, and lecturer.

6th Annual Training Program on "Formulation & Process Development For Oral Solid Dosage Forms", Princeton, NJ (April – May 2009). Acted as the program director, moderator, and lecturer.

7th Annual Training Program on "Formulation & Process Development For Oral Solid Dosage Forms", Princeton, NJ (August – September 2010). Acted as the program director, moderator, and lecturer.

8th Annual Training Program on "Formulation & Process Development For Oral Solid Dosage Forms", Princeton, NJ (August 2011). Acted as the program director, moderator, and lecturer.

9th Annual Training Program on "Formulation & Process Development For Oral Solid Dosage Forms", Princeton, NJ (August 2014). Acted as the program director, moderator, and lecturer.

5. Mentoring of Graduate Students:

Honors:

Nancy Chang, "The reworkability of micro-crystalline cellulose formulations", 1991.

Elizabeth Vogl, "Preformulation studies on two model powders and three experimental powders using an Integrated Compaction Research System", 1991.

Grace Chen, "Compaction characteristics of powder mixtures", 1992

Master of Science:

Rachan Sirihorachai, Non-Thesis: "Compaction Data Evaluation Methods", 1996.

Melek Sena Geyik "Investigations on the effect of fluidized granulation bed process parameters on the granulation and tableting properties of oxarbazepinebased formulations", 2010

Doctor of Philosophy:

Lata Maganti, "Compaction studies on the surelease coated pellets", 1991.

Matthew J. Mollan, Jr., "Characterization of a roller compacted maltodextrin for direct compression", 1993.

Colleen E. Driscoll, "The role of punch displacement profiles on the optimization of compaction of materials", 1996.

Rachan Sirihorachai (1990-97): "Application of Neural Networks to the Compaction Simulators".

Susan Wendel (1990-97): "The Prediction of Spray Drying Formulations and Processes for Pharmaceutical Powders".

Post-doctoral Fellow:

Dr. Ellay.Okutgen, "Development of a standard method to test the tabletability of pharmaceutical materials and establishment of a compaction data bank", 1991-1993.

Research Associate:

Dr. Ellay Okutgen, "Development of a standard method to test the tabletability of pharmaceutical materials and establishment of a compaction data bank", 1994-1995.

6. Service to professional/scientific organizations:

Founder of Expert Systems Focus Group, AAPS (2001)

Founder of Excipients Focus Group, AAPS (2001)

Chairperson, Expert Systems Focus Group, AAPS (2001-2003)

Chairperson, Excipients Focus Group, AAPS (2003 - 2005)

Chairperson, Process Development Focus Group, AAPS (1995 - 1998)

Steering Committee Member, Excipients Focus Group, AAPS (2001 – present)

Steering Committee Member, Process Development Focus Group, AAPS (1998 - present)

AAPS Program Committee Member (1996-1997)

AAPS Short Course Committee Member (1997 - 2000)

NJPhAST Program Committee Member (1996-1997, 2001)

NJPhAST Program Committee Chair (1997 - 1998)

7. Teaching and Technical/Managerial Experience:

Undertaken a training program (designed specifically for Dr. Çelik) at Sandoz-Switzerland in order to assume a responsibility to establish and lead the Galenical R&D department at Sandoz-Turkey.

Responsibilities at Sandoz-Turkey included establishment of a Galenical Research Lab, reformulation of an existing effervescent tablet, initiation of some projects on validation and computerization techniques, and training of the Quality Assurance Staff on solid dosage forms.

At Smith Kline French Labs., established and pioneered the use of the first computer controlled "Compaction Simulator System" in the USA.

Established and directed the Pharmaceutical Compaction Research Laboratory and Information Center at Rutgers University.

Contributed to the design and development of a state-of-art Integrated Compaction Research System (Compaction Simulator) at Rutgers.

Assisted over fifteen pharmaceutical companies in their solid dosage formulation projects. Also, acted as a consultant to the FDA and the pharmaceutical industry worldwide.

Taught Drug Delivery (undergraduate), Problems in Pharmaceutics (undergraduate), and Pharmaceutical Processes and Equipment (graduate) courses.

Acted as the AACP delegate to the Council of Faculties for the Rutgers College of Pharmacy.

Served as the director of honors program.

Acted as the (member and the) chair of the Admissions Committee.

Served as a member in a number of committees including (but not limited to) the: Standards Committee, Graduate School, Minority Concerns Committee, Curriculum Committee Academic Standards Committee, and Unit Safety Committee.

Finally, founded a company, Pharmaceutical Technology International, Incorporated (PTI Inc), in order to develop management tools, databases and expert systems for and to provide expert consultant service to the pharmaceutical industry worldwide.

8. Awards and recognitions:

Faculty Academic Service Increment Program Award (1991, 1993, 1994)

Who is who in science and engineering (1995)

Commission of Science & Technology of New Jersey Award (1996)

Received over fifty grants at Rutgers University in the total amount of more than \$1,100.000 for the following projects:

Establishment of the Pharmaceutical Compaction Research Lab. & Information Center:

Berlex Laboratories Inc (\$25,000); Ciba-Geigy (\$25,000); Eli Lilly (\$25,000); Glaxo (\$25,000); Hoffman-LaRoche (\$25,000); Johnson & Johnson Corporation (\$7,000); Lederle (\$25,000); McNeil Consumer Products Company (\$6,000); McNeil Pharmaceuticals (\$6,000); Merck Sharp & Dohme (\$ 25,000); Ortho Pharmaceutical (\$6,000); Park Davis (\$15,000); Pfizer (\$25,000); Sandoz (\$25,000); Schering-Plough (\$25,000); Squibb (\$25,000); Syntex (\$25,000).

General Research: Hoffman-La Roche: \$7,500 (1989); RWJ-Pharmaceutical Research Institute: \$4,000 (1989); Takeda-USA: \$3,000 (1989), \$3,000 (1990), \$1,000 (1991); Mendell: \$12,000 (1990), \$15,250 (1992), \$16,000 (1993); Hoffman-La Roche: \$4,000 (1990); SmithKline Beecham: \$5,000 (1992); McNeil Consumer Products Company: \$7,500 (1992); Syntex \$10,000 (1993).

Compaction studies on surelease coated pellets: Colorcon: \$ 20,000 (1990-91); Sandoz: \$10,000 (1990-91)

Characterization of a roller compacted maltodextrin for direct compression: Mendell: \$13,300 (1991-92), \$13,860 (1992-93)

Scale up studies in milling process using Model 193 and 197 Quadro-Comil: Quadro Engineering Inc. \$5,000 (1994).

A study on the dimensional changes of tablets as a factor causing internal stress development within film coating: RWJ-Pharm. Research Inst. \$8,000 (1994).

Development of a compaction data bank: Hoffman-La Roche: \$8,000 (1990); J & J Corporation \$ 6,000 (1990); McNeil C.P.Company: \$10,000 (1990); RWJRI Ortho Pharm: \$6,000 (1990); Takeda - USA: \$5,000 (1990); Takeda - Japan: \$5,000 (1990); Mendell: \$45,000 (1993-94), \$22,500 (1994-95); \$150,000 (1995-99).

Tableting Expert Systems: Bayer \$50,000 (1996-98); Hoffman-La Roche \$5,000 (1996-97)

Support for the Annual PCRI&IC symposia: Berlex \$40,500 (1991-94), Registrations: \$30,000 (1991-1994); National Science Foundation: \$10,000 (1995)

Equipment Support: Sitco: \$10,000 (1991); VanKel: \$7,500 (1992); RWJ-PRI: \$5,000 (1992); Quadro: \$15,000 (1993)

Direct fabrication and evaluation of orthopedic bone implants via 3 dimensional printed technology (A collaborative project with Therics): Commission of Science & Technology of NJ: \$100,000 (1996-97)

The Best Industrial Pharmacy Poster Prize - FIP Congress İstanbul 2009 (Student: Sena Erdil, Poster entitled "The Effect of Fluidized Bed Systems on Granule Flowability and Compaction Properties")

9. Sustained recognition for expertise and technical leadership:

Acted as consultant to the FDA (1993) and the following (pharmaceutical, food, excipient, and equipment) companies and law firms: American Nutritional Laboratories, Inc. (1994 -1996)

American Nutritional Laboratories, Inc. (1994 - 19 Advanced Care Products (1997-1998) Bayer (1996, 1998-2001) Berlex Laboratories, Inc. (1993) Best Foods (1996) Biogen Idex (2010-2011) Bird & Bird, LLP (2011) Boehringer-Ingelheim (2007-2012) Bryan Cave (1998-1999), Burroughs Wellcome (1993) Carter-Wallace (1992) Chadbourne & Parke LLP, (2001-2002) Chela (2001) Chelsea Laboratories (1995 - 1996) CoCensys (1996 - 1998) Colorcon (1996) Cyanamid (1992) Darby & Darby Professional Corporation (1998) Darby & Darby (2004-2005, 2008-2009) Eckhaus & Olson Law Firm (1996 - 1997) Fish & Richardson, P.C. (2005) Gardner Roberts, LLP (2009) G.D. Searle & Co. (1993) Gilead Sciences (2001) Glaxo (1990 - 1991) Goodmans LLP (2010) Heenan Blaikie (2003 – 2004) Hazzard & Hore (2005, 2006-2008) Hitchman and Springs, LLP (2009) IPS (1998-2000) IIR – PTI – Educational Program (2001) Janssen Ortho LLC (2000) Jones Day (2004 – present) Kirkland & Ellis (2002) Latham & Watkins LLP (2004) Lerner, David, Littenberg, Krumholz & Mentlik, LLP (2004-present) Leprino Foods (1996 - 1997) Lord Bissel & Brook (2001 – 2002) McCarter & English, LLP (2014 – Present) Mendell, USA (1990 - 1996) Mendell, UK (1993 - 1995) Merck Sharp & Dohme (1990 - 1991) Nabisco (1990 - 1992) Nicolet Instruments (1990) Novartis Pharmaceuticals R&D (2010-2012) Novartis Pharmaceuticals Suffern Manufacturing Site (2012-2013) Oread (1998) Osler Hoskin Harcourt LLP (2006-2007) Quinn Emanuel (2011) Quinn Emanuel Urguhart& Sullivan, LLP (2014 - Present) Pain Therapeutics (2001) Price, Heneveld, Cooper, DeWitt & Litton (2001-2007) Sitco (1992 - 1993) SK&F Labs (1989 - 1991) SKB (1997) SMI (2001) Sterne, Kessler, Goldstein & Fox, P.L.L.C. (2006) Therics (1997-2003) Technomic – Educational Program (1998-2000) Union Carbide (1995 - 1996) University of Maryland Pharmaceuticals (1997) University of Wisconsin – Educational Program (1998) Wargo and French (2006-2008) Wishart, Norris, Hennnger & Pittman, PA (2001-2002)

Woodcock Washburn Kurts Mackiewicz & Norris Law Firm (1997)