# Curriculum Vitae Richard N. Dalby

### Personal Information

Qualifications	Ph.D., B. Pharm.
Office Address	University of Maryland, Department of Pharmaceutical Sciences, 20 North Pine Street, Baltimore, Maryland 21201.
	+1 (410) 706-3245 / rdalby@rx.umaryland.edu
Educational Summary	
Sept. 1984 to Oct. 1988	University of Kentucky College of Pharmacy. Ph.D. in Pharmaceutical Sciences supervised by Dr. Peter R. Byron.
Sept. 1980 to June 1983	Nottingham University School of Pharmacy, B. Pharm. (Honors).
Employment Summary	
July 2003 to present	Professor, Department of Pharmaceutical Sciences, University of Maryland (July 1996 to June 2003, Associate Professor; Sept. 1992 to June 1996, Assistant Professor).
Sept. 1992 to present	Affiliate Professor, School of Pharmacy, Medical College of Virginia / Virginia Commonwealth University (July 1996 to June 2003, Affiliate Associate Professor; Sept. 1992 to June 1996, Affiliate Assistant Professor).
Jan 2010 to June 2016	Associate Dean for Academic Affairs, School of Pharmacy, University of Maryland. Subsumed responsibilities of Associate Dean for Curricular and Instructional Resources in January 2012.
Jan. 2009 to Dec 2009	Graduate Program Director, Department of Pharmaceutical Sciences, University of Maryland.
May 1997 to July 2003	Vice Chair, Department of Pharmaceutical Sciences, University of Maryland.
Aug. 2001 to Jan. 2002	Acting Chair, Department of Pharmaceutical Sciences, University of Maryland.
May 1997 to Sept. 1999	Graduate Program Director, Department of Pharmaceutical Sciences, University of Maryland.
Dec. 1989 to Aug. 1992	Research Assistant Professor at Medical College of Virginia / Virginia Commonwealth University, Department of Pharmacy and Pharmaceutics.
Oct. 1988 to Nov. 1989	Development Scientist, Fisons Pharmaceuticals (now sanofi aventis). Responsible for development of MDIs & DPIs. Offered promotion to Section Leader in 1989.
Oct. 1984 to Sept. 1988	Teaching and research assistant at the University of Kentucky College of Pharmacy.
Sept. 1983 to Sept. 1984	Pharmaceutical industry pre-registration training at Roche Pharmaceuticals and hospital pre-registration training at University College Hospital.
Jun. to Sept. 1981 & 1982	Preregistration Pharmacy Student with the Boots Company (Community pharmacy).

#### Membership of Professional Organizations

Fellow of the American Association of Pharmaceutical Scientists and member of the Royal Pharmaceutical Society of Great Britain (M.R. Pharm. S., Registered Pharmacist in United Kingdom, License Number 78009, not current),.

#### Research Interests

Formulation and evaluation of pressurized metered dose inhaler, dry powder, nebulizer, and nasal spray products. Development and evaluation of existing and proposed test methods for inhalation products. Laboratory testing and patient evaluation of novel pulmonary and nasal delivery devices. Design of patient education aids.

#### Papers

- Clinical implications of the Stiolto<sup>®</sup> Respimat<sup>®</sup> Soft Mist<sup>™</sup> inhaler for patients with chronic obstructive pulmonary disease. Gary T. Ferguson and Richard N. Dalby. Journal of Postgraduate Medicine (Submitted).
- Automated Actuation of Nasal Spray Products: Effect of Hand Related Variability on the In Vitro Performance of Flonase® Nasal Spray; Diane V. Doughty, Wenchi Hsu and Richard N. Dalby. Drug Development and Industrial Pharmacy, Vol. 40, No. 6, Pages 711-718, June 2014. DOI:10.3109/03639045.2013.777735.
- Methodology for the In Vitro Evaluation of the Delivery Efficiency from Valved Holding Chambers with Facemasks; Zhen Xu, Wenchi Hsu, Dirk von Hollen, Ashwin Viswanath, Kurt Nikander and Richard Dalby Journal of Aerosols in Medicine and Pulmonary Drug Delivery, Volume 27, Supplement 1, S44-54, 2013. DOI: 10.1089/jamp.2013.1074. <u>PMID: 24219816</u>.
- 4. <u>Development of Respimat and its Clinical Utility in Respiratory Disorders</u>, R N Dalby, J Eicher and B Zierenberg, Medical Devices: Evidence and Research. Medical Devices: Vol 1, No 4, pages 145–155, 2011.
- Effect of Various Formulation and Administration Related Factors on Deposition Pattern of Nasal Spray Pumps. Vipra Kundoor and Richard N. Dalby. Pharmaceutical Research, Volume 28, Number 8, 1895-1904, 2011. PMID: 21499839.
- Automated Actuation of Nasal Spray Products: Determination and Comparison of Adult and Pediatric Settings. D. V. Doughty, C. Vibbert, M. E. Bollinger, A. Kewalramani and R. N. Dalby. Drug Development and Industrial Pharmacy. Vol. 37, No. 3, pages 359-366, 2010.
- 7. <u>Thousand Years of Pharmaceutical Aerosol's Conference Paper. Deposition, imaging and clearance: What remains to be done?</u> Aerosol Medicine and Pulmonary Drug Delivery, Volume 23, Suppl 2, pages 1-19, 2010.
- Assessment of Facial and Ocular Deposition of Nebulized Aerosol Using a Color Based Method. Vipra Kundoor and Richard N. Dalby. Drug Development and Industrial Pharmacy, Pages 1-5, June 2010. PMID: 20545511.
- 9. Demonstrating Bioequivalence of Locally Acting Orally Inhaled Drug Products (OIPs): Workshop Summary Report, Cosponsored by Product Quality Research Institute (PQRI) and Inhalation and Nasal Technology Focus Group (INTFG). Wallace P. Adams, Richard C. Ahrens, Mei-Ling Chen, David Christopher, Badrul A. Chowdhury, Dale P. Conner, Richard Dalby, Kevin Fitzgerald, Leslie Hendeles, Anthony J. Hickey, Günther Hochhaus, Beth L. Laube, Paul Lucas, Sau L. Lee, Svetlana Lyapustina, Bing Li, Dennis O'Connor, Neil Parikh, David A. Parkins, Prasad Peri, Gary R. Pitcairn, Michael Riebe, Partha Roy, Tushar Shah, Gur Jai Pal Singh, Sandra Suarez Sharp, Julie D. Suman, Marjolein Weda, Janet Woodcock and Lawrence Yu. J. Aerosol Medicine and Pulmonary Drug Delivery. Volume 23, Number 1, pp. 1–29, 2010.
- Assessment of Nasal Spray Deposition Pattern In A Silicone Human Nose Model Using A Color Based Method. Vipra Kundoor and Richard Dalby. Pharmaceutical Research, Volume 27, Number 1, Pages 30-36. January, 2010. DOI: 10.1007/s11095-009-0002-4.
- 11. <u>Effect of Flexible Dip-tubes and Shaking on Spray Weight Consistency in Nasal Sprays</u>. Diane Doughty, Lei Li and Richard N. Dalby. J. Aerosol Medicine and Pulmonary Drug Delivery, Volume 23, Number 2, pages 69-75, 2010.

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- Phospholipid Induced In Vivo Particle Migration to Enhance Pulmonary Deposition. Sudipta Ganguly, Vikas Moolchandani, Natalie Eddington, Joseph Roche, Paul S. Shapiro, Shailaja Somaraju and Richard N. Dalby. J. Aerosol Medicine and Pulmonary Drug Delivery, Vol. 21, No. 4: 343-350, Dec 2008.
- 13. <u>Phase I Clinical Trial of Repeat Dose Terameprocol Vaginal Ointment in Healthy Female</u> <u>Volunteers</u>. Niharika Khanna, Richard Dalby, Alyson Connor, Ann Church, Jennifer Stern and Neil Frazer. Sexually Transmitted Diseases. 35(6):577-582, 2008.
- 14. <u>Phase I/II Clinical Safety Studies of Terameprocol Vaginal Ointment</u>. Niharika Khanna, Richard Dalby, Ming Tan, Stephanie Arnold, Jennifer Sternand & Neil Frazer. Gynecologic Oncology, Volume 107, Issue 3, 554-562, 2007.
- 15. The Analysis and Prediction of Functional Robustness of Inhaler Devices. Pallavi Nithyanandan, Stephen W. Hoag and Richard N. Dalby. Journal of Aerosol Medicine, 20 (1), 19-37, 2007.
- 16. Validity of In Vitro Tests on Aqueous Spray Pumps as Surrogates for Nasal Deposition, Absorption and Biologic Response. Julie D. Suman, Beth L. Laube and Richard Dalby, J. Aerosol Medicine, 19 (4), 510-521, 2006.
- 17. Positive Expiratory Pressure Changes Aerosol Distribution in Patients with Cystic Fibrosis. Beth L. Laube, David E. Geller, Ta-Chun Lin, □Richard N. Dalby, Marie Diener-West and Pamela L. Zeitlin. Respiratory Care, 50 (11), 1438-1444, November 2005.
- The Effect of Formulation Variables and Breathing Patterns on the Site of Nasal Deposition in an Anatomically Correct Model. Yang Guo, Beth Laube and Richard Dalby. Pharmaceutical Research 22 (11), 1871-1878, November 2005.
- 19. Who Nose, Richard Dalby, Yang Guo and Julie Suman. European Pharmaceutical Review, 10 (1), 96-100, 2005.
- 20. <u>A Review of the Development of Respimat® Soft Mist Inhaler</u>. Dalby, R, Spallek, M and Voshaar, T. International Journal of Pharmaceutics, Volume 283, Issues 1-2, 1-9, 2004.
- Drug Delivery to the Nasal Cavity: In Vitro And In Vivo Assessment. Stephen P. Newman, Gary R Pitcairn and Richard N. Dalby. Critical Reviews in Therapeutic Drug Carrier Systems, 21 (1), 21-66, 2004.
- 22. <u>Inhalation Therapy: Technical Milestones in Asthma Treatment</u>, Richard Dalby and Julie Suman. Advanced Drug Delivery Reviews, 55 (7), 779-791, 2003.
- 23. Pulmonary Drug Delivery What's Next, Richard Dalby. European Pharmaceutical Review, 2, 70-73, June 2003
- 24. Allergen Challenge and Deposition of Nedocromil Sodium in Asthma, B.L. Laube, T. Lin, A. Valleteau, R.N. Dalby, F.B. Diemer and A.G. Togias. Journal of Aerosol Medicine, 15(4), 415-426, 2002.
- 25. Predicting the Quality of Powders for Inhalation from Surface Energy, David P. Cline and Richard N. Dalby. Pharmaceutical Research, 9 (19), September 2002.
- 26. <u>Novel system to investigate the Effects Of Inhaled Volume And Rates Of Rise In Simulated</u> <u>Inspiratory Air Flow On Fine Particle Output From A Dry Powder Inhaler (DPI).</u> Varsha Chavan and Richard Dalby. AAPS PharmSci; 4 (2) article 6 (2002).
- 27. Relevance of In Vitro Tests of Nasal Solutions to Predict In Vivo Deposition., J.D. Suman, B.L. Laube, T. Lin, G. Brouet, and R. Dalby. Pharmaceutical Research, 19 (1) : 1-6 (2002).
- Targeting Aerosol Deposition In Patients With Cystic Fibrosis: Effects Of Alterations In Particle Size And Inspiratory Flow Rate, Beth L. Laube, Rajkumari Jashnani, Richard N. Dalby and Pamela Zeitlin. Chest ;118:1069 -1076 (2000).
- 29. Effect Of Rise In Simulated Inspiratory Flow Rate And Carrier Particle Size On Powder Emptying From Dry Powder Inhalers, Varsha Chavan and Richard Dalby, American Association Of Pharmaceutical Scientists, AAPS PharmSci; 2 (2) article 10 (2000).
- 30. Inhaled ATP Causes Mucin Release From Goblet Cell Of Intact Rat, Chan Young Shim, K. Chul Kim, Mi-Jeong Jo, Kyu Hwan Park, Richard Dalby and Kwang Ho Ko. Journal of Experimental Lung Research, 26: 1-11 (2000).

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- Nasal Nebulizers Versus Nasal Spray Pumps: An Investigation Of Deposition And Mucociliary Clearance. Julie Suman, Beth L. Laube and Richard N. Dalby. Pharmaceutical Research, 16 (10): 1648-1652 (1999).
- 32. The Efficacy Of Slow Vs. Faster Inhalation Of Cromolyn Sodium In Protecting Against Allergen Challenge In Patients With Asthma, Beth L. Laube, Alan M. Edwards, Richard N. Dalby, Peter Creticos and Philip Norman. J. Allergy and Clinical Immunology, 101 (4) Part 1, 475-483 (1998).
- Evaluation Of Aerosol Drug Output From The Optichamber Spacer : Comparison To The Aerochamber In A Model System, Richard N. Dalby, Shailaja Somaraju, Varsha Chavan and Dayna Jarvis. Journal of Asthma, 35(2), 173-177 (1998).
- Predicting In Vivo Lung Deposition Of Cromolyn Sodium From In Vitro Estimates, Beth L. Laube, Rajkumari Jashnani and Richard N. Dalby. J. Aerosol Medicine, 11 (Supplement 1), 35-42 (1998). Also presented at the international Society for Aerosols in Medicine Focus Symposium, Towards meaningful laboratory tests for evaluation of pharmaceutical aerosols, San Juan, PR, January, 1997.
- 35. Liquefied Propellant Density Measurement And Utility, Shailaja Somaraju, Richard N. Dalby and Michael Pierpont. Pharmaceutical Technology, 21(10) (1997).
- 36. Semi-Automated Spray Pattern Testing Of Nasal Sprays, Shailaja Somaraju, Julie Suman, Richard Dalby and Walter Stridick. Pharmaceutical Technology, 21(5), 58-64 (1997).
- Comparison Of A Respiratory Suspension Aerosolized By An Air Jet And Ultrasonic Nebulizer, Susan L. Tiano and Richard N. Dalby. Pharmaceutical Development and Technology, 1 (3), 261-268 (1996).
- Testing Of Dry Powder Aerosol Formulations In Different Environmental Conditions, Rajkumari N. Jashnani, Peter R. Byron and Richard N. Dalby. International Journal of Pharmaceutics, 113, 123-130 (1994).
- 39. Pitfalls And Opportunities In The Inertial Sizing And Output Testing Of Nebulizers, Richard N. Dalby and Susan L. Tiano. Pharmaceutical Technology, 17 (9), 144-156 (1993).
- Preparation, Characterization, And Dissolution Kinetics Of Two Novel Albuterol Salts; Rajkumari N. Jashnani, Peter R. Byron and Richard N. Dalby. Journal of Pharmaceutical Science, 82 (6), 613-616 (1993).
- 41. Validation Of An Improved Rotating Disk Dissolution Apparatus; Rajkumari N. Jashnani, Peter R. Byron and Richard N. Dalby. Journal of Pharmaceutical Science, 82 (6), 670-671 (1993).
- Axial Ratio Measurement For Early Detection Of Crystal Growth In Suspension Type Metered Dose Inhalers; Elaine M. Phillips, Peter R. Byron and Richard N. Dalby. Pharmaceutical Research, 10 (3), 454-456 (1993).
- Droplet Drying And Electrostatic Collection A Novel Alternative To Conventional Comminution Techniques; Richard N. Dalby, Venkatesh Naini and Peter R. Byron. Journal of Biopharmaceutical Sciences, 3(1), 91-99 (1992).
- 44. Safety Assessment Of MDIs Containing Flammable Propellants; Richard N. Dalby. Journal of Biopharmaceutical Sciences, 3 (1), 49-57 (1992).
- 45. Prediction And Assessment Of Flammability Hazards Associated With Metered Dose Inhalers Containing Flammable Propellants; Richard N. Dalby. Pharmaceutical Research, 9 (5), 636-642 (1992).
- 46. Metered Dose Inhalers Containing Flammable Propellants: -Perspectives And Some Safety Evaluation Procedures; Richard N. Dalby and Peter R. Byron. Pharmaceutical Technology, 15 (10), 54-66 (1991).
- 47. Determination Of Drug Solubility In Aerosol Propellants; Richard N. Dalby, Elaine M. Phillips and Peter R. Byron. Pharmaceutical Research, 8(9), 1206-1209 (1991).
- 48. Possible Replacements For CFC-Propelled Metered-Dose Inhalers; Richard N. Dalby. Medical Device Technology, 21-25 (1991).
- 49. Special Considerations In The Formulation Of Suspension Type Metered Dose Inhalers; Richard N. Dalby. Aerosol Age, 22-89 (1990).

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- CFC Propellant Substitution: P-134a As A Potential Replacement For P-12 In MDIs; Richard N. Dalby, Peter R. Byron, H.R. Shepherd and Elaine Papadopoulos. Pharmaceutical Technology, 14,(3), 26-33 (1990).
- 51. Optimized Inhalation Aerosols. I. The Effect Of Spherical Baffle Size And Position Upon The Output Of Several Pressurized Nonaqueous Suspension Formulations; Peter R. Byron, Richard N. Dalby and Anthony J. Hickey. Pharmaceutical Research, 6 (3), 225-229 (1989).
- Effects Of Surfactants On Aerosol Powders In Suspension. Implications For Airborne Particle Size; Anthony J. Hickey, Richard N. Dalby and Peter R. Byron. International Journal of Pharmaceutics, 4, 267-270 (1988).
- Comparison Of The Output Particle Size Distributions From Pressurized Aerosols Formulated As Solutions Or Suspensions, Richard N. Dalby and Peter R. Byron. Pharmaceutical Research, 5 (1), 36-39, January (1988).
- 54. Effects Of Heat Treatment On The Permeability Of Polyvinylalcohol Films To A Hydrophilic Solute; Peter R. Byron and Richard N. Dalby. Journal of Pharmaceutical Sciences, 76 (1), 65-67 (1987).

#### Miscellaneous (Unreviewed) Papers

- 1. Sparking Innovation in Drug Delivery. Richard N. Dalby. <u>The Medicine Maker</u> (November 2015).
- The Respiratory Drug Delivery (RDD<sup>®</sup>) Conferences. Richard Dalby and Pierre Carlotti. <u>Inhalation</u>, 9(5), pages 6-8, October 2015.
- 3. <u>In vitro Bioequivalence Testing of Nasal Sprays</u>, Diane V. Doughty, Vipra Kundoor, Feiyan Jin, Wenchi Hsu and Richard Dalby, Inhalation, 3(1) 22-26, 2009.
- 4. How to Participate in Respiratory Drug Delivery Meetings, Richard N. Dalby, Joanne Peart and Peter R. Byron. <u>Inhalation</u>, October 2007.
- 5. Letter to the Editor. J. Aerosol Med. Concerning "Validity of In Vitro Tests on Aqueous Spray Pumps as Surrogates for Nasal Deposition, Absorption and Biologic Response. Julie D. Suman, Beth L. Laube and Richard Dalby, J. Aerosol Medicine, 19 (4), 510-521, 2006.
- 6. Meeting Report. The Annual Respiratory Drug Delivery® Symposium, Richard Dalby. Touch Briefings, June 2007.
- 7. Meeting Report. Respiratory Drug Delivery Europe 2007. Peter R. Byron, Richard N. Dalby and Joanne Peart. Expert Reviews in Respiratory Medicine, 1(1), 2007.

#### Abstracts

- 1. Creating a Comprehensive Exam to Prepare Students for the PCOA. Andrew Coop, Lisa Lebovitz, Shannon R. Tucker, George Anagnostou, Christopher Klimas and Richard N. Dalby. AACP Annual Meeting, Anaheim, CA, (July 2016).
- 2. Recruiting Allies Kids, Colleges, and Communities. Helping Win the Battle for the Best Pharmacy Applicants. Richard Dalby, Cherokee Layson Wolf, Lisa Lebovitz, Shannon R. Tucker, Margaret Hayes & Alexander Wong. AACP Annual Meeting, Anaheim, CA, (July 2016).
- 3. Potentially Bioactive or Toxic Metals in E-cigarette Materials of Construction. Sarah L. J. Michel, Maureen A. Kane, Abraham Schneider, Thao Vo, Geoffrey Shimberg and Richard N. Dalby. In Respiratory Drug Delivery 2016, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman, Paul Young and Daniela Traini, Editors, Book 3, ISBN 1-933722-96-7, p583-586; Davis Healthcare International Publishing, River Grove, Illinois (April 2016).
- 4. Plume Geometry Evaluation of Solution-type Metered Dose Inhalers Formulated Using Effervescent Aerosol Technology. Mukul S. Kelkar and Richard N. Dalby. In Respiratory Drug Delivery 2016, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman, Paul Young and Daniela Traini, Editors, Book 3, ISBN 1-933722-96-7, p579-582; Davis Healthcare International Publishing, River Grove, Illinois (April 2016).
- 5. <u>Pharmacy Curriculum Outcomes Assessment (PCOA). Love it or Hate it, It's Required!</u> Richard Dalby, Lisa Lebovitz, Shannon Tucker, Cherokee Layson Wolf, Andrew Coop, Joey Mattingly and Nicki Brandt. AACP Annual Meeting, National Harbor, DC (July 2015).
- 6. <u>How PharmD Students Perceive and Reflect on Direct and Sometimes Uncomfortable</u> <u>Conversations About Professionalism</u>. Cherokee Layson-Wolf and Richard Dalby. AACP Annual Meeting, National Harbor, DC (July 2015).

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- 7. Physics for Pre-pharmacy: Is a Spirometer Faster than a Racecar? Alexander Wong, Richard Dalby and Kathleen J Pincus. American Association of Physics Teachers (AAPT), College Park, Maryland (July 2015).
- Formulation of Suspension-type Pressurized Metered Dose Inhalers Using Effervescent Aerosol Technology. Mukul S. Kelkar and Richard N. Dalby. In Respiratory Drug Delivery Europe 2015, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman, Paul Young and Daniela Traini, Editors, Book 2, ISBN 1-933722-88-6, p493-496; Davis Healthcare International Publishing, River Grove, Illinois (May 2015).
- Formulation of Solution-type Pressurized Metered Dose Inhalers Using Effervescent Aerosol Technology. Mukul S. Kelkar and Richard N. Dalby. In Respiratory Drug Delivery Asia 2014, Richard N. Dalby, Peter R. Byron, Joanne Peart, Paul Young and Daniela Traini, Editors, Davis Healthcare International Publishing, River Grove, Illinois (November 2014).
- Child and Caregiver Reaction to Use of a Prototype Inhalation Monitor as a Training Tool. Mona G Tsoukleris, Jill Morgan, Francoise Pradel, Mary E Bollinger, Richard Dalby and Wenchi Hsu. Association of Asthma Educators Annual Meeting, San Antonio, TX. August 2014. Accepted as a top abstract to be presented from the podium.
- 11. <u>Career Preparation. The Final Frontier: Maintaining Student Attention During Off Campus</u> <u>Experiences</u>. Richard Dalby, Shannon Tucker, Lisa Lebovitz and Cherokee Layson Wolf. AACP Annual Meeting, Dallas, TX, July 2014.
- 12. Contrasting Approaches and Experiences with Electronic Examinations. Richard Dalby, Veronica Shuford, Shannon Tucker and Brigitte Sicat. AACP Annual Meeting, Dallas, TX, July 2014.
- 13. <u>A Simple and Effective Programmatic Assessment Process for Continuous Quality Improvement</u>. Lisa Lebovitz and Richard Dalby. AACP Annual Meeting, Dallas, TX, July 2014. Abstract received the 2014 AACP Award for Excellence in Assessment.
- 14. Planning an IPE Day, Lebovitz L, Congdon H, Dalby R, Mallott, D and Pecukonis E. All Together Better Health, Pittsburgh, PA, June 2014.
- Effervescent Aerosols: A Novel Formulation Technology for Pressurized Metered Dose Inhalers. Mukul S. Kelkar and Richard N. Dalby. In Respiratory Drug Delivery 2014, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman, Paul Young and Daniela Traini, Editors, Davis Healthcare International Publishing, River Grove, Illinois Vol 3, pp 669-672 (2014). Selected for Posters on the Podium presentation.
- 16. Does Trust in the Pharmacist Correlate with Improved Asthma Outcomes, a Pilot Study. Jill Morgan, Mona Tsoukleris, Richard Dalby, Wenchi Hsu and Françoise Pradel. The 23rd Pediatric Pharmacy Advocacy Group Annual Meeting, Nashville, TN, April 2014.
- 17. Child and Caregiver Reaction to Use of a Prototype Inhalation Monitor as a Training Tool. Mona G Tsoukleris, Jill Morgan, Francoise Pradel, Mary E Bollinger, Richard Dalby and Wenchi Hsu. ASHP Midyear Meeting, Orlando, FL. December 2013.
- In vitro Delivery Efficiency of Valved Holding Chambers with or without Facemasks. Z Xu, M Kelkar, D von Hollen, A Viswanath, K Nikander and R Dalby. Drug Delivery to the Lungs, Edinburgh, Scotland, December 2013.
- 19. Novel Approach to an Assessment Committee. Lisa Lebovitz, Fadia T. Shaya and Richard N. Dalby. AACP Annual Meeting, Chicago, IL. July 2013.
- 20. Relationship between Student Confidence and Cumulative GPA Upon Completion of Didactic PharmD Coursework. Lisa Lebovitz, Stuart T. Haines, Deborah A. Sturpe, David S. Roffman and Richard N. Dalby. AACP Annual Meeting, Chicago, IL. July 2013.
- 21. Valved Holding Chambers and Facemask Systems: The Relationship of Facemask Leakage and in vitro Drug Delivery Efficiency. Zhen Xu, Wenchi Hsu, Dirk von Hollen, Ashwin Viswanath, Kurt Nikander and Richard Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Chicago, IL, October 2012.
- 22. Assessment of Facemask Seal Leakage from Six VHC Systems on Two Pediatric Simulated Anatomical Models Under Simulated Breathing Conditions. Z. Xu, D. von Hollen, W.Hsu, K. Nikander and R. Dalby. European Respiratory Society, Vienna, Austria. September 2012.
- 23. Delivery Efficiency from Valved Holding Chambers with Facemasks: A Comparative Study Using Soft Anatomical Face Models. Zhen Xu, Wenchi Hsu, Dirk von Hollen, Ashwin Viswanath, Kurt

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Nikander and Richard N Dalby. In Respiratory Drug Delivery 2012, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman, Stephen Farr and Paul Young, Editors, Davis Healthcare International Publishing, Vol 3, pp 809-814 (2012).

- 24. Statistically Significant Improvement in Inhaler Technique Among Patient Volunteers Using an Instrumented Inhaler. Wenchi Hsu, Lin Hao, Mona Tsoukleris, Jill Morgan, Mary Bollinger, Francoise Pradel & Richard Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Washington, DC, October 2011.
- 25. Preliminary Evaluation of an Automated Andersen Cascade Impactor The "A3G". Zhen Xu, Rajesh Maheshwari, Krishna Maheshwari & Richard Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Washington, DC, October 2011.
- 26. Breath by Breath Delivered Dose Comparison from Three Valved Holding Chambers with Facemasks Under Simulated Pediatric Breathing Conditions. W. Hsu, D von Hollen, Z. Xu, T Bei, K Nikander and R Dalby. European Respiratory Society, Amsterdam, The Netherlands. September 2011.
- 27. Does an Integrated Curriculum Lead to Improved Confidence to Practice? Raymond C. Love University of Maryland; Lisa Lebovitz, Yunting Fu, and Richard Dalby, University of Maryland School of Pharmacy. AACP Annual Meeting. San Antonio, Texas. July 2011.
- 28. Evaluation of Delivery Efficiency from a Valved Holding Chamber with Facemask under Simulated Conditions. Wenchi Hsu, Zhen Xu, Dirk von Hollen, Tao Bai, Kurt Nikander and Richard Dalby. In Respiratory Drug Delivery Europe 2011, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Paul Young, Editors, Davis Healthcare International Publishing, May 2011.
- 29. Comparative Analysis of In-use Actuation Parameters with In Vitro Performance of Nasal Spray Pumps. Gerallt Williams, Richard N. Dalby and Diane V. Doughty. In Respiratory Drug Delivery Europe 2011, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Paul Young, Editors, Davis Healthcare International Publishing, May 2011.
- 30. The Effect of Particle Size and Shape on Drug Uptake and Release of Nasal Suspension Formulations. Feiyan Jin and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, New Orleans, LA, November 2010.
- Using an Instrumented Inhaler as a Training Aid to Improve Inhaler Technique Among Patient Volunteers. Wenchi Hsu, Mona Tsoukleris, Jill Morgan, Mary E. Bollinger & Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, New Orleans, LA, November 2010.
- 32. Cross-Course Testing Concept and Implementation of Coordinated Quizzes at the University of Maryland School of Pharmacy. Lisa Lebovitz, Douglas A. Nutter, Yunting Fu, David S. Roffman & Richard Dalby. AACP Annual Meeting, Seattle, WA, July 2010.
- 33. In Vitro Beclomethasone Dipropionate Dissolution and Uptake Rates From Nasal Suspensions Comprised of Differing Primary Drug Particle Sizes. Feiyan Jin and Richard Dalby. Richard N. Dalby, Diane Doughty and Vipra Kundoor. In Respiratory Drug Delivery 2010, Orlando, FL. Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Paul Young, Editors, Davis Healthcare International Publishing, April 2010.
- 34. Realistic Evaluation of a Valved Holding Chamber with Facemask Using a Soft Anatomical Model Face to Evaluate Aerosol Output Under Simulated Use Conditions. Wenchi Hsu, Tao Bai, Dirk von Hollen, Kurt Nikander and Richard Dalby. In Respiratory Drug Delivery 2010, Orlando, FL. Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Paul Young, Editors, Davis Healthcare International Publishing, April 2010.
- 35. Validation of a Method to Visualize the Effect of Cascade Impactor Operating Temperature on Stage Deposition. Wenchi Hsu, Vipra Kundoor and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Los Angeles, CA. November 2009.
- Influence of Adult and Pediatric Hand-Related Variability on in vitro Performance of Flonase<sup>®</sup> Nasal Spray. D. V. Doughty, C. Vibbert, M. E. Bollinger, A. Kewalramani and R. N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Los Angeles, CA. November 2009.
- In Vitro Uptake of Nasal Sprays Containing Suspension Formulations in Calu-3 Human Airway Cells. Feiyan Jin and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Los Angeles, CA. November 2009.

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- Visualization of Facial and Ocular Deposition Using a Color Based Technique. Vipra Kundoor and Richard Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Los Angeles, CA. November 2009.
- 39. Visualizing the Effect of Cascade Impactor Operating Temperature on the Size and Evaporation Rate of Nebulized Droplets. Wenchi Hsu, Vipra Kundoor and Richard N. Dalby. In Respiratory Drug Delivery Europe 2009, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Paul Young, Editors, Davis Healthcare International Publishing, May 2009.
- 40. In vitro and in vivo Terameprocol efficacy studies in HPV infection models. Christensen N, Dalby R, Khanna N. The 25th International Papillomavirus Conference, Malmö, Sweden, May 2009.
- 41. Uptake and local metabolism of beclomethasone dipropionate in Calu-3 human airway cells. Feiyan Jin and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Atlanta, GA. November 2008.
- 42. Comparison of Deposition Patterns of Nasal Nebulizers and Aqueous Nasal Spray Pumps Using a Colorimetric Technique. Vipra Kundoor and Richard Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Atlanta, GA. November 2008.
- 43. Determination of Patient-Relevant Settings for In Vitro Evaluation of Flonase Using Automated Actuation Stations. Diane Doughty and Richard Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Atlanta, GA. November 2008.
- 44. The accuracy of Ventolin® dose counters using a force-instrumented pressurized metered dose inhaler under simulated use conditions. Wenchi Hsu and Richard Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Atlanta, GA. November 2008.
- 45. Assessment of Nasal Spray Deposition in a Nose Model Using a Colorimetric Technique Influence of Formulation and Airflows, Vipra Kundoor and Richard N. Dalby. In Respiratory Drug Delivery 2008, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Paul Young, Editors, Davis Healthcare International Publishing, May 2008.
- 46. Assessment of Nasal Spray Deposition in a Nose Model Using Colorimetric Techniques. Vipra Kundoor and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. November 2007.
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- 48. Handedness and Gender Effects on the Derivation of Machine Actuation Parameters for Nasal Sprays. Diane Doughty and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. November 2007.
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- 8. The Respiratory Drug Delivery English to Chinese Glossary of Technical Terms (呼吸道药物递送相关专业词汇中英文对照表)(ISBN 1-933722-63-0). The translations are a collaboration between students and faculties at the University of Maryland, Virginia Commonwealth University and the Shanghai Institute of Pharmaceutical Industry. Davis Healthcare, River Grove, Illinois (May, 2012).
- Respiratory Drug Delivery 2012 (ISBN Book 1, 1-933722-57-6; Book 2, 1-933722-58-4; Book 3, 1-933722-99-2), Richard N. Dalby, Peter R. Byron, Joanne Peart, Stephen J. Farr, Julie D. Suman and Paul Young, Editors, Davis Healthcare, River Grove, Illinois (May, 2012).
- Respiratory Drug Delivery Europe 2011, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Paul Young, Editors, Davis Healthcare International Publishing, River Grove, Illinois (May 2011).
- 11. 呼吸道药物递送的基本理论与实践 Respiratory Drug Delivery: Essential Theory and Practice, Stephen Newman, Editor (ISBN 1-933722-26-6). Richard Dalby (理查德·多尔比) managed translation into Chinese (ISBN 978-7-122-10756-5). Chemical Industry Press. (April, 2011).
- Respiratory Drug Delivery 2010 (ISBN Book 1, 1-933722-41-X; Book 2, 1-933722-42-8; Book 3, 1-933722-43-6), Richard N. Dalby, Peter R. Byron, Joanne Peart, Stephen J. Farr, Julie D. Suman and Paul Young, Editors, Davis Healthcare, River Grove, Illinois (April, 2010).
- Respiratory Drug Delivery Europe 2009 (ISBN Book 1, 1-933722-30-4; Book 2, 1-933722-31-2), Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie D. Suman and Paul Young, Editors, Davis Healthcare, River Grove, Illinois (May, 2009).

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- In vitro Testing of Inhaled Products. Richard Dalby and Peter Byron. In Respiratory Drug Delivery: Essential Theory and Practice (ISBN 1-933722-26-6.), Stephen Newman, Editor. RDD Online / Virginia Commonwealth University, Richmond VA, (April 2009).
- Respiratory Drug Delivery 2008 (ISBN Book 1, 1-933722-21-5; Book 2, 1-933722-22-3; Book 3, 1-933722-23-1), Richard N. Dalby, Peter R. Byron, Joanne Peart, Stephen J. Farr, Julie D. Suman and Paul M. Young, Editors, Davis Healthcare, River Grove, Illinois (May 2008)
- 16. Respiratory Drug Delivery Europe 2007 (ISBN 1-933722-07-X), Richard N. Dalby, Peter R. Byron, Joanne Peart and Julie D. Suman, Editors, Davis Healthcare, River Grove, Illinois (April, 2007).
- 17. Medical Devices For The Delivery Of Therapeutic Aerosols To The Lungs, Richard N. Dalby, Anthony J. Hickey and Susan L. Tiano. In Inhalation Aerosols, Second Edition (ISBN 10: 0-8493-4160-4, Anthony J. Hickey, Editor, Informa Healthcare USA, Inc., New York, NY (2007).
- Characterization Of Aerosol Performance, Jolyon Mitchell and Richard N. Dalby. In Pulmonary Drug Delivery (ISBN 978-3-87193-322-6). Henrik Luessen and Karoline Bechtold-Peters, Editors. 282-305, Editio Cantor Verlag (2007).
- Respiratory Drug Delivery X 2006 (ISBN Book 1, 1-930114-95-8; Book 2, 1-930114-96-6; Book 3, 1-930114-97-4), Richard N. Dalby, Peter R. Byron, Joanne Peart, Stephen J. Farr and Julie D. Suman, Editors, Davis Healthcare, River Grove, Illinois (April, 2006).
- 20. Respiratory Drug Delivery Europe 2005 (ISBN 1-930114-80-X), Richard N. Dalby, Peter R. Byron, Joanne Peart and Julie D. Suman, Editors, Davis Healthcare, River Grove, Illinois (May, 2005).
- Analytical Testing of Nasal and Pulmonary Products Using Patient-derived Parameters Realism Versus Reproducibility, Richard N. Dalby in Respiratory Drug Delivery Europe 2005 (ISBN 1-930114-80-X), Richard N. Dalby, Peter R. Byron, Joanne Peart, Stephen J. Farr and Julie D. Suman, Editors, Davis Healthcare, River Grove, Illinois (Vol 1, 35-44, May, 2005).
- 22. Respiratory Drug Delivery IX (ISBN 1-930114-63-X, Volume I; 1-930114-64-8, Volume II; 1-930114-65-6, Volume III), Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie D. Suman and Stephen J. Farr, Editors, Davis Horwood International Publishers, Surrey, UK (April, 2004).
- 23. Inverse Gas Chromatography as a Tool to Link Theory and Practice. David Cline and Richard Dalby. In Respiratory Drug Delivery IX, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie D. Suman and Stephen J. Farr, Editors, Davis Horwood International Publishers, Surrey, UK (Vol 1, 297-302, April, 2004).
- 24. Respiratory Drug Delivery VIII (ISBN 1-930114-51-6, Volume I; 1-930114-52-4, Volume II), Richard N. Dalby, Peter R. Byron, Joanne Peart and Stephen J. Farr, Editors, Davis Horwood International Publishers, Surrey, UK (May, 2002).
- 25. Respiratory Drug Delivery VII (ISBN 1-930114-14-1, Volume I; 1-930114-16-8, Volume II), Richard N. Dalby, Peter R. Byron and Stephen J. Farr, Editors, Serentec Press, Raleigh, NC (2000).
- Are In vitro Tests of Nasal Solutions Predictive of In vivo Deposition, Julie D. Suman, Beth L. Laube, Ta-Chun Lin, Guillaume Brouet, and Richard Dalby. In Respiratory Drug Delivery VII (ISBN 1-930114-14-1), Richard N. Dalby, Peter R. Byron and Stephen J. Farr, Editors, Serentec Press, Raleigh, NC (2000).
- Nasal Nebulizers Versus Aqueous Nasal Spray Pumps: A Comparison Of Deposition Patterns In Human Volunteers, Julie Suman, Beth L. Laube and Richard Dalby. In Respiratory Drug Delivery VI (ISBN 1-57491-076-0), Richard N. Dalby, Peter R. Byron and Stephen J. Farr, Editors, Interpharm Press, Buffalo Grove, IL (1998).
- Respiratory Drug Delivery VI (ISBN 1-57491-076-0), Richard N. Dalby, Peter R. Byron and Stephen J. Farr, Editors. Interpharm Press Buffalo Grove, IL (1998).
- 29. Pulmonary Delivery of Human Protein C and Factor IX. Shalabh Gupta, Francis Moussy, Richard N. Dalby, Shirley I. Miekka and Duane F. Bruley. In Oxygen Transport to Tissue XVIII, Nemoto and LaManna, Eds., Plenum Press, New York, NY (1997).
- 30. Inhalation Technologies For Local And Systemic Drug Delivery, Richard N. Dalby, Teltech Technical Knowledge Service, Minneapolis, MN (1996).
- Medical Devices For The Delivery Of Therapeutic Aerosols To The Lungs, Richard N. Dalby, Anthony J. Hickey and Susan L. Tiano. In Inhalation Aerosol Handbook (ISBN 0-8247-9702-7), Anthony J. Hickey, Editor, Marcel Dekker, New York, NY (1996).

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- 32. Respiratory Drug Delivery V (ISBN 1-57491-018-3), Richard N. Dalby, Peter R. Byron and Stephen J. Farr, Editors. Interpharm Press Buffalo Grove, IL (1996).
- Rational Testing Methods For Nebulizers And Respiratory Solutions, Richard N. Dalby and Susan L. Tiano. In Respiratory Drug Delivery IV (ISBN 0-935184-61-9), Peter R. Byron, Richard N. Dalby and Stephen J. Farr, Editors, Interpharm Press, Buffalo Grove, IL (1994).
- 34. Respiratory Drug Delivery IV (ISBN 0-935184-61-9), Peter R. Byron, Richard N. Dalby and Stephen J. Farr, Editors, Interpharm Press, Buffalo Grove, IL (1994).
- Optimizing The Effect Of Inhaled Medications By Altering Inspiratory Flow Rate, Beth L. Laube, Peter S. Credicos, Richard N. Dalby and Philip S. Norman. In Respiratory Drug Delivery IV (ISBN 0-935184-61-9), Peter R. Byron, Richard N. Dalby and Stephen J. Farr, Editors, Interpharm Press, Buffalo Grove, IL (1994).
- Halohydrocarbons : Pharmaceutical Uses, Richard N. Dalby, in Volume 7 of the Encyclopedia of Pharmaceutical Technology (ISBN 0-8247-2806-8), J. Boylan and J. Swarbrick, Editors. Marcel Dekker, New York, NY (1993).
- Respiratory Drug Delivery III, Richard N. Dalby and Peter R. Byron, Editors. J. Biopharm. Sci., 3 (1 & 2), 1992.
- 38. Respiratory Drug Delivery II, Richard N. Dalby and Richard Evans, Editors. Published by University of Kentucky College of Pharmacy (1990).

Invited Oral Presentations

Presentations at pharmaceutical companies are not listed since many consider the topics confidential. I deliver approximately two to four such presentations annually.

- 1. Recent developments and emerging needs in pulmonary and nasal drug administration. Virginia Commonwealth University School of Pharmacy. Richmond, VA (October 2017).
- 2. Basic Mechanism & Efficacy of Aerosols in Drug Delivery. Workshop at Society of Forensic Toxicologists (SOFT), Dallas, TX. (October 2016).
- 3. In Pursuit of Exam Excellence: Course and Curricular Level Initiatives to Enhance Exam Quality. Anne M. Schullo-Feulner, Kristin K. Janke, Lisa Lebovitz and Richard N. Dalby. Special session at AACP Annual Meeting, Anaheim, CA (July 2016).
- 4. Basic Mechanism & Efficacy of Aerosols in Drug Delivery. Workshop at American Association of Forensic Scientists, Las Vegas, NV. (February 2016).
- 5. The Professionalism Project: Anxiety Provoking, Time Consuming Yet Absolutely Essential. Cherokee Layson Wolf and Richard Dalby. Mini-session at AACP Annual Meeting, National Harbor, DC (July 2015).
- How Existing Inhaled Products Might Evolve. A Road Map To New Formulations And Devices, With Some Implications For Future Bioequivalence Evaluations. FDA OGD, Office of Bioequivalence. White Oak, MD (June 2015).
- 7. Platforms of the Future: Expanding the Route Map for Formulations and Devices. Richard Dalby. In Respiratory Drug Delivery Europe 2015; Book 1, ISBN 1-933722-87-8; p131-141. Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman, Paul Young and Daniela Traini, Editors, Davis Healthcare International Publishing, River Grove, Illinois (May 2015). RDD Europe 2015, Nice, France (May 2015).
- 8. "The Invaluable Learning from Five Rookie Mistakes." A roundtable session at the AACP Annual Meeting, Dallas, TX (July 2014).
- "Contrasting Approaches and Experiences with Electronic Examinations." Richard Dalby, Veronica Shuford, Shannon Tucker and Brigitte Sicat. Mini-session at AACP Annual Meeting, Dallas, TX (July 2014).
- 10. "A Simple and Effective Programmatic Assessment Process for Continuous Quality Improvement." Lisa Lebovitz and Richard Dalby. Mini-session at AACP Annual Meeting, Dallas, TX (July 2014).
- 11. "Recent Developments in Pharmaceutical Aerosol Delivery". Chemical and Biological Weapons Technical Expertise Forum. Battelle, Arlington Virginia, June 4, 2012.
- 12. "Bioequivalence for OINDP: Progress and remaining hurdles identified by 40 experts with 1000 years of combined aerosols experience" and "New Approaches to Nasal Spray Evaluation:

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Pediatric Versus Adult Actuation Profiles & Anatomically Based Spray Pattern Tests" at 5<sup>th</sup> Symposium on Nasal and Pulmonary Drug Delivery, Mumbai, India, November 10-11, 2011.

- "Predispose for the Nose: The Profile of a Promising Nasally Delivered Drug Candidate." Roundtable on Drug Delivery Barriers – Biology, Candidate Selection Criteria and Formulation Strategies. AAPS National Meeting, Washington DC. October 24, 2011.
- 14. "The Medicinal Magic of Modern Compounding Potions Class for the 21st Century." Presentation in conjunction with NIH/NLM touring Harry Potter's World: Renaissance Science Magic and Medicine exhibition at University of Maryland Health Sciences Library, Baltimore, MD, October 19, 2011.
- 15. "Introduction to Lung Delivery and Current Pulmonary Drug Delivery Systems", "Alternative Methods to Characterize the Performance of Inhaled Products" and "Novel Enabling Pulmonary Drug Delivery Devices". All presented at Inhalation Aerosol Technology Short Course, FDA CDHR / CDER Staff College, White Oak Campus, Silver Spring, Maryland. December 2, 2010.
- 16. "Emerging BE Issues in pMDIs and DPIs" and "Formulation Development: Regulatory Perspective" at Symposium on Nasal and Pulmonary Drug Delivery, Delhi (November 16-17) and Hyderabad (November 19-20, 2010), India.
- 17. "New Approaches to Nasal Spray Evaluation: Pediatric Actuation Profiles and Anatomically-Based Spray Pattern Tests". Richard N. Dalby, Diane Doughty and Vipra Kundoor. In Respiratory Drug Delivery 2010, Orlando, FL. Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Paul Young, Editors, David Healthcare International Publishing, April 2010.
- 18. "Emerging BE Issues in pMDIs and DPIs." Philadelphia Pharmaceutical Forum, Philadelphia, PA, March, 2010.
- 19. "Lung Deposition and Regulatory Opinion." 1000 Years of Pharmaceutical Aerosols What remains to be done? Reykjavik, Iceland, October 2009.
- "Emerging BE Issues in pMDIs and DPIs" and "Formulation Development: Regulatory Perspective" at 4<sup>th</sup> Symposium On Advances In Pulmonary And Nasal Drug Delivery, The Indian Pharmaceutical Association, Mumbai, India, September, 2009.
- 21. Pharmacy and Pharmaceutical Sciences in the United States. Bombay College of Pharmacy, India, September 2009.
- 22. "Inhaled Medication When Tablets Just Won't Work". Chemistry Department, College of Notre Dame of Maryland, Baltimore. March 2009.
- 23. "Spray and Pay Are There More Meaningful and Less Expensive Tests of Nasal Spray Bioequivalence?" Formulation Design & Development (FDD) Focus Group Roundtable at the American Association of Pharmaceutical Scientists Annual Meeting, Altanta, GA. November 2008.
- 24. *"Formulation Strategies for HFA pMDIs"* and *DPI Device and Formulation Development* at Practical Approaches to Nasal and Pulmonary Drug Delivery, Suzhou, China, November, 2008.
- 25. "Particle Size and The Andersen Cascade Impactor Special Issues For Nebulizers. FDA Center for Devices and Radiological Health (CDRH). Rockville, Maryland, April 2008.
- 26. "What are the Issues Facing the Generic Industry". Combined meeting of the Generic Pharmaceuticals and Bioequivalence Focus Groups at the American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. November 2007.
- 27. "Introduction to Pulmonary Drug Delivery." University of Kentucky College of Pharmacy, Lexington, KY, November 2007.
- 28. "Where Will You Fit In? Equipping Graduates for Careers in Pharmacy and Pharmaceutical Sciences" and "Theory and Operation of The Andersen and Next Generation Impactors". Bombay College of Pharmacy, India, October 2007.
- 29. "pMDI Formulation Strategies with HFA Propellants" and "Advanced Pulmonary Delivery Devices" at 3<sup>rd</sup> Symposium On Advances In Pulmonary And Nasal Drug Delivery, The Indian Pharmaceutical Association, Mumbai, India, October, 2007.
- 30. Is Bioequivalence Broken? Alternative Approaches to Demonstrating Similarity in ONIDPs. AAPS Inhalation Technology Focus Group, Baltimore, Maryland, September 2007.

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- The Andersen Cascade Impactor and Next Generation Impactor Demonstration, Data Analysis, and Tricks of the Trade. FDA Office of Generic Drugs (OGD), CDER Visiting Professor Lecture Series, Rockville, Maryland, November 2006.
- 32. "Fundamental Principles of Pulmonary Drug Delivery" and "Formulation of Pressurized Metered Dose Inhalers" at Practical Approaches to Nasal and Pulmonary Drug Delivery, San Paulo, Brazil, October, 2006.
- 33. "Fundamental Principles of Pulmonary Drug Delivery", "Formulation of Pressurized Metered Dose Inhalers" and "Fundamental Principles of Nasal Drug Delivery" at Practical Approaches to Nasal and Pulmonary Drug Delivery, Hangzhou, China, September, 2006.
- 34. Evaluation of In Vitro Performance Testing for Product Comparison. Symposium on Dry Powder Inhalers (DPIs). FDA Office of Generic Drugs (OGD) Regulatory Science Training Series, Gaithersburg, Maryland, August 2005.
- 35. Pulmonary and Nasal Devices. AAPS Workshop on Nasal and Pulmonary Delivery : Technology and Future Directions. San Francisco, CA, June 2005
- 36. Emerging Pulmonary and Nasal Aerosol Drug Delivery Systems. MITRE Corporation Intelligence Community Scientific Mini-Symposia. McLean Virginia, June 2005.
- 37. Analytical Testing of Nasal and Pulmonary Products Using Patient-Derived Parameters Realism vs. Reproducibility. RDD Europe 2005, Paris France, May 2005.
- 38. Communication Basics for Effective Communication and Teaching. American Society for Pharmacology and Experimental Therapeutics. San Diego, CA, April 2005.
- 39. "Fundamental Principles of Pulmonary Drug Delivery", "Formulation of Pressurized Metered Dose Inhalers" and "Fundamental Principles of Nasal Drug Delivery" at Practical Approaches to Nasal and Pulmonary Drug Delivery, Shangai, China, September, 2004.
- 40. The Future of Aerosol Therapy in Hospitals. Conference by the Sea 2004, Maryland/District of Columbia Society for Respiratory Care, Inc. Ocean City, MD. September, 2004.
- 41. Pulmonary Drug Delivery. College of Pharmacy, University of Nepal, Nepal, March 2004.
- 42. "Fundamental Principles of Pulmonary Drug Delivery", "Formulation of Pressurized Metered Dose Inhalers" and Formulation of Dry Powder Inhalers" at 2<sup>nd</sup> Symposium on Pulmonary and Nasal Drug Delivery, The Indian Pharmaceutical Association, Mumbai, India, March, 2004.
- 43. Latest Advances in Nasal Drug Delivery. Practical Approaches to Nasal and Pulmonary Drug Delivery, Delray Beach, FL, February, 2004.
- 44. Pulmonary Drug Delivery Systems. The Indian Pharmaceutical Association Andera Pradesh, Hyderabad, India, December, 2003.
- 45. Introduction to Nasal Drug Delivery, Nasal Spray Product Testing Workshop, Next Breath. Baltimore, MD, February and August, 2003, May and September 2004.
- 46. In Vitro Techniques Used to Characterize Intranasal Aerosols. 14<sup>th</sup> Congress, International Society for Aerosols in Medicine (ISAM), Baltimore, MD, June 2003
- 47. Pulmonary Drug Delivery. University of Kentucky College of Pharmacy, Lexington, KY, March 2003.
- 48. Tools of the Trade Emerging Techniques for Developing Pulmonary Drug Delivery Systems, 29th Annual Meeting of the Controlled Release Society, Seoul, South Korea, July 2002.
- 49. In Vitro Equivalence Testing of Inhalation Aerosols and Nasal Sprays. FDA Center for Drug Evaluation and Research (CDER) Visiting Professor Lecture Series, Rockville, Maryland, July 2002.
- 50. Are In Vitro Tests of Nasal Solutions Predictive of In Vivo Deposition? A case study of Analytical Techniques Applied to Aqueous Nasal Sprays. University of Arizona School of Pharmacy, Tucson, AZ, May 2002
- 51. Testing Cigarette Additives as Though They Were Pharmaceutical Excipients. Presentation to the Ingredients Added to Cigarettes Committee of the Life Sciences Research Office, FASEB. February, 2002. (In support of, Phase One- The Feasibility of Testing Ingredients Added to Cigarettes, Daniel M. Byrd, Editor, LSRO, 2004 (ISBN0-9753167-0-2).
- 52. Nasal Formulations and Testing Protocols. Practical Approaches to Nasal and Pulmonary Drug Delivery, Paris, France, January, 2002.

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- 53. Are In Vitro Tests of Nasal Solutions Predictive of In Vivo Deposition? Analytical Land O' Lakes Conference, Madison, WI, August 2001.
- 54. Nasal Drug Delivery, Virginia Commonwealth University, Richmond, VA, October 2000.
- 55. Critical Factors for Nasal Sprays, Analytical Land O' Lakes Conference, Madison, WI August 2000.
- 56. Symposium On MDI Aerosol Delivery The Science, American Association of Respiratory Care Annual Meeting, Atlanta, GA, November 1998 (0.1CE credits).
- 57. Latest Research In Aerosol Technology, American Association of Physician Specialists annual meeting, Colorado Springs, CO, June 1998 (0.2 CE credits).
- 58. Aerosol Drug Delivery Systems, Asthma Management Institute, Joint University of Maryland and Temple University continuing education program. Baltimore, MD, May 1998.
- Aerosol Drug Delivery Beyond The Medihaler!, Senior Pharmacists Association of Maryland / Baltimore Veteran Druggists Association / Wedgewood Club, Baltimore, MD, April 1998 (0.1CE credits).
- 60. What The Package Insert Doesn't Tell You About Spacers, American Academy of Allergy, Asthma and Immunology, American Association of Immunologists, and Clinical Immunology Society, joint annual meeting, San Francisco, CA, February, 1997.
- 61. Delivery Of Aerosols By Dry Powder Inhalers, Aerosol Therapy Update, Johns Hopkins University, School of Hygiene and Public Health, Baltimore, MD, November, 1996.
- 62. Inhalation Aerosol Technologies For The Next Century. 36th Annual Eastern Pharmaceutical Technology Meeting, New Brunswick, NJ, November, 1996.
- 63. Sizing Aerosols Generated By Nebulizers The Challenges. Philadelphia Pharmaceutical Forum, Graduate Student Poster Night, King of Prussia, PA, March 1996.
- 64. Respiratory Therapy, Nebulizer Systems And Testing And Specifications Nebulizers, Respiratory Delivery : Year 2000. An international symposium organized by the Arnold and Marie Schwartz College of Pharmacy and Health Sciences, Newark, NJ, November 1994.
- 65. Special Considerations In The Testing Of Nebulizers And Pump Sprays. American Organization of Analytical Chemists International Special Symposium; Recent advances in the analysis of pharmaceutical inhalation products for process control and quality assessment. St. Louis, MO, April 1994.
- 66. Controlled Drug Delivery To The Human Respiratory Tract A Liposome Based Approach. UMBC Department of Chemical and Biochemical Engineering, Baltimore, MD, March 1994.
- 67. Rational For An In Vivo Bioequivalence Waiver For Solution Type Metered Dose Inhalers And Pumps. Delivered to FDA OGD and Pulmonary NDA sections, and FDA Generic Drugs Advisory Committee, Rockville, MD, September 1993.
- Inhalation Aerosol Generation Using Nebulizers Pharmaceutical Testing Considerations; First International Conference on Pharmaceutical and Food Sciences and Technology, Chicago, IL. August 1993.
- 69. Flammable Propellants. Do They Have A Place In Metered Dose Inhalers? Delivered to the 1992 H.B. Kostenbauder Post-Graduate Research Conference, University of Kentucky, October, 1992.
- 70. Recent Advances In Metered Dose Inhaler Technology. Presented to School of Pharmacy, University of Maryland at Baltimore, January 1992.
- 71. Defining Acceptable Standards For MDIs Formulated With New Propellants. Regulatory Issues in Aerosol Drug Development, Arlington, Virginia, June 1991. Published in conference proceedings, University of Kentucky, June 1991.
- 72. Possible Replacements For CFC Propelled Metered Dose Inhalers. Given at the Medical Device Technology conference in Cologne, West Germany, November, 1990. Published in conference proceedings, Aster Publishing Corp. USA, Chester, United Kingdom, 209-221.
- 73. Determination Of Drug Solubility In Aerosol Propellants Using A Novel Filtration Apparatus. Delivered to the 1990 H.B. Kostenbauder Post-Graduate Research Conference, University of Kentucky, October, 1990.
- 74. The Metered Dose Inhaler Past, Present And Future. Presented to School of Pharmacy, Medical College of Virginia, May 1991.

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75. Sustained release terbutaline sulfate aerosols. Interphex USA, July 1988, New York. Published in conference proceedings, Cahners Exposition Group, Des Plaines, Illinois, 23-45.

#### Patents

- 1. Phospholipid-Based Inhalation System. Shailaja Somaraju, Julie Suman, Sudipta Ganguly and Richard Dalby. United States Patent 8,591,954 assigned to Next Breath LLC, November, 2013.
- Methods and compositions for treatment of intraepithelial neoplasia. Neil Frazer, Jonathan Heller, Rocio Lopez, Melissa Rhodes, Ru Chih C. Huang, Richard Dalby and Niharika Khanna. United States Patent 8,440,648 assigned to Erimos Pharmaceuticals and University of Maryland, Baltimore and Johns Hopkins University, May 2013.
- 3. Tacrolimus Compositions for Aerosol Administration. Richard N. Dalby and Ralph Niven. US Non-Provisional Patent Application Number 13/168,856, filed June 24, 2011 & PCT Patent Application Number PCT/US11/41839, filed June 24, 2011. Assigned to University of Maryland. (Abandoned).
- Formulations for delivery of beclomethasone dipropionate by metered dose inhalers containing no chlorofluorocarbon propellants. Richard N. Dalby and Peter R. Byron. United States Patent 5,202,110 assigned to Virginia Commonwealth University, April 1993.
- Formulations for delivery of drugs by metered dose inhalers with reduced or no chlorofluorocarbon content. Peter R. Byron and Richard N. Dalby. United States Patent 5,190,029 assigned to Virginia Commonwealth University, March 1993.
- Formulations for delivery of drugs by metered dose inhalers with reduced or no chlorofluorocarbon content. Peter R. Byron and Richard N. Dalby. United States Patent, 5,182,097 assigned to Virginia Commonwealth University, January 1993.

#### CE and Un-Reviewed Publications

- Child and Caregiver Perceptions of the Roles of their Pharmacists in Providing Asthma Care. Grace Herr, Mona G Tsoukleris, Jill Morgan, Richard Dalby, Wenchi Hsu & Françoise Pradel. American Soceity of Health-System Pharmacists 2013 Midyear Clinical Meeting. Student Poster Abstract 2-147 <u>http://www.ashp.org/DocLibrary/Midyear13/Student-Poster-Abstracts.pdf</u>. (December 2013).
- Drug Delivery Systems in Asthma and COPD. Weighing the Options for Oral and Inhaled Therapies. An Educational Supplement to Pulmonary Reviews, Richard N. Dalby and James L. Sublett. Clinicians Group, Jobson Publishing, New York, NY (January 2004).

#### National and International Service

- Respiratory Drug Delivery (RDD) Symposium, co-organizer, publication coordinator, editor (with 1. several co-editors), Scientific Poster Session and Exhibition moderator, and frequent podium session moderator. Next meetings; RDD 2018 (Tucson, AZ, April 2018) & RDD Asia 2018 (India. November 2018). Past meetings; RDD Europe 2017, Juan les Pins, France; RDD Asia 2016, Goa, India; RDD 2016, Scottsdale, AZ; RDD Europe 2015, Nice, France; RDD Asia 2014, Goa, India; RDD 2014. Puerto Rico; RDD Europe 2013, Berlin, Germany; RDD 2012, Phoenix, AZ; RDD Europe 2011, Berlin Germany; RDD 2010, Orlando, FL; RDD Europe 2009, Lisbon, Portugal; RDD 2008, Phoenix, AZ; RDD Europe 2007, Paris, France; RDD 2006, Boca Raton, FL; RDD Europe 2005, Paris, France; RDD IX (2004), Palm Desert, CA; RDD VIII (2002), Tucson, AZ; RDD VII (2000), Tarpon Springs, FL; RDD VI (1998), Hilton Head, SC, RDD V (1996), Phoenix, AZ; RDD IV (1994), Richmond, VA; RDD III (1992), Williamsburg, VA; and RDD II (1990), Keystone, CO. These are international meetings drawing between 400-750 participants. This is arguably the world's premier pharmaceutical aerosol meeting attended by researchers, executives and regulatory personnel. The resulting proceeding, which are my primary contribution, typically exceed 1000 pages, and are considered by many to be the most up-to-date reference on advances associated with nasal and pulmonary drug delivery. I also review abstracts for, and organize a poster session / exhibition with up to 150 presenters and 100 exhibitors.
- 2. Director, Inhalation Aerosol Technology Workshop (IATW). I created and annually conducted this introductory short course on pharmaceutical aerosols. Customized courses are available to pharmaceutical companies and regulators on request. The format includes one to four days of

lectures, workshops and laboratory sessions. Open courses were run annually between 1992 and 2010.

- 3. Evaluation Team Member and Periodic Report Reviewer, Middle States Commission on Higher Education, 2013-present. Site visits in 2013, 2014 and 2015. Two PRRs in 2016 and participation in the Committee on Periodic Review Reports.
- 4. AAPS Regulatory Science Section Fellows Selection Committee, 2010-2013
- Created and managed an Inhalation Aerosol Technology Short Course, FDA CDHR / CDER Staff College, White Oak Campus, Silver Spring, Maryland. December 2, 2010. Involved faculty from UMB, VCU and the pharmaceutical industry giving oral presentations and running three laboratory demonstrations.
- 6. Moderator, "In vitro Approaches to Demonstrating Bioequivalence" PQRI Workshop on Demonstrating Bioequivalence of Orally Inhaled Drug Products. Bethesda, MD, March 2009.
- 7. Moderator, "In vitro Bioequivalence Testing for Aerosol Products: From Today to Tomorrow." AAPS national meeting, November 2008.
- 8. "Steering Committee Member, AAPS Generic Pharmaceuticals Focus Group, December 2006present.
- 9. Member of LSRO's expert panel which reviewed "Scientific Methods To Evaluate Potential Reduced-Risk Tobacco Products". Member of Exposure Assessment Committee. May 2005 – January 2007. Our report, "New Testing And Evaluation Process Developed For Potential Reduced-Risk Tobacco Products" was edited by Catherine L. St. Hilaire, and published by LSRO, Bethesda, Maryland in April 2007 (ISBN 0-9753167-7-X). The follow up report, "Exposure Assessment in the Evaluation of Potential Reduced Risk Tobacco Products" was edited by Kara D. Lewis, and published by LSRO in April 2008 (ISBN 978-0-9753167-9-5).
- 10. Special Reviewer, Special Emphasis Panel (Development of Novel Drug and Gene Delivery Systems and Devices), National Institutes of Health, Bethesda, Maryland, July 2003.
- 11. FDA consultant for purpose of membership in the Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Sciences, FDA (1999 - 2002).
- 12. Moderator, Aerosolized Medications and Regulatory Guidance, 14<sup>th</sup> Congress, International Society for Aerosols in Medicine (ISAM), Baltimore, MD, June 2003.
- 13. Expert reviewer, International Pharmaceutical Aerosol Consortium (IPAC) briefing book, <u>Ensuring</u> <u>Patient Care - The Role Of The HFA MDI</u>, 1996, and revision in 1999 (www.ipacmdi.com/documents/EPC.pdi).
- 14. Organizer & roundtable moderator, Nasal Delivery Beyond Aqueous Spray Pumps, American Association Of Pharmaceutical Scientists National Meeting, San Francisco, CA. 1998.
- 15. Planning Committee member, American Association Of Pharmaceutical Scientists Eastern Regional Meeting, 1998.
- 16. Task Force member, American Academy of Allergy and Clinical Immunology, and American College of Allergy and Immunology, joint working group on Aerosolized Medication and Delivery Devices, 1996 1999.
- 17. Academic representative on American Association Of Pharmaceutical Scientists Easter Regional Meeting Posters and Podium, and PDD committees, 1995-1996.
- 18. Editorial Advisory Board member, Pharmaceutical Research, 1995 1997.
- 19. Reviewer for: Pharmaceutical Research, Medical Device Technology, Pharmaceutical Technology, Journal of Biopharmaceutical Sciences, Journal of Pharmaceutical Sciences and Pharmaceutical Development and Technology.
- 20. Abstract reviewer for American Association Of Pharmaceutical Scientists Annual Meeting (Pharmaceutical Technology Section), 1995 to 1997.
- 21. Special Reviewer, National Institutes of Health, Pharmacology Study Section, Bethesda, Maryland, 1993-96, and 1998.
- 22. Session moderator (Novel pharmaceutical aerosol delivery systems) for the First International Conference on Pharmaceutical and Food Sciences and Technology, sponsored by the Fine Particle Society and Controlled Release Society, Chicago, IL. August 1993.

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23. Session moderator (New Propellants: Impact on Quality Assurance of Aerosol Dosage Forms) for Regulatory Issues in Aerosol Drug Development, Arlington, Virginia, June 1991.

#### Miscellaneous Scholarly Activities

- Contributed to experiments and a report by the National Institute of Standards and Technology for the Department of Homeland Security on "Development of a Test Kit for Swipe Sampling: Evaluation of Polymer Microspheres as Analytical Test Materials". Robert Fletcher and Matthew Staymates. February 2010.
- 2. Presenter at the annual University of Maryland Graduate School Survival Skills Seminar Series on Mentoring. 1998 2003.
- 3. Implementation of an Integrated Course Sequence, University of Oklahoma School of Pharmacy Retreat, OK, May, 1998.
- 4. Implementation of an Integrated Clinical and Pharmaceutical Science Pharm. D. Course, Northeastern University School of Pharmacy Retreat, Boston, MA, February, 1998.
- 5. Graduate Research Association of Students in Pharmaceutics (GRASP) advisor, 1994 & 2000.
- 6. University of Maryland Graduate Research Symposium Poster Judge, 1998 -2003.
- 7. Instructor, A three hour interactive workshop presented at the Pharm Tech Conference, Inhalation Aerosols: The Patient Device Interface, East Rutherford, NJ, September 1996.
- Instructor, University of Maryland School of Pharmacy and Food and Drug Administration Office of Generic Drugs - Pharmacy and Pharmaceutical Care Lecture Series. What's Wrong With Metered Dose Inhalers? February 1994.
- Instructor, University of Maryland School of Pharmacy and Food and Drug Administration Office of Generic Drugs - Review Staff Development Program. Presented: "Formulation and manufacture of solutions and suspensions", February 1994; "Introduction to inhaled dosage forms", March 1993 and "Oral Modified Drug Delivery Systems", January 1993.
- 10. Visiting Scientist, Boehringer Ingelheim Pharmaceuticals. Organized by the Pharmaceutical Manufacturers Association, July 6-17, 1992.
- 11. Workshop organizer, Particle-Size Effects of the Drug Substance in Dose Delivery Systems, Pharm. Tech. Conference, New Brunswick, New Jersey, September 1991.

Special Awards and Recognition

- 1. 2014, American Association of Colleges of Pharmacy Award for Excellence in Assessment.
- 2. 2004, Elected a Fellow of the American Association of Pharmaceutical Scientists.
- 3. 2002, Appointed Deans Distinguished Educator, UMB School of Pharmacy.
- 4. 1998 Graduate Student voted Faculty of the Year, UMB School of Pharmacy.
- 5. 1996 Faculty voted Teacher of the Year, School of Pharmacy, UMB.

#### Consulting

I provide confidential consulting services, workshops and seminars, primarily to pharmaceutical and biotechnology industries, FDA, and allied law and investment banking firms.

Examples of consulting activities include:

- Critically reviewing proprietary inhalation delivery systems, failure mode analysis and new device matching to NCEs.
- Formulation, test method development and trouble-shooting for inhaled and nasal drug products, including writing and review of SOPs, and validation of data analysis spreadsheets.
- Assembly and proofing of pre-IND, IND and CMC documentation prior to submission to FDA. Participation in meetings with FDA.
- Data interpretation associated with clinical and in vitro inhalation studies.
- Company specific aerosol equipment demonstrations and training courses.

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Reviews of pulmonary and nasal products and markets, and participation in due diligence reviews on • pulmonary and nasal devices and formulation platforms for pharmaceutical companies and investment banking firms.

#### Miscellaneous Experience

- Clients include national and international companies. •
- Service as an independent consultant for over 25 years. •
- Expert witness and advisor for pharmaceutical companies engaged in intellectual property and other • types of disputes associated with inhaled and nasal medications / devices.
- Chairing and serving on Multidisciplinary Project Teams and Scientific Advisory Boards. •

To the best of my knowledge, this is a true and accurate representation.

I chard Dalky ard Dalby, Ph.D.

Richard Dalby, Ph.D. 3 October 2017

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