

# Curriculum Vitae

## Richard N. Dalby

### Personal Information

Qualifications Ph.D. (University of Kentucky), M.R. Pharm. S. (Registered Pharmacist in UK, License # 78009), B. Pharm. (University of Nottingham).

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### 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

Jan. 2009 to present Graduate Program Director, Department of Pharmaceutical Sciences, University of Maryland.

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).

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).

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### Membership of Professional Organizations

Fellow of the American Association of Pharmaceutical Scientists and member of the Royal Pharmaceutical Society of Great Britain.

### 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. More details at : [www.pharmacy.umaryland.edu/faculty/rdalby/](http://www.pharmacy.umaryland.edu/faculty/rdalby/)

### Papers

1. Assessment of Nasal Spray Deposition Pattern In A Silicone Human Nose Model Using A Color Based Method. Vipra Kundoor and Richard Dalby. Pharmaceutical Research (In preparation, June 2009).
2. Effect of Flexible Dip-tubes and Shaking on Spray Weight Consistency in Nasal Sprays. Diane Doughty, Lei Li and Richard N. Dalby. J. Aerosol Medicine and Pulmonary Drug Delivery. (Accepted, June 2009).
3. [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.
4. [Phase I Clinical Trial of Repeat Dose Terameprocol Vaginal Ointment in Healthy Female Volunteers](#). Niharika Khanna, Richard Dalby, Alyson Connor, Ann Church, Jennifer Stern and Neil Frazer. Sexually Transmitted Diseases. 35(6):577-582, 2008.
5. [Phase I/II Clinical Safety Studies of Terameprocol Vaginal Ointment](#). Niharika Khanna, Richard Dalby, Ming Tan, Stephanie Arnold, Jennifer Sternand & Neil Frazer. Gynecologic Oncology, Volume 107, Issue 3, 554-562, 2007.
6. 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.
7. 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.
8. 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.
9. [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.
10. Who Nose, Richard Dalby, Yang Guo and Julie Suman. European Pharmaceutical Review, 10 (1), 96-100, 2005.
11. [A Review of the Development of Respimat® Soft Mist Inhaler](#). Dalby, R, Spallek, M and Voshaar, T. International Journal of Pharmaceutics, Volume 283, Issues 1-2 , 1-9, 2004.
12. 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.
13. [Inhalation Therapy: Technical Milestones in Asthma Treatment](#), Richard Dalby and Julie Suman. Advanced Drug Delivery Reviews, 55 (7), 779-791, 2003.
14. Pulmonary Drug Delivery - What's Next, Richard Dalby. European Pharmaceutical Review, 2, 70-73, June 2003

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15. 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.
16. Predicting the Quality of Powders for Inhalation from Surface Energy, David P. Cline and Richard N. Dalby. *Pharmaceutical Research*, 9 (19), September 2002.
17. [Novel system to investigate the Effects Of Inhaled Volume And Rates Of Rise In Simulated Inspiratory Air Flow On Fine Particle Output From A Dry Powder Inhaler \(DPI\)](#). Varsha Chavan and Richard Dalby. *AAPS PharmSci*; 4 (2) article 6 (2002).
18. 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).
19. [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).
20. [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).
21. 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).
22. 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).
23. 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).
24. 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).
25. 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.
26. Liquefied Propellant Density - Measurement And Utility, Shailaja Somaraju, Richard N. Dalby and Michael Pierpont. *Pharmaceutical Technology*, 21(10) (1997).
27. Semi-Automated Spray Pattern Testing Of Nasal Sprays, Shailaja Somaraju, Julie Suman, Richard Dalby and Walter Stridick. *Pharmaceutical Technology*, 21(5), 58-64 (1997).
28. 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).
29. 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).
30. 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).
31. 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).
32. 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).

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33. 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).
34. 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).
35. Safety Assessment Of MDIs Containing Flammable Propellants; Richard N. Dalby. *Journal of Biopharmaceutical Sciences*, 3 (1), 49-57 (1992).
36. Prediction And Assessment Of Flammability Hazards Associated With Metered Dose Inhalers Containing Flammable Propellants; Richard N. Dalby. *Pharmaceutical Research*, 9 (5), 636-642 (1992).
37. 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).
38. Determination Of Drug Solubility In Aerosol Propellants; Richard N. Dalby, Elaine M. Phillips and Peter R. Byron. *Pharmaceutical Research*, 8(9), 1206-1209 (1991).
39. Possible Replacements For CFC-Propelled Metered-Dose Inhalers; Richard N. Dalby. *Medical Device Technology*, 21-25 (1991).
40. Special Considerations In The Formulation Of Suspension Type Metered Dose Inhalers; Richard N. Dalby. *Aerosol Age*, 22-89 (1990).
41. 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).
42. 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).
43. 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).
44. 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).
45. 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. [In vitro Bioequivalence Testing of Nasal Sprays](#), Diane V. Doughty, Vipra Kundoor, Feiyan Jin, Wenchi Hsu and Richard Dalby, *Inhalation*, 3(1) 22-26, 2009.
2. How to Participate in Respiratory Drug Delivery Meetings, Richard N. Dalby, Joanne Peart and Peter R. Byron. [Inhalation](#), October 2007.
3. 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.
4. Meeting Report. The Annual Respiratory Drug Delivery® Symposium, Richard Dalby. *Touch Briefings*, June 2007.
5. Meeting Report. Respiratory Drug Delivery Europe 2007. Peter R. Byron, Richard N. Dalby and Joanne Peart. *Expert Reviews In Respiratory Medicine*, 1(1), 2007.

## Richard Dalby, Ph.D.

### Abstracts

1. 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, David Healthcare International Publishing, May 2009.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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, David Healthcare International Publishing, May 2008.
8. 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.
9. The Effect of Volunteer Study-derived Actuation Parameters on Sprayed Droplet Size. Wenchi Hsu, Diane V. Doughty and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. November 2007.
10. 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.
11. Preliminary Study on the Bioequivalence in Nasal Sprays Containing Suspension Formulations. Feiyan Jin and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. November 2007.
12. Influence of Shaking on the Spray Weight of Nasal Spray Pumps; Lei Diao and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. November 2007.
13. Characterization of Delivered Dose and Droplet Size Distribution of Flovent HFA Utilizing the Next Generation Impactor (NGI) and Breath Simulation with OptiHaler. Tao Bai and Richard N. Dalby, American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. November 2007.
14. Phospholipid Induced In-Vivo Particle Migration To Enhance Pulmonary Deposition. Sudipta Ganguly, Vikas Moolchandani, Joseph Roche, Paul S. Shapiro, Shailaja Somaraju, Natalie Eddington and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. November 2007.
15. Determination of Automated Nasal Actuator Parameters Based on a Twenty Volunteer Study. Diane V. Doughty and Richard N. Dalby. In Respiratory Drug Delivery Europe 2007, Richard N. Dalby, Peter R. Byron, Joanne Peart and Julie Suman, Editors, David Healthcare International Publishing, April 2007.

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16. Modification of Nasal Spray Dip Tubes to Decrease Formulation Waste and Improve Content Uniformity by Decreasing the Number of Sprays in the Tail-Off Period. Diane Doughty and Richard N. Dalby. Parenteral Drug Association National Meeting, Las Vegas, NV. March 2007.
17. A Novel Way to Increase the Efficiency of Nasal Spray Pumps. Diane Doughty and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. October 2006.
18. The Influence of Tilt Angles on the Efficiencies of Jet Nebulizers. Feiyan Jin and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. October 2006.
19. A Phospholipid-Based Inhalation System: Formulation And Characterization Of Particle Migration On Lung Epithelial Cell Surfaces. Sudipta Ganguly, Paul S. Shapiro, Shailaja Somaraju and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. October 2006.
20. Semi-automated Detection of Deposited Particle Migration On Cultured Lung Epithelial Cells. Sudipta Ganguly, Paul S. Shapiro, Shailaja Somaraju and Richard N. Dalby. In Respiratory Drug Delivery 2006, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Stephen J. Farr, Editors, David Healthcare International Publishing, April 2006.
21. Characterization of Metered Dose Inhaler Robustness: A Stress Analysis and Mechanical Failure Study. Pallavi Nithyanandan, Sudipta Ganguly, Stephen W. Hoag and Richard N. Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. November 2005.
22. Prediction Of Mechanical Failure In Metered Dose Inhalers (MDIs) Using Finite Element Analysis (FEA). Pallavi Nithyanandan, Stephen Hoag and Richard Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. November 2005.
23. An In Vitro Lung Model for Evaluation of Particle Movement in Response to Exogenous Surfactants. Sudipta Ganguly, Paul S. Shapiro, Shailaja Somaraju and Richard N. Dalby. In Respiratory Drug Delivery Europe 2005, Richard N. Dalby, Peter R. Byron, Joanne Peart and Julie Suman, Editors, David Healthcare International Publishing, May 2005.
24. In Vitro Performance of the New ProChamber Valved Holding Chamber Tested at a Constant Flow. D von Hollen, E Lieberman, R Dalby and H Wu. American Thoracic Society Annual Meeting, San Diego, California. May 2005.
25. In vitro Performance of the OptiChamber Advantage Valved Holding Chamber with Removable Facemask. D von Hollen, E Lieberman, H Wu and R Dalby. American Thoracic Society Annual Meeting, San Diego, California. May 2005.
26. Performance Results of a New, Portable Aerosol Delivery Device Compared to a Conventional Jet Nebuliser. D von Hollen, E Lieberman, R Dalby and H Wu. International Society for Aerosols in Medicine Annual Meeting. Perth, Australia, March 2005. (J. Aerosol Med., 18(1), 124, 2005).
27. Anatomically Correct Nose Model Reduced Likely Lung Deposition of Nasal Sprays Compared to Glass Domes. Y. Guo and R. Dalby, American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, Maryland. November 2004.
28. Development of a Rational Test Method for the Analysis of Robustness of Inhaler Devices. Pallavi Nithyanandan, Stephen Hoag and Richard Dalby. American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, Maryland, November 2004.
29. Comparison of the % Droplets <9um for Aqueous Nasal Sprays as Measured by Andersen Cascade Impaction (ACI) and Laser Diffraction (LD). Julie D. Suman, Shailaja Somaraju and Richard Dalby. Pfeiffer Nasal Drug Delivery Conference III, Princeton, NJ. April, 2004.
30. In Vitro Characterization of a Captisol-Enabled® Budesonide Inhalation Solution in Ultrasonic and Air-Jet Nebulizers. R. O. Zimmerer, J. D. Pipkin, S. Somaraju, J. D. Suman, G. Su and R. N. Dalby. In Respiratory Drug Delivery IX, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Stephen J. Farr, Editors, David Horwood International Publishing, April 2004.

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31. Investigation of the Effect of Formulation Variables on In Vitro Performance of Nasal Sprays. Yang Guo, Julie Suman and Richard Dalby. In Respiratory Drug Delivery IX, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Stephen J. Farr, Editors, David Horwood International Publishing, April 2004.
32. Analysis of Functional Robustness of Inhaler Devices: Response of pMDIs to Mechanical Stresses. Pallavi Nithyanandan, Stephen Hoag and Richard Dalby. In Respiratory Drug Delivery IX, Richard N. Dalby, Peter R. Byron, Joanne Peart, Julie Suman and Stephen J. Farr, Editors, David Horwood International Publishing, April 2004.
33. Effect of Viscosity on Plume Geometry, Spray Pattern and Droplet Size of Nasal Sprays. Yang Guo and Richard Dalby. Philadelphia Pharmaceutical Forum, Philadelphia, PA, March, 2004.
34. Comparison of the Particle Size Distribution and Percent of Droplet Size Less Than 9 $\mu$ m for Solution and Suspension Nasal Sprays Using Andersen Cascade Impaction and Laser Diffraction. Geraldine S. Su, Julie D. Suman, Shailaja Somaraju and Richard Dalby. Practical Approaches to Nasal and Pulmonary Drug Delivery, Delray Beach, Florida, February, 2004.
35. "Effect of Extractor Height on Laser-based Droplet Size Distribution from Nasal Sprays, Practical Approaches to Nasal and Pulmonary Drug Delivery II (Valois Conference, Delray Beach, FL. February 2004.
36. In-Vitro Study of pMDI-Delivered HFA Proventil from Two Valved Holding Chambers. H. Wu, Ph.D. and R. Dalby, Ph.D., American Academy of Pediatrics. New Orleans, LA, November 2003.
37. Effect of Viscosity and Actuation Force on Plume Geometry of Nasal Formulations. Yang Guo, Richard Dalby and Julie Suman. AAPS, October 2003.
38. Comparison of the % Droplets <9 $\mu$ m for Aqueous Nasal Sprays as Measured by Andersen Cascade Impaction (ACI) and Laser Diffraction (LD). Julie D. Suman, Shailaja Somaraju and Richard Dalby. Nasal and Pulmonary Drug Delivery Conference VII, Barcelona, Spain, September, 2003.
39. Predicting Lung Penetration of Aqueous Nasal Sprays by Changing Air Flow Rates and Entry Port Dimensions During In Vitro Testing. Yang Guo and Richard Dalby. International Society for Aerosol in Medicine Annual International Congress, Baltimore, MD, June 2003. Published in Journal of Aerosol Medicine, 16 (2), 223 (Abstract 141).
40. Performance Characterization of pMDI-Delivered HFA-Albuterol from Two Valved Holding Chambers, H. Wu, Ph.D. and R. Dalby, Ph.D., American Thoracic Society Annual Meeting, Seattle, Washington, May 2003.
41. Performance Characterization of pMDI-Delivered Ventolin from Two Valved Holding Chambers, H. Wu, Ph.D. and R. Dalby, Ph.D., American College of Asthma, Allergy and Immunology National Meeting, San Antonio, Texas, November 2002.
42. Influence Of Entry Port Dimensions And Air Flow Rates On Aqueous Nasal Spray Deposition In The Anderson Cascade Impactor. Yang Guo and Richard Dalby. American Association of Pharmaceutical Scientists National Meeting, Toronto, Canada, October 2002.
43. Manipulation Of The Particle Size Of Aerosol Formulation Ingredients Using A Laboratory Scale Fluid Energy Mill. Pallavi Nithyanandan and Richard Dalby. American Association of Pharmaceutical Scientists National Meeting, Toronto, Canada, October 2002 .
44. Predicting the Quality of Powders for Inhalation. David Cline and Richard Dalby. In Respiratory Drug Delivery VIII, Richard N. Dalby, Peter R. Byron, Joanne Peart and Stephen J. Farr, Editors, David Horwood International Publishing, May 2002.
45. Realistic In-Vitro Assessment of Dry Powder Inhalers. Zhili Li and Richard N. Dalby. In Respiratory Drug Delivery VIII, Richard N. Dalby, Peter R. Byron, Joanne Peart and Stephen J. Farr, Editors, David Horwood International Publishing, May 2002.
46. Documenting Nasal Bioequivalence from In Vitro Characteristics to Physiologic Response, Julie D. Suman, Beth L. Laube and Richard Dalby. In Respiratory Drug Delivery VIII, Richard N. Dalby, Peter R. Byron, Joanne Peart and Stephen J. Farr, Editors, David Horwood International Publishing, May 2002

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47. Performance Characterization of pMDI-Delivered Fluticasone From Two Valved Holding Chambers. H. Wu, Ph.D. and R. Dalby, Ph.D., American Thoracic Society Annual Meeting, Atlanta, Georgia, May 2002.
48. Performance Of Two Valved Holding Chambers At Low Flow Rates In An In Vitro Test System. R. Dalby, T. Lin, H. Wu, D. von Hollen and L. Ziegler. American College of Asthma, Allergy and Immunology National Meeting, Orlando, Florida, November 2001.
49. Searching for a Valid In vitro - In vivo Correlation for Documenting Nasal Bioequivalence (T3448). J.D. Suman, B.L. Laube, T. Lin, G. Brouet and R. Dalby. American Association of Pharmaceutical Scientists National Meeting, Denver, CO, October 2001.
50. Predicting the Quality of Powders for Inhalation from Surface Energy (T3237). David Cline and Richard Dalby. American Association of Pharmaceutical Scientists National Meeting, Denver, CO, October 2001.
51. Use of Simulated Inhaled Volumes, Flow Rates and Flow Rate Ramps to Evaluate In Vitro Dry Powder Inhaler Performance (T3109). Varsha Chavan and Richard Dalby. American Association of Pharmaceutical Scientists National Meeting, Denver, CO, October 2001.
52. Time Slicing The Aerosol Cloud Emitted From Dry Powder Inhaler Using Simulated Inhalations (T3187). Z. Li and R. N. Dalby. American Association of Pharmaceutical Scientists National Meeting, Denver, CO, October 2001.
53. Performance Of Two Valved Holding Chambers At Low Flow Rates In An In Vitro Test System, R. Dalby, H. Wu, T. Lin, D. von Hollen and L. Ziegler. American Academy of Pediatrics National Conference and Exhibition, San Francisco, California, October 2001.
54. Intranasal Delivery in Humans: Are In Vitro Aerosol Characteristics Relevant to In Vivo Deposition Pattern? J.D. Suman B. Laube and R. Dalby. 13th International Congress on Aerosols in Medicine, International Society for Aerosols in Medicine, Interlaken, September 2001.
55. Derived Surface Energy - A Formulation Tool for Inhaled Powders. David Cline and Richard Dalby. Abstract accepted at the First International Gas Chromatography Symposium, London, UK, Sept 2001.
56. Criteria-based Assessment of Professional Abilities. Richard Dalby, Karen Plaisance and Robert Michocki. American Association of Colleges of Pharmacy Annual Meeting in Toronto, Canada, June 2001. American Journal of Pharmaceutical Education, Vol. 65, 111S, Winter Supplement 2001.
57. Assessment of General and Professional Abilities in the Third Professional Year via Compounding Skills. Richard Dalby and James Polli. American Association of Colleges of Pharmacy Annual Meeting in Toronto, Canada, June 2001. American Journal of Pharmaceutical Education, Vol. 65, 92S, Winter Supplement 2001.
58. Student Usage of Course Materials On The Internet. Richard Dalby, Karen Plaisance and Robert Michocki. American Association of Colleges of Pharmacy Annual Meeting in Toronto, Canada, June 2001. American Journal of Pharmaceutical Education, Vol. 65, 90S, Winter Supplement 2001.
59. Performance of a Dry Powder Inhaler Under Different Inhaled Volumes and Rates of Rise in Simulated Inspiratory Airflow. Varsha Chavan and Richard Dalby. American Association of Pharmaceutical Scientists National Meeting, Indianapolis, IN, October 2000.
60. Julie Suman and Richard Dalby, A Practical Guide to Performing In Vitro Tests on Nasal Delivery Systems, presented at Emerging Topics in Development of Pulmonary and Nasal Delivery Systems at the American Association of Pharmaceutical Scientists National Meeting, Indianapolis, IN, October 2000.
61. Positive Expiratory Pressure rhDNAse and Aerosol Distribution in Cystic Fibrosis, B. Laube, T. Lin, D Geller, R. Dalby and P. Zeitlin. Fourteenth Annual North American CF Conference, Baltimore, MD. November, 2000. Pediatric Pulmonology (Suppl 20): 247 (2000).
62. Aerosol Output And Particle Size Characteristics Of Tobramycin Solution For Inhalation Administered To A Ventilator Circuit Via Three Different Jet Nebulizers, Ta-Chun Lin, Richard

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- Dalby, Jenn Visich and Peter Challoner. Chest 2000, San Francisco, CA, November, 2000. Chest 118(4) (Suppl): 237S (2000).
63. Effect of Rate of Rise in Simulated Inspiratory Flow Rate on Dry Powder Inhaler Performance, Varsha Chavan 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).
  64. Computerized Training Tools to Assist Patients in Using Their Inhaler Correctly Zhili Li 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).
  65. In Vitro Performance Measurements Of Aqueous Nasal Spray Pumps May Not Predict In Vivo Deposition Pattern, J.D. Suman, B.L. Laube , T. Lin, G. Brouet, R. Dalby. American Association Of Pharmaceutical Scientists National Meeting, PharmSci Supplement, 1(4) Online, 2686 (1999).
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  84. Particles For Inhalation Produced By Spray Drying And Electrostatic Precipitation Of Different Protein-Sugar Solutions, Venkatesh Naini, Peter R. Byron and Richard N. Dalby. In Respiratory Drug Delivery V (ISBN 1-57491-018-3), Peter R. Byron, Richard N. Dalby and Stephen J. Farr, Editors, Interpharm Press, Buffalo Grove, IL, 382-384, (1996).
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  87. Liquefied Propellant Density - Measurement And Utility, Shailaja Somaraju, Richard N. Dalby and Michael Pierpont. American Association Of Pharmaceutical Scientists National Meeting, Pharmaceutical Research, 12 (9), S182 (1995).
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93. Aerosolization Of A Model Respiratory Suspension From An Air-Blast And Ultrasonic Nebulizer, Susan L. Tiano and Richard N. Dalby. American Association Of Pharmaceutical Scientists Eastern Regional Meeting, New Brunswick, NJ (1995).
94. Evaluation Of Patient Nebulizer Use, Measurement Of Nebulizer Flow Rate And Output. Tracy L. Allen, Richard N. Dalby, and Mary Lynn McPherson. 142st A.Ph.A. Annual Meeting in Orlando, FL (1995).
95. In-Vivo Absorption Of Four Naproxen Formulations With Varying Dissolution Rates, Natalie D. Eddington, James L. Leslie, R. Gary Hollenbeck, Richard N. Dalby, Vinod Shah and Lawrence J. Lesko. American Association Of Pharmaceutical Scientists National Meeting, Pharmaceutical Research, 11 (10), S431 (1994).
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97. Effect Of Scale-Up And Processing Conditions On The Dissolution Of Naproxen Tablets, Richard N. Dalby, Stephen R. Anderson, Dudley A. Demarest, R. Gary Hollenbeck and Paul Schwartz. American Association Of Pharmaceutical Scientists National Meeting, Pharmaceutical Research, 11 (10), S163 (1994).
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99. Alterations In Inspiratory Flow Rate Effect The Large Airway Response To Aerosolized Albuterol In Patients With Asthma, B.L. Laube, P.S. Creticos, R.N. Dalby and P.S. Norman. The American Journal of Respiratory and Critical Care Medicine, 149 (Supplement), A203 (1994).
100. A Partial Pictorial Survey Of Olde Inhalation Delivery Devices, Richard N. Dalby and Nicholas C. Miller. A poster presented at Respiratory Drug Delivery IV, Richmond, Virginia (1994).
101. Rational Comparison Of Nebulizer Performance, Susan L. Tiano and Richard N. Dalby. A poster presented at the 141st A.Ph.A. Annual Meeting in Seattle, WA, March 1994.
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104. Dry Powder Inhaler Performance In Different Environments, R.N. Jashnani, P.R. Byron and R.N. Dalby. American Association Of Pharmaceutical Scientists National Meeting, Pharmaceutical Research, 10 (10), S196 (1993).
105. Nebulizers And Respiratory Solutions : Testing In Three Inertial Impactors, Susan L. Tiano and Richard N. Dalby. American Association Of Pharmaceutical Scientists National Meeting, Pharmaceutical Research, 10 (10), S142, (1993).
106. A Worksheet For Examining The Effects Of Particle Size And pH On The Dissolution Profiles Of Solid Dosage Forms, R. Gary Hollenbeck, Richard N. Dalby, Judy McGlone and Vinod Shah.

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  108. Electrostatic Collection Of Particles Suitable For Inhalation, Venkatesh Naini, Richard N. Dalby and Peter R. Byron. American Association Of Pharmaceutical Scientists National Meeting, Pharmaceutical Research, 8 (10), S122 (1991).
  109. Evaluation And Prediction Of Elastomer Swelling In Metering Valve Components, Richard N. Dalby and Peter R. Byron. American Association Of Pharmaceutical Scientists National Meeting, Pharmaceutical Research, 8 (10), S121 (1991).
  110. Safety Evaluation Of Metered Dose Inhalers Containing Flammable Propellants, Richard N. Dalby and Peter R. Byron. American Association Of Pharmaceutical Scientists National Meeting, Pharmaceutical Research, 8 (10), S121 (1991).
  111. Determination Of Drug Solubility In Aerosol Propellants Using A Novel Filtration Apparatus, Richard N. Phillips and Peter R. Byron. American Association Of Pharmaceutical Scientists National Meeting, Pharmaceutical Research, 7(9), S82 (1990).
  112. Relationship Between Particle Morphology And Drug Release Properties After Hydration Of Aerosols Containing Liposome Forming Ingredients, Richard N. Dalby and Peter R. Byron. American Association Of Pharmaceutical Scientists National Meeting, Pharmaceutical Research, 5 (10), S94 (1988).
  113. Liposome Formation Following Actuation Of Lecithin Containing Metered Dose Inhalers (MDIs), Richard N. Dalby and Peter R. Byron. Journal of Pharmaceutical Sciences, 76 (11), S262 (1987).
  114. Comparison Of The Output Particle Size Distributions From Pressurized Aerosols Formulated As Solutions And Suspensions, Richard N. Dalby and Peter R. Byron. British Pharmaceutical Society National Meeting. Journal of Pharmacy and Pharmacology, 39, 72P (1987).
  115. Effects Of Heat Treatment On The Permeability Of Polyvinylalcohol Films, Richard N. Dalby and Peter R. Byron. American Association Of Pharmaceutical Scientists National Meeting, Washington, DC (1986).

### Book Chapters and Books Edited

1. 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).
2. 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).
3. 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, Julie D. Suman and Paul M. Young, Editors, Davis Healthcare, River Grove, Illinois (May 2008)
4. 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).
5. 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).
6. 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).
7. 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 and Julie D. Suman, Editors, Davis Healthcare, River Grove, Illinois (April, 2006).

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8. 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).
9. 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 and Julie D. Suman, Editors, Davis Healthcare, River Grove, Illinois (Vol 1, 35-44, May, 2005).
10. 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).
11. 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).
12. 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).
13. 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).
14. 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).
15. 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).
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17. 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).
18. Inhalation Technologies For Local And Systemic Drug Delivery, Richard N. Dalby, Teltech Technical Knowledge Service, Minneapolis, MN (1996).
19. 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).
20. 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).
21. 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).
22. 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).
23. 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).

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24. 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).
25. Respiratory Drug Delivery III, Richard N. Dalby and Peter R. Byron, Editors. J. Biopharm. Sci., 3 (1 & 2), 1992.
26. 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 3-5 such presentations annually.

1. Lung Deposition and Regulatory Opinion. 1000 years of pharmaceutical aerosols – What remains to be done? Reykjavik, Iceland, October 2009.
2. “Inhaled Medication – When Tablets Just Won’t Work”. Chemistry Department, College of Notre Dame of Maryland, Baltimore. March 2009.
3. *“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, Atlanta, GA. November 2008.
4. *“Formulation Strategies for HFA pMDIs”* and *DPI Device and Formulation Development* at Practical Approaches to Nasal and Pulmonary Drug Delivery, Suzhou, China, November, 2008.
5. “Particle Size and The Andersen Cascade Impactor - Special Issues For Nebulizers. FDA Center for Devices and Radiological Health (CDRH). Rockville, Maryland, April 2008.
6. “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.
7. “Introduction to Pulmonary Drug Delivery.” University of Kentucky College of Pharmacy, Lexington, KY, November 2007.
8. “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.
9. “pMDI Formulation Strategies with HFA Propellants” and “Advanced Pulmonary Delivery Devices” at Symposium On Advances In Pulmonary And Nasal Drug Delivery, The Indian Pharmaceutical Association, Mumbai, India, October, 2007.
10. Is Bioequivalence Broken? Alternative Approaches to Demonstrating Similarity in ONIDPs. AAPS Inhalation Technology Focus Group, Baltimore, Maryland, September 2007.
11. 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.
12. “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.
13. “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.
14. 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.

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15. Pulmonary and Nasal Devices. AAPS Workshop on Nasal and Pulmonary Delivery : Technology and Future Directions. San Francisco, CA, June 2005
16. Emerging Pulmonary and Nasal Aerosol Drug Delivery Systems. MITRE Corporation Intelligence Community Scientific Mini-Symposia. McLean Virginia, June 2005.
17. Analytical Testing of Nasal and Pulmonary Products Using Patient-Derived Parameters – Realism vs. Reproducibility. RDD Europe 2005, Paris France, May 2005.
18. Communication Basics for Effective Communication and Teaching. American Society for Pharmacology and Experimental Therapeutics. San Diego, CA, April 2005.
19. “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.
20. 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.
21. Pulmonary Drug Delivery. College of Pharmacy, University of Nepal, Nepal, March 2004.
22. “Fundamental Principles of Pulmonary Drug Delivery”, “Formulation of Pressurized Metered Dose Inhalers” and Formulation of Dry Powder Inhalers” at Symposium on Pulmonary and Nasal Drug Delivery, The Indian Pharmaceutical Association, Mumbai, India, March, 2004.
23. Latest Advances in Nasal Drug Delivery. Practical Approaches to Nasal and Pulmonary Drug Delivery, Delray Beach, FL, February, 2004.
24. Pulmonary Drug Delivery Systems. The Indian Pharmaceutical Association – Andhra Pradesh, Hyderabad, India, December, 2003.
25. Introduction to Nasal Drug Delivery, Nasal Spray Product Testing Workshop, Next Breath. Baltimore, MD, February and August, 2003, May and September 2004.
26. In Vitro Techniques Used to Characterize Intranasal Aerosols. 14<sup>th</sup> Congress, International Society for Aerosols in Medicine (ISAM), Baltimore, MD, June 2003
27. Pulmonary Drug Delivery. University of Kentucky College of Pharmacy, Lexington, KY, March 2003.
28. 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.
29. 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.
30. 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
31. 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).
32. Nasal Formulations and Testing Protocols. Practical Approaches to Nasal and Pulmonary Drug Delivery, Paris, France, January, 2002.
33. Are In Vitro Tests of Nasal Solutions Predictive of In Vivo Deposition? Analytical Land O' Lakes Conference, Madison, WI, August 2001.
34. Nasal Drug Delivery, Virginia Commonwealth University, Richmond, VA, October 2000.
35. Critical Factors for Nasal Sprays, Analytical Land O' Lakes Conference, Madison, WI August 2000.
36. Symposium On MDI Aerosol Delivery - The Science, American Association of Respiratory Care Annual Meeting, Atlanta, GA, November 1998 (0.1CE credits).

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37. Latest Research In Aerosol Technology, American Association of Physician Specialists annual meeting, Colorado Springs, CO, June 1998 (0.2 CE credits).
38. Aerosol Drug Delivery Systems, Asthma Management Institute, Joint University of Maryland and Temple University continuing education program. Baltimore, MD, May 1998.
39. Aerosol Drug Delivery - Beyond The Medihaler!, Senior Pharmacists Association of Maryland / Baltimore Veteran Druggists Association / Wedgewood Club, Baltimore, MD, April 1998 (0.1CE credits).
40. 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.
41. Delivery Of Aerosols By Dry Powder Inhalers, Aerosol Therapy Update, Johns Hopkins University, School of Hygiene and Public Health, Baltimore, MD, November, 1996.
42. Inhalation Aerosol Technologies For The Next Century. 36th Annual Eastern Pharmaceutical Technology Meeting, New Brunswick, NJ, November, 1996.
43. Sizing Aerosols Generated By Nebulizers - The Challenges. Philadelphia Pharmaceutical Forum, Graduate Student Poster Night, King of Prussia, PA, March 1996.
44. 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.
45. 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.
46. Controlled Drug Delivery To The Human Respiratory Tract - A Liposome Based Approach. UMBC Department of Chemical and Biochemical Engineering, Baltimore, MD, March 1994.
47. 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.
48. Inhalation Aerosol Generation Using Nebulizers - Pharmaceutical Testing Considerations; First International Conference on Pharmaceutical and Food Sciences and Technology, Chicago, IL. August 1993.
49. 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.
50. Recent Advances In Metered Dose Inhaler Technology. Presented to School of Pharmacy, University of Maryland at Baltimore, January 1992.
51. 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.
52. 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.
53. 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.
54. The Metered Dose Inhaler - Past, Present And Future. Presented to School of Pharmacy, Medical College of Virginia, May 1991.
55. Sustained release terbutaline sulfate aerosols. Interphex USA, July 1988, New York. Published in conference proceedings, Cahners Exposition Group, Des Plaines, Illinois, 23-45

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### Patents

1. Phospholipid-Based Inhalation System. PCT Application US2007/022638. Richard Dalby, Sudipta Ganguly, Shailaja Somaraju and Julie Suman. Assigned to Next Breath LLC, October 26, 2007.
2. Methods and compositions for treatment of intraepithelial neoplasia. US Application 11/572,349 non-provisional patent application. Niharika Khanna and Richard Dalby. Co-owned by Erimos Pharmaceuticals and UMD, January 19, 2007.
3. Formulations for delivery of beclomethasone dipropionate by metered dose inhalers containing no chlorofluorocarbon propellants. Richard N. Dalby and Peter R. Byron. United States Letters Patent, 5,202,110 assigned to Virginia Commonwealth University, April 1993.
4. Formulations for delivery of drugs by metered dose inhalers with reduced or no chlorofluorocarbon content. Peter R. Byron and Richard N. Dalby. United States Letters Patent, 5,190,029 assigned to Virginia Commonwealth University, March 1993.
5. Formulations for delivery of drugs by metered dose inhalers with reduced or no chlorofluorocarbon content. Peter R. Byron and Richard N. Dalby. United States Letters Patent, 5,182,097 assigned to Virginia Commonwealth University, January 1993.

### CE and Un-Reviewed Publications

1. 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

1. Respiratory Drug Delivery (RDD) Symposium, co-organizer, publication coordinator, editor (with 4 co-editors), Scientific Poster Session and Exhibition moderator, and frequent podium session moderator. Next meeting; RDD 2010, Orlando Florida, April 2010. Past meetings; RDD Europe 2009, Lisbon, Portugal; RDD 2008, Phoenix; RDD Europe 2007, Paris, France; RDD 2006, Boca Raton, April 2006; RDD Europe 2005, Paris, France, May 2005; RDD IX, Palm Desert, May 2004; RDD VIII, Tucson, AZ, May 2002; RDD VII, Tarpon Springs, FL, May, 2000; RDD VI, Hilton Head, SC, April 1998; RDD V, Phoenix, AZ, April, 1996; RDD IV, Richmond, VA, May 1994; RDD III, Williamsburg, VA, May 1992; and RDD II, Keystone, CO, March 1990. These are international meetings drawing between 300-800 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, exceed 1000 pages, and are considered by many to be the most up-to-date reference on advances associated with medical aerosol drug delivery. I also review abstracts for, and organize a poster session / exhibition with approximately 150 presenters and 100 exhibitors.
2. Director, Inhalation Aerosol Technology Workshop (IATW). I created and annually conduct this introductory short course on pharmaceutical aerosols. The format includes 3 or 4 days of lectures, workshops and laboratory sessions. Open courses have been run annually since 1992 and customized courses have been presented to several pharmaceutical companies. <https://rxsecure.umaryland.edu/research/rdalby/IATW%20Web%20Pages/iatw.htm>
3. Moderator, "In vitro Approaches to Demonstrating Bioequivalence" PQRI Workshop on Demonstrating Bioequivalence of Orally Inhaled Drug Products. Bethesda, MD, March 2009.
4. Moderator, "In vitro Bioequivalence Testing for Aerosol Products: From Today to Tomorrow." AAPS national meeting, November 2008.
5. "Steering Committee Member, AAPS Generic Pharmaceuticals Focus Group, December 2006-present.
6. 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

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- 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).
7. Special Reviewer, Special Emphasis Panel (Development of Novel Drug and Gene Delivery Systems and Devices), National Institutes of Health, Bethesda, Maryland, July 2003.
  8. 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).
  9. Moderator, Aerosolized Medications and Regulatory Guidance, 14<sup>th</sup> Congress, International Society for Aerosols in Medicine (ISAM), Baltimore, MD, June 2003.
  10. Expert reviewer, International Pharmaceutical Aerosol Consortium (IPAC) briefing book, [Ensuring Patient Care - The Role Of The HFA MDI](#), 1996, and revision in 1999 ([www.ipacmdi.com/documents/EPC.pdi](http://www.ipacmdi.com/documents/EPC.pdi)).
  11. Organizer & roundtable moderator, Nasal Delivery - Beyond Aqueous Spray Pumps, American Association Of Pharmaceutical Scientists National Meeting, San Francisco, CA. 1998.
  12. Planning Committee member, American Association Of Pharmaceutical Scientists Eastern Regional Meeting, 1998.
  13. 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.
  14. Academic representative on American Association Of Pharmaceutical Scientists Eastern Regional Meeting Posters and Podium, and PDD committees, 1995-1996.
  15. Editorial Advisory Board member, Pharmaceutical Research, 1995 - 1997.
  16. Reviewer for: Pharmaceutical Research, Medical Device Technology, Pharmaceutical Technology, Journal of Biopharmaceutical Sciences, Journal of Pharmaceutical Sciences and Pharmaceutical Development and Technology.
  17. Abstract reviewer for American Association Of Pharmaceutical Scientists Annual Meeting (Pharmaceutical Technology Section), 1995 to 1997.
  18. Special Reviewer, National Institutes of Health, Pharmacology Study Section, Bethesda, Maryland, 1993-96, and 1998.
  19. 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.
  20. 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

1. Presenter at the annual University of Maryland Graduate School Survival Skills Seminar Series on Mentoring. 1998 - 2003.
2. Implementation of an Integrated Course Sequence, University of Oklahoma School of Pharmacy Retreat, OK, May, 1998.
3. Implementation of an Integrated Clinical and Pharmaceutical Science Pharm. D. Course, Northeastern University School of Pharmacy Retreat, Boston, MA, February, 1998.
4. Graduate Research Association of Students in Pharmaceutics (GRASP) advisor, 1994 & 2000.
5. University of Maryland Graduate Research Symposium Poster Judge, 1998 -2003.
6. Instructor, A three hour interactive workshop presented at the Pharm Tech Conference, Inhalation Aerosols: The Patient - Device Interface, East Rutherford, NJ, September 1996.
7. 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.

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8. 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.
9. Visiting Scientist, Boehringer Ingelheim Pharmaceuticals. Organized by the Pharmaceutical Manufacturers Association, July 6-17, 1992.
10. 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. 2004, Elected a Fellow of the American Association of Pharmaceutical Scientists.
2. 2002, Appointed Deans Distinguished Educator, UMB School of Pharmacy.
3. 1998 Graduate Student voted Faculty of the Year, UMB School of Pharmacy.
4. 1996 Faculty voted Teacher of the Year, School of Pharmacy, UMB (\$1000 and attendance at American Association of Colleges of Pharmacy Annual Meeting, Reno, NV).

### 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 recent 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.
- Reviews of pulmonary and nasal products and markets, and participation in due diligence reviews on pulmonary and nasal devices and formulation platforms for investment banking firms.

### Miscellaneous Experience

- Clients included national and international companies.
- Service as an independent consultant for over 20 years.
- Expert witness and advisor for pharmaceutical companies engaged in intellectual property disputes associated with inhaled medications and 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.



Richard Dalby, Ph.D.

23 June 2009