

IPAC-RS PUBLICATIONS

2000-2011

Last updated: November 2011

Including output of collaborative efforts (e.g., through the Product Research Quality Institute) where IPAC-RS was the main driver and enabler

2011 – Manuscripts in Preparation

- **Orally Inhaled Products: Good Cascade Impaction Practices, AIM and EDA. (Book).** Terrence P Tougas, Jolyon P Mitchell, Svetlana Lyapustina, Editors. *Manuscript in preparation.*
- **Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products (Book).** D. J. Ball, D. L. Norwood, C. L. M. Stults, L. M. Nagao, eds. *Manuscript in preparation.*
- **Definitions of Shelf Life.** D. Christopher, P. Forenzo, M. Golden, P. Hudson, N. Patterson, M. Quinlan, S. Lyapustina, D. Sandell, J. Schwenke, W. Stroup, D. Thomas and T. Tougas. *Manuscript in preparation.*
- **Elastomers in Orally Inhaled and Nasal Drug Products, Part I: Elastomer Selection and Qualification.** D. M. Dohmeier, G. Reckzuegel, D. L. Norwood, C. L. M. Stults, L. M. Nagao. *To be published in Inhalation.*
- **Elastomers in Orally Inhaled and Nasal Drug Products, Part II: Control Strategies.** D. M. Dohmeier, G. Reckzuegel, D. L. Norwood, C. L. M. Stults, L. M. Nagao. *To be published in Inhalation.*

2011 – Published

- **Introduction to IPAC-RS.** R. Ormiston, J. Schumacher, and L. Shtohryn. *Inhalation October 2011.* <http://www.inhalationmag.com/Content/viewRequest.aspx?ID=9729559d-32e5-43d5-88d7-62a63cb90d2d&fi=1>
- **Challenges and Opportunities in Implementing the FDA Default Parametric Tolerance Interval Two One-Sided Test for Delivered Dose Uniformity of Orally Inhaled Products.** Greg Larner, Andrew Cooper, Svetlana Lyapustina, Stefan Leiner David Christopher, Helen Strickland, Michael Golden, Hans-Joachim Delzeit, Emil M. Friedman. *AAPS PharmSciTech 2011 DOI: 10.1208/s12249-011-9683-1* <http://www.springerlink.com/content/f0175288762377v1/>
- **Non-impactor-Based Methods for Sizing of Aerosols Emitted from Orally Inhaled and Nasal Drug Products (OINDPs)** Jolyon Mitchell, Richard Bauer, Svetlana Lyapustina, Terrence Tougas, and Volker Glaab. *AAPS PharmSciTech 2011 Vol 12(43) DOI: 10.1208/s12249-011-9662-6*; <http://www.springerlink.com/content/a77825787gg0r244/fulltext.pdf>
<http://www.springerlink.com/openurl.asp?genre=article&id=doi:10.1208/s12249-011-9662-6>
<http://www.springerlink.com/content/a77825787gg0r244/>
- **Efficient Data Analysis in Quality Assessment.** Terrence P Tougas. *RDD Europe 2011 (2011), Vol 1, pp 209-214* <http://www.rddonline.com/publications/articles/article.php?ArticleID=1591&return=1>

- **Detecting Differences in APSD: Efficient Data Analysis (EDA) vs. Stage Grouping** J. David Christopher, Monisha Dey. *RDD Europe 2011 (2011), Vol 1, pp 215-224*
<http://www.rddonline.com/publications/articles/article.php?ArticleID=1592&return=1>
- **Efficient Data Analysis for MDIs and DPIs: Failure Mode Effect Analysis** Volker Glaab, Adrian Goodey, Svetlana Lyapustina, Jolyon P Mitchell. *RDD Europe 2011 (2011), Vol 1, pp 225-236* <http://www.rddonline.com/publications/articles/article.php?ArticleID=1593&return=1>
- **When Could Efficient Data Analysis (EDA) Fail? Theoretical Considerations** Jolyon P Mitchell, J. David Christopher, Terrence P Tougas, Volker Glaab, Svetlana Lyapustina. *RDD Europe 2011 (2011), Vol 1, pp 237-246*
<http://www.rddonline.com/publications/articles/article.php?ArticleID=1594&return=1>
- **Product Lifecycle Approach to Cascade Impaction Measurements.** Terrence Tougas, Dave Christopher, Jolyon Mitchell, Svetlana Lyapustina, Michiel Van Oort, Richard Bauer, Volker Glaab. *AAPS PharmSciTech 2011* DOI: 10.1208/s12249-011-9590-5.
- **Role of Pharmacokinetics in Establishing Bioequivalence for Orally Inhaled Drug Products: Workshop Summary Report.** Dennis O'Connor, Wallace P. Adams, Mei-Ling Chen, Peter Daley-Yates, John Davis, Hartmut Derendorf, Murray P. Ducharme, Anders Fuglsang, Myra Herrle, Günther Hochhaus, Susan M. Holmes, Sau L. Lee, Bing V. Li, Svetlana Lyapustina, Stephen Newman, Martin Oliver, Beverley Patterson, Joanne Peart, Guirag Poochikian, Partha Roy, Tushar Shah, Gur Jai Pal Singh, Sandra Suarez Sharp. *J Aer Medicine and Pulmonary Drug Delivery. 24(3)2011: 119-135* doi:10.1089/jamp.2011.0878
<http://www.liebertonline.com/doi/abs/10.1089/jamp.2011.0878>

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- **Extension of the Abbreviated Impactor Measurement (AIM) Concept to Incorporate Simultaneous Determination of Delivered Dose Uniformity with Efficient Data Analysis Metrics Pertinent to Aerodynamic Particle Size (AIM-DDU Apparatus).** Jolyon Mitchell, Terrence Tougas, J. David Christopher and Svetlana Lyapustina. DDL 21. 2010; *Journal of Aerosol Medicine and Pulmonary Drug Delivery*.
- **Use of Polymeric Materials in Orally Inhaled and Nasal Drug Products.** D.M. Dohmeier, D.L. Norwood, G. Reckzuegel, C.L.M. Stults, and L.M. Nagao. *Medical Device Technology*.
- **Advancing Quality of Materials Through Collaboration with the Supply Chain: The Work of the IPAC-RS OINDP Materials Working Group.** M. Hodgson, J. Mullis, G. Reckzuegel, A. Feilden, J. Creasey, C. L. M. Stults, L. M. Nagao. Proceedings Extractables and Leachables for Pharmaceutical Products 2010. RAPRA, September 2010.
- **Abbreviated Impactor Measurement (AIM) and Efficient Data Analysis (EDA) concepts: A partnership for the assurance of Oral Inhaled Product (OIP) quality.** Mitchell, Tougas, Christopher, Bauer, Church, Dey, Glaab, Goodey, Holmes, Iley, Lyapustina, Patel, Quiroz, Russell-Graham, Strickland, Svensson, Van Oort, Wu. *Inhalation*, December 2010, pp. 8-12.
<http://www.ecn5.com/ecn.images/customers/1983/publisher/1941/INH1210.pdf>
- **Efficient Data Analysis (EDA) and Abbreviated Impactor Measurement (AIM) Concepts** T.P. Tougas, J.D. Christopher, J.P. Mitchell and S. Lyapustina. *Respiratory Drug Delivery 2010*. Orlando, Florida, USA, April 25-29 2010. RDD 2010, Vol 2 (2010): pp 599-604

- **Relative Precision Study of Inhaler Aerodynamic Particle Size Distribution (APSD) Metrics by Full Resolution and Abbreviated Andersen Cascade Impactors (ACIs). Part 2 – Investigation of Bias in Extra-Fine Mass Fraction with HRT-AIM Impactor.** Jolyon P Mitchell, Mark W Nagel, Cathy C Doyle, Rubina S Ali, Valentina I Avvakoumova, J. David Christopher, Jorge Quiroz, Helen Strickland, Terrence Tougas, Svetlana Lyapustina. *AAPS PharmSciTech*. 2010 doi: 10.1208/s12249-010-9473-1
- **Relative Precision of Inhaler Aerodynamic Particle Size Distribution (APSD) Metrics by Full Resolution and Abbreviated Andersen Cascade Impactors (ACIs): Part 1.** Jolyon P Mitchell, Mark W Nagel, Cathy C Doyle, Rubina S Ali, Valentina I Avvakoumova, J. David Christopher, Jorge Quiroz, Helen Strickland, Terrence Tougas, Svetlana Lyapustina. *AAPS PharmSciTech*. 2010, 11(2):843 – 851. doi: 10.1208/s12249-010-9452-6
- **Generalized Simplified Approaches For MMAD Determination.** David Christopher, Monisha Dey, Lana Lyapustina, Jolyon Mitchell, Terrence Tougas, Mike Van Oort, Helen Strickland, Bruce Wyka. *USP Pharmacopeial Forum* 36(3), pp 812-823. May – June 2010
- **¹Demonstrating Bioequivalence of Locally Acting Orally Inhaled Drug Products (OIPs): Workshop Summary Report.** 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, Lawrence Yu. *Journal of Aerosol Medicine and Pulmonary Drug Delivery*. February 2010, 23(1): 1-29. doi:10.1089/jamp.2009.0803. <http://www.liebertonline.com/doi/abs/10.1089/jamp.2009.0803> and http://www.pqri.org/pdfs/DTC/Articles/JAMP_article_final_draft.pdf

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- **Use of Polymeric Materials in Orally Inhaled and Nasal Drug Products.** Dan M. Dohmeier, Daniel L. Norwood, Gaby Reckzuegel, Cheryl L.M. Stults, Lee M. Nagao. *Medical Device Technology*. Volume 20, Number 2, pp. 32-38. March/April 2009. <http://www.devicelink.com/mdt/>.
- **International approaches to regulation and quality standards for orally inhaled and nasal drug products.** Tim Chesworth, Paul Lafferty, Svetlana Lyapustina, Guillaume Brouet, David Christopher, John Hart. *Inhalation*. December 2009. www.inhalationmag.com
- **Improved Quality Control Metrics for Cascade Impaction Measurements of Orally Inhaled Drug Products (OIPs).** Terrence P. Tougas, David Christopher, Jolyon P. Mitchell, Helen Strickland, Bruce Wyka, Mike Van Oort, Svetlana Lyapustina. *AAPS PharmSciTech* 2009. DOI: 10.1208/s12249-009-9312-4 pp. 1276 – 1285 <http://www.springerlink.com/content/j316855116723866/>
- **Risk Management for Combination Products. The need for improved risk management practices for orally inhaled and nasal drug product.** Tim Chesworth, Paul Lafferty, Svetlana Lyapustina, Guillaume Brouet, David Christopher, and John Hart. *Inhalation*. October 2009, pp. 12-15. www.inhalationmag.com

¹ A “Most Downloaded Article” of that journal in 2010. See <http://www.liebertpub.com/mcontent/files/JAMPfastfacts91910.pdf>

- **A “Compare And Contrast” of International Guidelines Impacting Pharmaceutical Development of New And Subsequent Market Entry OINDPs.** The International Industry Coordination Group (IICG) of the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), J Schumacher, R Ormiston, R Alekel, B Berner, N Bowles, M James, JR Keegstra, S Lyapustina, A Rignall, C Rogerson, B Thompson, N Childerhouse, R Musa, T Peveri, A Pratt, MA Smith, G Toth, D Voelker and E Wyka. *J Aerosol Med. Pulmonary Drug Delivery*. 22(2):207. 2009. DOI:10.1089/jamp.2008.00A3.
- **A “Compare and Contrast” of International Guidelines Impacting Clinical Development of New and Subsequent Market Entry OINDPs.** The International Industry Coordination Group (IICG) of the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), J Schumacher, R Ormiston, R Alekel, B Berner, N Bowles, M James, JR Keegstra, S Lyapustina, A Rignall, C Rogerson, B Thompson, N Childerhouse, R Musa, T Peveri, A Pratt, MA Smith, G Toth, D Voelker and E Wyka. *J Aerosol Med. Pulmonary Drug Delivery*. 22(2):207. 2009. DOI:10.1089/jamp.2008.00A3.
- **Rationalized Approach to Chemistry, Manufacturing & Control (CMC) Requirements for Orally Inhaled and Nasal Drug Products (OINDPS) Based on Risk Management.** The IPAC-RS Risk Management Working Group: S Horhota, R Berger, N Butterworth, B Davidson, A Grant, S Kaerger, S Leiner, S Lyapustina, R Patel and A Purrington. *J Aerosol Med. Pulmonary Drug Delivery*. 22(2):206. 2009. DOI:10.1089/jamp.2008.00A3.
- **Improved Accuracy of MMAD Determination Compared with USP Method.** T Tougas, D Christopher, M Dey, S Lyapustina, J Mitchell, and M Van Oort. *J Aerosol Med. Pulmonary Drug Delivery*. 22(2):181. 2009. DOI:10.1089/jamp.2008.00A3.
- **Evaluation Of An Approach For Characterizing Sources Of Variability In Cascade Impaction Particle Size Determinations.** T Tougas, D Christopher, S. Lyapustina, J Mitchell, J Quiroz, H Strickland, and B Wyka. *J Aerosol Med. Pulmonary Drug Delivery*. 22(2):181. 2009. DOI:10.1089/jamp.2008.00A3
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- **²A Two One-Sided Parametric Tolerance Interval Test For Control of Delivered Dose Uniformity** S. Novick, D. Christopher, M. Dey, S. Lyapustina, M. Golden, S. Leiner, B. Wyka, H.-J. Delzeit, C. Novak and G. Lerner.
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 - Part 2 – Effect of Changing Parameters.** DOI: 10.1208/s12249-009-9269-3. *AAPS PharmSciTech* 2009 10(3)2009;841-849. <http://www.pharmagateway.net/ArticlePage.aspx?DOI=10.1208/s12249-009-9269-3>

⁰=This three-part series of articles has won the AAPS "2010 Outstanding Manuscript Award". See http://www.eurekalert.org/pub_releases/2010-11/aaop-apa111510.php

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10.1208/s12249-009-9271-9. *AAPS PharmSciTech* 2009 Vol 10. No 3, September 2009. pp. 829-840. <http://www.pharmagateway.net/ArticlePage.aspx?DOI=10.1208/s12249-009-9271-9>

- **Quality By Design For Analytical Methods Intended For Use With Orally Inhaled And Nasal Drug Products (OINDPs).** Andy Rignall, J. David Christopher, Andrew J Crumpton, Kevin Hawkins, J. Sebastian Kaerger, Svetlana Lyapustina, Holger Memmesheimer, Adrian Parkinson. *RDD Europe 2009*, Vol 2 (2009): pp 315-318.
- **Rationalized Approach to Chemistry, Manufacturing & Control (CMC) Requirements for Orally Inhaled and Nasal Drug Products (OINDPs) Based on Risk Management.** Stephen T Horhota, Robert L Berger, Noel Butterworth, Don C Chambers, Barbara S Davidson, Andrew C Grant, J. Sebastian Kaerger, Stefan Leiner, Svetlana Lyapustina, Rajni Patel, Ann M Purrington. *RDD Europe 2009*, Vol 2 (2009): pp 319-322.
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- **Simplifying OINDP Regulations: Addressing the complex international regulatory environment governing Chemistry, Manufacturing and Controls (CMC) for Orally Inhaled and Nasal Drug Products (OINDPs)** Horhota, Leiner, Berger, Purrington, Kaerger, Lyapustina, Butterworth, Patel, Davidson, Grant, Smith. *Inhalation Magazine* (December 2008), pp.14-19. www.inhalationmag.com
- **Quality By Design For Analytical Methods Intended For Use With Orally Inhaled And Nasal Drug Products (OINDPS).** A. Rignall, B. Benson, D. Christopher, A. Crumpton, K. Ennis, K. Hawkins, S. Lyapustina, H. Memmesheimer, A. Parkinson, M. A. Smith, B. Wyka. *PharmTech Europe* Vol 20 No 10 (October 2008). <http://www.ptemag.com/pharmtecheurope/Validation/Quality-by-Design-for-analytical-methods-for-use-w/ArticleStandard/Article/detail/553258> and *PharmTech Asia Pacific* <http://www.ptasiapacific.com/ptasiapacific/Dosage+Forms/Quality-by-Design-for-analytical-methods-for-use-w/ArticleStandard/Article/detail/565545> Vol. 2, No 4 (December 2008)
- **Best Practices for Extractables and Leachables in Orally Inhaled and Nasal Drug Products: An Overview of the PQRI Recommendations.** D. L. Norwood, D. Paskiet, M. Ruberto, T. Feinberg, A. Schroeder, G. Poochikian, Q. Wang, T. J. Deng, F. DeGrazio, M. K. Munos, L. M. Nagao. *Pharmaceutical Research*, 25(4), 727-739 (2008).
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- **Development of Safety Qualification Thresholds and Their Use in Orally Inhaled and Nasal Drug Product Evaluation.** D. Ball, J. Blanchard, D. Jacobson-Kram, R. O. McClellan, T. McGovern, D. L. Norwood, W. M. Vogel, R. Wolff, and L. Nagao. *Toxicological Sciences*. Vol 97, No 2, pp. 226–236 (2007).
- **Best Practices for Managing Quality and Safety of Foreign Particles in Orally Inhaled and Nasal Drug Products, and an Evaluation of Clinical Relevance** James Blanchard, James Coleman, Courtney Crim, Claire D'Abreu-Hayling, Lou Fries, Raouf Ghaderi, Barbara Haeberlin, Richard Malcolmson, Stanley Mittelman, Lee Nagao, Ilie Saracovan, Liuda Shtohryn, Caesar Snodgrass-Pilla, Mikael Sundahl and Ronald Wolff
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- **GMP Guideline for Suppliers of OINDP Device Components**
<https://www.signmeup.com/site/reg/register.aspx?fid=N82VGK7> (2006)
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