

## IPAC-RS PUBLICATIONS

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Links to IPAC-RS articles published in Inhalation and archived there:

- [An introduction to the International Pharmaceutical Aerosol Consortium on Regulation and Science \(IPAC-RS\), October 2011](#)
- [An IPAC-RS update: A practitioner's perspective on human factors, October 2012](#)
- [An IPAC-RS update: Delivery Systems, L&E and GRRO, August 2013](#)
- [Inhaler adherence is everyone's responsibility: Conclusions of the IPAC-RS Patient Concordance Initiative, December 2013](#)
- [An IPAC-RS update: Events and GRRO, Cascade Impaction and Device working groups, December 2014](#)
- [IPAC-RS: 15 years of research, advocacy and consensus building, February 2016](#)
- [Abbreviated impactor measurement \(AIM\) and efficient data analysis \(EDA\) concepts: Current questions and future considerations, February 2016](#)
- [An update on the activities of IPAC-RS, December 2017](#)

2020

**Addressing the Need for Controls on Particle Bounce and Re-entrainment in the Cascade Impactor and for the Mitigation of Electrostatic Charge for Aerodynamic Particle Size Assessment of Orally Inhaled Products: An Assessment by the International Consortium on Regulation and Science (IPAC-RS)** William Doub, Stephen Stein, Jolyon Mitchell, Adrian Goodey. *AAPS PharmSciTech* 21, Article number: 239 (August 2020) <https://link.springer.com/article/10.1208/s12249-020-01720-1>

**Evaluation of the Sensitivity and Robustness of Modified Chi-Square Ratio Statistic for Cascade Impactor Equivalence Testing Through Monte Carlo Simulations.** Abhinav Kurumaddali, David Christopher, Helen Strickland, Beth Morgan, Christopher Wiggenhorn, Stephen Stein, Svetlana Lyapustina & Günther Hochhaus. *AAPS PharmSciTech*; vol. 21, Article number: 147 (May 2020) <https://link.springer.com/article/10.1208/s12249-020-01664-6>

**Posters at the Joint Virtual IPAC-RS RDD 2020 Symposium** (April 2020) <https://www.ipacrs.org/ipac-rs-symposium>

**The Liability of Fine Particle Dose (FPD). Can we rely on the fine particle dose metric alone for quality control?** Adrian P. Goodey, Jolyon P. Mitchell, William H. Doub & J. David Christopher. *Inhalation* magazine, <https://www.e-digitaleditions.com/i/1229406-inh0420/19> (April 2020).

**Reflections on Digital Health Tools for Respiratory Applications.** Andy Dundon, David Cipolla, Jolyon Mitchell, and Svetlana Lyapustina. *Journal of Aerosol Medicine and Pulmonary Drug Delivery* Published Online: 16 Mar 2020 <https://doi.org/10.1089/jamp.2020.1597>

**2019**

**Performance of the Population Bioequivalence (PBE) Statistical Test with Impactor Sized Mass Data** *AAPS PharmSciTech* (2019) 20:296. DOI: 10.1208/s12249-019-1507-8

Stephanie Chen, Beth Morgan, Hayden Beresford, Elise Burmeister Getz, David Christopher, Göran Långström, Helen Strickland, Christopher Wiggenhorn, and Svetlana Lyapustina. <https://rdcu.be/bPqke> or <https://link.springer.com/content/pdf/10.1208%2Fs12249-019-1507-8.pdf>

**Overview of Brazilian Requirements for Therapeutic Equivalence of Orally Inhaled and Nasal Drug Products.** Marcia Silva, Helena Costa, Bruna Nardy, Lee Nagao, Gustavo Mendes Lima Santos. *AAPS PharmSciTech* August 2019, 20:235 <https://link.springer.com/article/10.1208/s12249-019-1415-y>

**Determination of Passive Dry Powder Inhaler Aerodynamic Particle Size Distribution by Multi-Stage Cascade Impactor: International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) Recommendations to Support Both Product Quality Control and Clinical Programs.** Jolyon P. Mitchell, Stephen W. Stein, William Doub, Adrian P. Goodey, J. David Christopher, Rajni B. Patel, Terrence P. Tougas, Svetlana Lyapustina. *AAPS PharmSciTech*. July 2019, 20:206 10.1208/s12249-019-1416-x <https://doi.org/10.1208/s12249-019-1416-x>

**Cascade Impactor Equivalence Testing: Comparison of the Performance of the modified Chi-Square Ratio Statistic (mCSRS) with the original CSRS and EMA's Average Bioequivalence Approach.** Abhinav Kurumaddali, David Christopher, Dennis Sandell, Helen Strickland, Beth Morgan, Juergen Bulitta, Christopher Wiggenhorn, Stephen Stein, Svetlana Lyapustina, Günther Hochhaus. doi:10.1208/s12249-019-1443-7 *AAPS PharmSciTech*; 2019;20:249; 1–17. <https://link.springer.com/article/10.1208%2Fs12249-019-1443-7>

**Comments on FDA Combination Product Guidance** submitted to FDA (2019), available at <https://www.regulations.gov/document?D=FDA-2019-D-0078-0006>.

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**Plume Geometry Testing Relevance and Methodology: An IPAC-RS Survey.** Frank Chambers, Samiran De, Sherryl Baxter, Adrian Parkinson, Bill Doub, Iain Breakwell, Manfred Fischer, and Lee M. Nagao. *RDD 2018*, Volume 2, 2018: 437-442. <https://www.rddonline.com/rdd/article.php?id=0&sid=103&ArticleID=2395&return=1>

**The application of Abbreviated Impactor Measurement and Efficient Data Analysis in the lifecycle of an orally inhaled product: A roadmap.** Goodey AP, Tougas T, Christopher JD, Doub W, Lyapustina S, Mitchell JP. *Pharm. Forum* 2018; 44(4) available at: <http://www.usppf.com/pf/pub/index.html> . Access is free but requires one-time registration. Visited July 26, 2019

**IPAC-RS Comments on the FDA 2018 CMC Guidance** [https://ad5a4c28-0460-4e72-b7af-0f1ef44f9e41.filesusr.com/ugd/932589\\_d116300e8fcd4fe6a805d4da5a536644.pdf](https://ad5a4c28-0460-4e72-b7af-0f1ef44f9e41.filesusr.com/ugd/932589_d116300e8fcd4fe6a805d4da5a536644.pdf) and on the FDA Docket at <https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=FDA-2018-D-1098>

**European Regulatory Developments for Orally Inhaled and Nasal Drug Products.** Santos, C., Marco, G., Nagao, L.M. et al. *AAPS PharmSciTech* October 2018, Volume 19, Issue 7, pp 3134–3140 (2018). <https://doi.org/10.1208/s12249-018-1154-5>

**CI Testing of Passive DPIs: Best Practices and Relevance to Patient Use – An IPAC-RS Viewpoint.** Stephen W. Stein, Jolyon P. Mitchell, William H. Doub, J. David Christopher, Adrian P. Goodey, Rajni B. Patel, Terrence P. Tougas, Svetlana Lyapustina *RDD 2018, Volume 1, 2018: 277-290*.

**Performance of the Population Bioequivalence (PBE) Statistical Test Using an IPAC-RS Database of Delivered Dose from Metered Dose Inhalers.** Beth Morgan, Stephanie Chen, David Christopher, Göran Långström, Christopher Wiggenhorn, Elise Burmeister Getz, Hayden Beresford, Thomas Hoffelder, Daniela Acerbi, Steven Andrews, Mark Berry, Monisha Dey, Joshi Keyur, Mary McKenry, Marisa Pertile, Helen Strickland, David Wilcox, Svetlana Lyapustina *AAPS PharmSciTech*. 2018 Apr;19(3):1410-1425. doi: 10.1208/s12249-017-0941-8. Epub 2018 Feb 12. <https://www.ncbi.nlm.nih.gov/pubmed/29435904>.

## 2017

**An Update on the activities of IPAC-RS.** Andy Rignall, Lee Nagao and Svetlana Lyapustina. *Inhalation Magazine*. November 2017. [https://www.inhalationmag.com/wp-content/uploads/CrossIndustryOrg/crossind\\_ipac-rs\\_2017\\_update.pdf](https://www.inhalationmag.com/wp-content/uploads/CrossIndustryOrg/crossind_ipac-rs_2017_update.pdf)

**Highlights from the 2017 IPAC-RS/ISAM Joint Workshop “New Frontiers in Inhalation Technology”** Smyth Hugh D., Colthorpe Paul, George Maureen, Jansen Paul, Fuglsang Anders, Armstrong Katherine E., and Lyapustina Svetlana. *Journal of Aerosol Medicine and Pulmonary Drug Delivery*. November 2017, ahead of print. <https://doi.org/10.1089/jamp.2017.1425>

**Discriminating Ability of Abbreviated Impactor Measurement Approach (AIM) to Detect Changes in Mass Median Aerodynamic Diameter (MMAD) of an albuterol/salbutamol pMDI aerosol.** J. David Christopher, Rajni B. Patel, Jolyon P. Mitchell, Terrence P. Tougas, Adrian P. Goodey, Jorge Quiroz, Patrik U. Andersson, Svetlana Lyapustina. *AAPS PharmSciTech*, 2017. doi:10.1208/s12249-017-0814-1. Available for onscreen reading at <http://rdcu.be/thJT> OnlineFirst at <http://link.springer.com/article/10.1208/s12249-017-0814-1>

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**The Application of Abbreviated Impactor Measurement and Efficient Data Analysis in the Lifecycle of an Orally Inhaled Product: A Roadmap.** Jolyon P Mitchell, Adrian P Goodey, Terrence Tougas, J David Christopher, Gareth Hardwell, Isabel Lopes, Svetlana Lyapustina. *USP 42 (6); 2016*.

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**The Abbreviated Impactor Measurement Concept as a Stand-Alone Alternative to the Full Resolution Cascade Impactor from the Perspective of their Calibration Traceability Chains.** Mitchell JP, Goodey A, Christopher J, Tougas TP, Lyapustina S. *Respiratory Drug Delivery* 2016. Volume 2, 2016: 389-394.

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Guenther Hochhaus, Craig Davis-Cutting, Martin Oliver, Sau L. Lee, Svetlana Lyapustina, *AAPS Journal*, June 2015, <http://link.springer.com/article/10.1208/s12248-015-9791-z>; in a themed issue at [http://link.springer.com/journal/12248/topicalCollection/AC\\_c5968a46132aea5799f5696f25ad4840](http://link.springer.com/journal/12248/topicalCollection/AC_c5968a46132aea5799f5696f25ad4840)

**Linking the Abbreviated Impactor Measurement (AIM) and Effective Data Analysis (EDA) of Aerodynamic Particle Size Data from Orally Inhaled Products (OIP) with the Product Lifecycle: Outcomes from Recently Designed Validation Experiments Leading to Practical Suggestions.** Jolyon P. Mitchell, Terrence Tougas, Rajni Patel, J. David Christopher, Steven C. Nichols, and Jorge Quiroz. *RDD Europe 2015*, pp. 345-350

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**2013**

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Mitchell JP, Tougas TP, Christopher J, Lyapustina S, Bauer R, Glaab V

*RDD Europe 2013. Volume 2, 2013: 363-368.***Inhaler Adherence is Everyone's Responsibility.** I. Peterson and B. Yawn. December 2013. *Inhalation*.[http://www.inhalationmag.com/dynamic/CrossIndustryOrg/crossind\\_ipac-rs\\_conclusions.pdf](http://www.inhalationmag.com/dynamic/CrossIndustryOrg/crossind_ipac-rs_conclusions.pdf)**An IPAC-RS Update: Delivery Systems, L&E and GRRO.** Ilse Peterson, Svetlana Lyapustina, LeeNagao. *Inhalation*, August 2013. <http://www.inhalationmag.com/Content/viewRequest.aspx?ID=b9b4ac3e-b5d3-498e-8b01-3fde97115f05&fi=1>**Good Cascade Impactor Practices, AIM and EDA for Orally Inhaled Products.** Terrence P Tougas,

Jolyon P Mitchell, Svetlana Lyapustina, Editors. Springer, New York. 2013. ISBN-13: 978-1461462958.

ISBN-10: 1461462959 <https://link.springer.com/book/10.1007%2F978-1-4614-6296-5> and[http://www.amazon.com/Cascade-Impactor-Practices-Inhaled-Products/dp/1461462959/ref=sr\\_1\\_1?s=books&ie=UTF8&qid=1361630438&sr=1-1](http://www.amazon.com/Cascade-Impactor-Practices-Inhaled-Products/dp/1461462959/ref=sr_1_1?s=books&ie=UTF8&qid=1361630438&sr=1-1)**2012****Efficient Data Analysis Case Study 1: Pressurized Metered Dose Inhalers Containing a Solution**

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*Respiratory Drug Delivery 2012. Volume 2, 2012: 441-446.***Efficient Data Analysis Case Study 2: Dry Powder Inhaler Formulation.** Joshi K, Carlson D, Finney C,

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*Respiratory Drug Delivery 2012. Volume 2, 2012: 447-452.***The Abbreviated Impactor Measurement and Efficient Data Analysis Concepts: Why Use Them and****When.** Mitchell JP, Tougas TP, Christopher J, Lyapustina S, Glaab V*Respiratory Drug Delivery 2012. Volume 3, 2012: 731-736.***The Abbreviated Impactor Measurement (AIM) and Efficient Data Analysis (EDA) concepts: Why****they are important and how to work with them.** Mitchell, Tougas, Lyapustina. *Inhalation*, December2012. <http://www.inhalationmag.com/Content/getArticle.aspx?ItemID=f3c68e42-dfb6-4387-a3eb-a04a32576aef>**If Dissolution Release Testing for Inhaled Products is Relevant, Then How? An IPAC RS Perspective**J.D. Christopher and M. Dey, *RDD 2012 Vol 1, pp 202-210*,<http://www.rddonline.com/publications/articles/article.php?ArticleID=1683&return=1>**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. *Inhalation Magazine*, October 2010.<http://www.inhalationmag.com/Content/getArticle.aspx?ItemID=ac60f86e-b9d8-478a-836d-1fbe38498e96>**On the Shelf Life of Pharmaceutical Products.** Robert Capen, David Christopher, Patrick Forenzo,

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**Challenges and Concerns with Development of an In Vitro Dissolution Test for Orally Inhaled Products (OIPs).** Trevor Riley; David Christopher; Jan Arp; Andrea Casazza; Agnes Colombani; Andrew Cooper; Monisha Dey, Janet Maas; Jolyon Mitchell; Maria Reiners; Nastaran Sigari; Terrence Tougas; Svetlana Lyapustina; *AAPS PharmSciTech: Volume 13, Issue 3 (2012), Pages 978-989.* DOI 10.1208/s12249-012-9822-3 <http://www.springerlink.com/openurl.asp?genre=article&id=doi:10.1208/s12249-012-9822-3>

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**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;12(4):1144-1156. DOI: 10.1208/s12249-011-9683-1 <http://www.springerlink.com/content/f0175288762377v1/> and <https://springerlink3.metapress.com/content/f0175288762377v1/resource-secured/?target=fulltext.pdf&sid=emqywwzdes32awdq51buisczp&sh=www.springerlink.com>

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**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  
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## 2010

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- The Federal Register notice for the 1998 Draft FDA Guidance for MDIs/DPIs: <https://www.gpo.gov/fdsys/pkg/FR-1998-11-19/pdf/98-30938.pdf>. That guidance can be found at:
  - <https://wayback.archive-it.org/7993/20170403220934/https://www.fda.gov/ucm/groups/fdagov-public/documents/document/ucm070573.pdf>
  - [https://wayback.archive-it.org/7993/20170405182634/https://www.fda.gov/ohrms/dockets/ac/00/backgrd/3634b1c\\_sectiond.pdf](https://wayback.archive-it.org/7993/20170405182634/https://www.fda.gov/ohrms/dockets/ac/00/backgrd/3634b1c_sectiond.pdf)

- <https://wayback.archive-it.org/7993/20170404224939/https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070573.pdf>
- <https://wayback.archive-it.org/7993/20170405182102/https://www.fda.gov/ohrms/dockets/ac/00/backgrd/3609b1j.pdf>
- The 2018 revised draft FDA Guidance for MDIs/DPIs is posted at <https://www.regulations.gov/docket?D=FDA-2018-D-1098>

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