IPAC-RS PUBLICATIONS

2000-2025

2026

Current Needs for Support for Nasally Inhaled Products (NPs) in the United States Pharmacopeia (USP): Recommendation from the Nasal Working Group of the International Pharamceutical Consortium on Regulation & Science (IPAC-RS). Jolyon P Mitchell, Wendy Bolf, William H Doub, Jamie Clayton, Goncalo Farias, Svetlana Ginsburg, Sana Hosseini, , Marcello Nuttini, Jasmine Perriolat, Alyssa Rubino, Lucas Silva, Neha Singh, Maria Smith, Stephen Stein, Xiangyin Wei, Enrico Zambelli. *Pharm.Forum*, accepted.

2025

Inhalable and Nasal Biologics: Analytical, Formulation, Development, and Regulatory Considerations. David Cipolla, Christopher Gruenloh, Nani Kadrichu, Philip Kuehl Lei Mao, Bing Li, Svetlana Lyapustina, Heidi Mansour, Franz-Josef Rehmann, Irene Rossi, Gur Jai Pal Singh, Julie Suman, Nurcin Ugur. *Journal of Aerosol Medicine and Pulmonary Drug Delivery* April 2025 https://www.liebertpub.com/doi/abs/10.1089/jamp.2024.0058

Reliability Expectations for Emergency-Use Nasal Products: IPAC-RS Considerations for Design and Development. Lynn M. Jordan, Adam Gibbons, Raphael D. Vincey, Medy Ballegoie, Sana Hosseini, MOD3 Pharma, Svetlana Lyapustina. Inhalation Magazine, 2025, in press

Excipients for Intranasal Pediatric Products. Lucas Silva and Svetlana Lyapustina. Inhalation Magazine, 2025, in press

Materials Compatibility Considerations for the Transition to Low Global Warming Potential Propellants for Pressurized Metered Dose Inhalers. Dohmeier, D., Sen, A., Cavecchi, A. et al. AAPS PharmSciTech 26, 65 (2025). https://doi.org/10.1208/s12249-025-03060-4; https://link.springer.com/article/10.1208/s12249-025-03060-4

2024

IPAC-RS Scenarios – Transition to LGWP Propellants in MDSs: Proposed Pathway to US FDA Approval (Nov 2024, IPAC-RS website)

UPDATED: Recommended Baseline Requirements for Materials Used in Orally Inhaled and Nasal Drug Products (OINDP) (Nov 2024, IPAC-RS website) https://www.ipacrs.org/_files/ugd/4267f8_f8211288cc6f4b86b631d0163bd800e3.pdf

Point of view: A better way to set specifications and control quality—general concepts and examples. An opinion article by representatives of the IPAC-RS Product Quality Demonstration Strategy (PQDS) Working Group. Helen Strickland; J. David Christopher; Beth Morgan; Greg Larner, and Svetlana Lyapustina. *Inhalation Magazine. October 2024*. https://www.e-digitaleditions.com/i/1527415-inh1024/0?

Regulatory Topics in Nasal Product Development: Pediatrics and Reliability Expectations. Gibbons A, Gold L, Hosseini S, Jordan L, Lyapustina S, Mccarry P, Perriolat JN, Silva L, Vincey RD, Wilcox D. Respiratory Drug Delivery 2024: 283-290.

IPAC-RS Summary of Global Regulatory Developments 2023 (March 2024)

IPAC-RS: An Update and Review of 2023. Mike Needham, Jen Wiley, Mary Kate Bielinski. *Inhalation* Magazine, February 2024. inh_20240201_0006.pdf (SECURED) (inhalationmag.com)

IPAC-RS Posters at DDL 2024

- **USP <601> and <1604> Give Different APSD Results**
- **Reliability Expectations for Emergency-Use Nasal Products: IPAC-RS Nasal Subteam Considerations ; AND https://ddl-conference.com/wp-content/uploads/2024/12/107.Gibbons.pdf**

  Adam Gibbons, Sana Hosseini, Lynn Jordan, Svetlana Lyapustina, Ralphael Vincey, David Wilcox. Reliability Expectations for Emergency-Use Nasal Products: IPAC-RS Nasal Subteam Considerations. DDL 2024. https://ddl-conference.com/wp-content/uploads/2024/12/107.Gibbons.pdf, Accessed April 12, 2025

IPAC-RS Posters at RDD 2024

- **Laser Diffraction Size Analysis of Products for Nasal Inhalation: A Survey of Expert Users**
  Doub WH, Mitchell JP, Hosseini S, Farias G, Carter I. Laser Diffraction Size Analysis of Products for Nasal Inhalation: A Survey of Expert Users.

- **Regulatory Topics in Nasal Product Development: Pediatrics and Reliability Expectations**
  Gibbons A, Gold L, Hosseini S, Jordan L, Lyapustina S, Mccarry P, Perriolat JN, Silva L, Vincey RD, Wilcox D. Regulatory Topics in Nasal Product Development: Pediatrics and Reliability Expectations. Respiratory Drug Delivery 2024: 283-290

2023

Year in Review 2023

Biocompatibility Considerations for Orally Inhaled and Nasal Drug Products and other Drug Device Combination Products *PDA Journal of Pharmaceutical Science and Technology* (November 2023)

Limitations of metrics used in the regulation of aerodynamic particle size distributions (APSDs) of orally inhaled products (OIPs) - An interview with Adrian Goodey of the IPAC-RS Cascade Impaction Working Group on reactions in the inhaler community to a series of published articles *Inhalation Magazine* (October 2023)

Laboratory Performance Testing of Aqueous Nasal Inhalation Products for Droplet/Particle Size Distribution: an Assessment from the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) | *AAPS PharmSciTech* (October 2023)
https://link.springer.com/article/10.1208/s12249-023-02665-x
William H. Doub, Julie M. Suman, Mark Copley, Adrian P. Goodey, Sana Hosseini & Jolyon P. Mitchell

IPAC-RS Summary of Global Regulatory Developments 2022 (August 2023)

Good Practices for the Laboratory Performance Testing of Aqueous Oral Inhaled Products (OIPs): An Assessment from the International Consortium on Regulation and Science (IPAC-RS). Mitchell JP, Carter I, Christopher JD, Copley M, Doub WH, Goodey A, Gruenloh CJ, Larson BB, Lyapustina S, Patel RB, Stein SW, Lostritto R, Suman JD. *AAPS PharmSciTech, (March 2023)*
https://link.springer.com/article/10.1208/s12249-023-02528-5

An Overview and Discussion of N-nitrosamine Considerations for Orally Inhaled Drug Products and Relevance to Other Dosage Forms. Lee Nagao, Hera Shams Khan, Fabienne Despres-Gnis, Cheryl L. M. Stults, James Mullis, Niran Nugara, Atish Sen. *AAPS PharmSciTech (January 2023)* https://link.springer.com/article/10.1208/s12249-022-02491-7

2022

IPAC-RS Year in Review 2022

Spray Pattern and Plume Geometry Testing and Methodology: An IPAC-RS Working Group Overview. S. Baxter, B. Myatt, S. Stein, A. Parkinson, F. Chambers, B. Doub, et al. *AAPS PharmSciTech* 2022 Vol. 23 #145. DOI: 10.1208/s12249-022-02278-w https://link.springer.com/article/10.1208/s12249-022-02278-w#citeas *s*

Moving Forward from "Fine Particle Fraction: The Good and the Bad". Jolyon P. Mitchell, William Doub, J David Christopher, Christopher J. Gruenloh , Rajni B Patel, Mark Copley, Steven Tignor, Stephen W. Stein, Svetlana Lyapustina, and Steven P. Newman. *Journal of Aerosol Medicine and Pulmonary Drug Delivery. 2022 vol 35. DOI: 10.1089/jamp.2022.0017* Moving Forward from "Fine Particle Fraction: The Good and the Bad" | Journal of Aerosol Medicine and Pulmonary Drug Delivery (liebertpub.com)

IPAC-RS Summary of Global Regulatory Developments 2021 (April 2022)

RDD-2022 -- Perspectives on the Evolving Regulatory Landscape for Inhaled and Nasal Products. S Prasad Peri, Ann Purrington, Svetlana Lyapustina, John Evans. *RDD 2022*

2021

IPAC-RS Year in Review 2021

Performance of Multiple-Batch Approaches to Pharmacokinetic Bioequivalence Testing for Orally Inhaled Drug Products with Batch-to-Batch Variability. Elise Burmeister Getz, Kevin J. Carroll, J. David Christopher, Beth Morgan, Scott Haughie, Alessandro Cavecchi, Christopher Wiggenhorn, Hayden Beresford, Helen Strickland & Svetlana Lyapustina. *AAPS PharmSciTech volume 22*, Article number: 225 (2021). https://doi.org/10.1208/s12249-021-02063-1

Efficient data analysis (EDA): Size, mass and common sense. William H. Doub, Adrian P. Goodey, Jolyon P. Mitchell, J. David Christopher and Ian Carter. *Inhalation Magazine*. August 2021 https://www.inhalationmag.com/

IPAC-RS Summary of Global Regulatory Development 2020 (May 2021)

2020

IPAC-RS Year in Review 2020

Cascade Impactor Stage Groupings: Poor Decisions from Degraded Data. A. Goodey, JP Mitchell, W Doub, JD Christopher**.** Inhalation, August 2020 https://www.e-digitaleditions.com/i/1276475-inh0820/11?

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

- Patient-Centric Considerations for PTIT: Addressing Unintended Consequences in the Draft 2018 Guidance by IPAC-RS Product Quality Demonstration Strategy Working Group, poster, 2020
- Designs for a Robust Outcome in Pharmacokinetic Bioequivalence Testing of Orally-Inhaled Drug Products with Batch-to-Batch Variability by IPAC-RS PK Batch-to-Batch Variability Working Group, poster, 2020
- Update from the Cascade Impactor Working Group by IPAC-RS Cascade Impactor Working Group, poster, 2020
- Sharing Information Across the Globe: IPAC-RS Global Regulatory Review and Outreach (GRRO) by GRRO Brazil, GRRO China, GRRO Europe and GRRO North America Working Groups, poster, 2020
- Common Use Error Matrix for pMDIs https://ad5a4c28-0460-4e72-b7af-0f1ef44f9e41.filesusr.com/ugd/932589_4c077e96166847719bafa71785fec2de.pdf, Poster and Excel spreadsheet by IPAC-RS Devices WG, 2020

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

IPAC-RS Year in Review 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.

An IPAC-RS Overview. *Inhalation*, Feb 2019**,** https://www.e-digitaleditions.com/i/1073928-inh0219/5 and https://www.e-digitaleditions.com/i/1073928-inh0219/0?

2018

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 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

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

Recommended Baseline Requirements for Materials used in Orally Inhaled and Nasal Drug Products (OINDP) *IPAC-RS, 2017.* https://ad5a4c28-0460-4e72-b7af-0f1ef44f9e41.filesusr.com/ugd/932589_4ddd4088c47d472c866194b64ddafa82.pdf

Human Factors Engineering (HFE): Patient-Centric Product Design. Summary of the Podium Talks and Panel Discussion in the HFE Session of the IPAC-RS Symposium. IPAC-RS. 2017. Available at http://ipacrs.org/assets/uploads/outputs/Human_Factors_Highlights_from_2016_IPAC-RS_RDD_Symposium.pdf

2016

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.*

A Free Online Tutorial About Cascade Impaction From IPAC-RS. Goodey A, Mitchell JP, Tougas TP, Christopher D, Lyapustina A. *Inhalation. October 2016.* http://www.inhalationmag.com/Content/viewRequest.aspx?ID=0876e946-d360-40e5-b5a3-d51af77508d4&fi=1

Patient Focus and Regulatory Considerations for Inhalation Device Design: Report from the 2015 IPAC-RS/ISAM Workshop Nicolas Roche, Gerhard Scheuch, John N Pritchard, Cornelia Nopitsch-Mai, Deepika A. Lakhani, Bhawana Saluja, Janine Jamieson, Andrew Dundon, Roisin Wallace, Susan Holmes, David Cipolla, Myrna B. Dolovich, Samir A. Shah, and Svetlana Lyapustina. *Journal of Aerosol Medicine and Pulmonary Drug Delivery. Vol. 30, No. 1, February 2017: 1-13. Online August 2016.* doi:10.1089/jamp.2016.1326. http://online.liebertpub.com/doi/abs/10.1089/jamp.2016.1326

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.*

A Comparison of the Performance of Efficient Data Analysis Versus Fine Particle Dose as Metrics for the Quality Control of Aerodynamic Particle Size Distributions of Orally Inhaled Pharmaceuticals. Tougas TP, Goodey AP, Hardwell G, Mitchell J, Lyapustina S. AAPS PharmSciTech. Online 11 April 2016. pp 1-11, http://link.springer.com/article/10.1208/s12249-016-0508-0

Risk Management for Materials and Components Used in Orally Inhaled and Nasal Drug Products. Cheryl L. M. Stults, Gaby Reckzuegel, Arthur Bailey, Jonathan Petersen, Lisa Dick, Thomas Feinberg, Andrew Feilden, Sara Miller, James Connors, Lee M. Nagao, *Pharmaceutical Research, January 2016.* http://link.springer.com/article/10.1007/s11095-015-1770-7

2015

Current Scientific and Regulatory Approaches for Development of Orally Inhaled and Nasal Drug Products: Overview of the IPAC-RS/University of Florida Orlando Inhalation Conference. 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

Regulatory Considerations for Approval of Generic Inhalation Drug Products in the US, EU, Brazil, China, and India. Sau L. Lee, Bhawana Saluja, Alfredo García-Arieta, Gustavo Mendes Lima Santos, Ying Li, Sarah Lu, Shuguang Hou, Juliet Rebello, Abhijit Vaidya, Jaideep Gogtay, Shrinivas Purandare, Svetlana Lyapustina. *The AAPS Journal volume 17, pages1285–1304 (2015)* https://link.springer.com/article/10.1208/s12248-015-9787-8

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* http://www.rddonline.com/publications/articles/article.php?ArticleID=2095&return=1

2014

Collaborative IPAC-RS Initiatives to Advance Device Development. Andy Dundon, Roisin Wallace, Fredrik Mannerstråle. *DDL-25. 2014* http://ddl-conference.com/files/DDL24Abstracts/37.Dundon/37.Dundon.pdf

Good Practices for Abbreviated Impaction Measurements (AIM) in dry powder inhalers (DPI). Geoff Daniels, Terrence Tougas, Jolyon Mitchell, Svetlana Lyapustina, August 2014, *Inhalation Magazine* http://www.inhalationmag.com/Content/viewRequest.aspx?ID=a251a48f-c358-4d95-9799-687d433cbe37&fi=1

Gaps in Statistical Approaches to Control of Delivered Dose Uniformity throughout Product Lifecycle. David Christopher, Emil Friedman, Michael Golden, Greg Larner, Svetlana Lyapustina, David Starbuck, Helen Strickland, February 2014, *Inhalation Magazine* http://www.inhalationmag.com/Content/getArticle.aspx?ItemID=6d229424-9186-4279-8361-7d3b5a7ec7dc

Device Design Development and Quality by Design. Dundon A, Swanbury P, Wilby M, de Kruif W. *Respiratory Drug Delivery 2014. Volume 1, 2014: 205-216.* http://www.rddonline.com/publications/articles/article.php?ArticleID=1903&return=1

2013

A Test is Not a Quality Standard: IPAC-RS Response to the Pharmacopeial Forum Stimulus Article "Methods for Measuring Uniformity in USP" Lyapustina S RDD Europe 2013. Volume 2, 2013: 309-312.

Challenges of Sizing Inhaler Aerosols: Bringing the Methods into the 21st Century
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

An IPAC-RS Update: Delivery Systems, L&E and GRRO. Ilse Peterson, Svetlana Lyapustina, Lee Nagao. 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

2012

Efficient Data Analysis Case Study 1: Pressurized Metered Dose Inhalers Containing a Solution Formulation. Mao L, Ponder D, Hughes A, White J, Joshi K, Glaab V, Mitchell JP, Lyapustina S
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, Fairbrother T, Mao L, Mitchell JP, Lyapustina S
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, December 2012*. 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, Charles Ireland, Oscar Liu, Svetlana Lyapustina, John O'Neill, Nate Patterson, Michelle Quinlan, Dennis Sandell, James Schwenke, Walter Stroup, and Terrence Tougas. *AAPS PharmSciTech September 2012, Volume 13, Issue 3, pp 911-918* DOI: 10.1208/s12249-012-9815-2
http://link.springer.com/article/10.1208%2Fs12249-012-9815-2

- ♦ Selected as the Editor's Choice 2012 Best *AAPS PharmSciTech* Manuscript

An IPAC-RS Update: A Practitioner's Perspective on Human Factors. S Eason, A. Dundon, J. Dixon, and I. Peterson. *Inhalation October 2012*. http://www.inhalationmag.com/dynamic/CrossIndustryOrg/crossind_ipac-rs_update.pdf

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

Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products. D. J. Ball, D. L. Norwood, C. L. M. Stults, L. M. Nagao, eds. Wiley, 2012. https://www.wiley.com/en-us/Leachables+and+Extractables+Handbook%3A+Safety+Evaluation%2C+Qualification%2C+and+Best+Practices+Applied+to+Inhalation+Drug+Products-p-9781118147689

Equivalence Considerations For Orally Inhaled Products For Local Action - ISAM/IPAC-RS European Workshop Report. Evans C, Cipolla D, Chesworth T, Agurell E, Ahrens R, García-Arieta A, Conner D, Dissanayake S, Dolovich M, Doub W, Fuglsang A, Golden M, Hermann R, Hochhaus G, Holmes S, Lafferty P, Lyapustina S, Nair P, O'Connor D, Parkins D, Peterson I, Reisner C, Sandell D, Singh GJP, Weda M, Watson P. *J. Aerosol Med Pulm Drug Delivery,2012.* DOI: 10.1089/jamp.2011.0968 Vol. 25, No. 3, June 2012: 117-139. http://online.liebertpub.com/doi/abs/10.1089/jamp.2011.0968
Abstract | Full Text HTML | Full Text PDF (429 KB) | Full Text PDF with Links (266 KB)

Significant restriction of the delivered dose uniformity criteria in the revised USP Chapter for Aerosols <601> J. Schumacher and S. Leiner. Inhalation magazine. April 2012. http://www.inhalationmag.com/dynamic/inh_usp_april2012.pdf Last accessed April 30, 2018

Critical evaluation of the revised and new USP chapters for aerosols: <601> and <5> [Pharm Forum 2011; 37(4)] J. Schumacher and S. Leiner. Inhalation magazine. February 2012. http://www.inhalationmag.com/dynamic/inh_usp_feb2012.pdf Accessed 5 Nov 2014

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. *Inhalation Magazine, February 2012.* http://www.inhalationmag.com/Content/getArticle.aspx?ItemID=0bdf18bb-350b-48d9-9aa8-102815667368

2011

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 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=emqywzdes32awdq51buisczp&sh=www.springerlink.com

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;12(3):965-988. 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* 2011:312-322. 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

2010

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*.

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

[1]**Demonstrating 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. Demonstrating Bioequivalence of Locally Acting Orally Inhaled Drug Products (OIPs): Workshop Summary Report - PubMed (nih.gov) http://www.liebertonline.com/doi/abs/10.1089/jamp.2009.0803 and http://www.pqri.org/pdfs/DTC/Articles/JAMP_article_final_draft.pdf

2009

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. *European Medical Device Technology*. Volume 20, Number 2, pp. 32-38. March/April 2009. http://www.emdt.co.uk/article/use-polymeric-materials-orally-inhaled-and-nasal-drug-products

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

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.

[1] A "Most Downloaded Article" of that journal in 2010. See http://www.liebertpub.com/mcontent/files/JAMPfastfacts91910.pdf

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

Improved Methods For Detecting Differences In Aerosol Particle Size Distributions Of Orally Inhaled Drug Products. T Tougas, D Christopher, S. Lyapustina, J Mitchell. *J Aerosol Med. Pulmonary Drug Delivery.* 22(2):169. 2009. DOI: 10.1089/jamp.2009.00A1. Freely available online at http://www.liebertonline.com/doi/pdfplus/10.1089/jamp.2009.00A1

[2]**A 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. Larner.

- **Part 1 –Characterization of FDA Proposed Test.** DOI: 10.1208/s12249-009-9270-x. *AAPS PharmSciTech* 2009 Vol 10. No 3, September 2009. pp. 820-828. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2802173/
- **Part 2 – Effect of Changing Parameters.** DOI: 10.1208/s12249-009-9269-3. *AAPS PharmSciTech* 2009 10(3)2009;841-849. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2802172/
- **Part 3 – Investigation of Robustness to Deviations from Normality.** DOI: 10.1208/s12249-009-9271-9. *AAPS PharmSciTech* 2009 Vol 10. No 3, September 2009. pp. 829-840. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2802133/

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.

Device Development And Design Control For Combination Products: Standards, Regulations and Current Practices for Orally Inhaled and Nasal Drug Products. Tim Chesworth, Paul Lafferty, Svetlana Lyapustina, Guillaume Brouet, David Christopher, John Hart. IPAC-RS 2009. <261188077>. Previous location: http://ipacrs.org/assets/uploads/outputs/Device_Paper_2009_Web.pdf

2008

Points to Consider for a P2 for an Orally Inhaled or Nasal Drug Product. J. Schumacher et al. 2008. https://ipacrs.org/assets/uploads/outputs/P2_Points_to_Consider.pdf

---

[2] 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

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).

Capabilities of Aerodynamic Particle Size Distribution (APSD) Measurements Based on Analysis of a Blinded Database. Terrence P. Tougas, David Christopher, Svetlana Lyapustina, Jolyon P. Mitchell, Rajni Patel. RDD-2008. Vol 1, pp.109-123. http://rddonline.org/pub/article.asp?ArticleID=1133

Minimizing Variability of Cascade Impaction Measurements in Inhalers and Nebulizers. M. Bonam, D. Christopher, D. Cipolla, B. Donovan, D. Goodwin, S. Holmes, S. Lyapustina, J. Mitchell, S. Nichols, G. Pettersson, C. Quale, N. Rao, D. Singh, T. Tougas, M. Van Oort, B. Walther, B. Wyka. *AAPS PharmSciTech*. http://www.springerlink.com/content/t22701k84w1665q4/ *DOI 10.1208/s12249-008-9045-9* (February 2008)

International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC) and European Pharmaceutical Aerosol Group (EPAG), \Justification of the request for a negative vote on ISO DIS 20072, `Aerosol drug delivery device design verification requirements and method'."
http://ipacrs.org/assets/uploads/comments/On_ISO_20072_Nov_07.pdf, 2008.

2007

A Perspective on the Challenges of Extractables, Leachables and Materials Supply for Orally Inhaled and Nasal Drug Products. J. Mullis, C. Stults, B. A. Falco, M. Munos, L. Nagao. *Pharmaceutical Review*. Nov-Dec 2007, pages 32-37 (2007).

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 http://www.springerlink.com/content/n07820358w6k5422/ *Pharmaceutical Research* (Vol 24, No 3, March, 2007).

An Introduction to IPAC-RS: What the industry group does for its member companies and for you. D. Cipolla and T. Tougas. *Inhalation 2007:1* . www.inhalationmag.com (2007)

Comparison of Two Approaches for Treating Cascade Impaction Mass Balance Measurements. B. Wyka, T. Tougas, J. Mitchell; H. Strickland, D. Christopher and S. Lyapustina *J. Aerosol Med.* Vol.20, No. 3, pp 236-256 (2007). http://www.liebertonline.com/doi/abs/10.1089/jam.2007.0609 Correction*: J. Aerosol Medicine and Pulmonary Drug Delivery.* March 1, 2008, 21(1): 155-156. http://www.liebertonline.com/doi/pdfplus/10.1089/jamp.2007.0679

Product Quality Research Institute Reports. DeLuca PP, Lyapustina S. *AAPS PharmSciTech. 2007; 8(1): Article 6.* AAPS PharmSciTech | Home (springer.com) . (2007)

Product Quality Research Institute Evaluation of Cascade Impactor Profiles of Pharmaceutical Aerosols

Part 1: Background for a Statistical Method. Adams WP, Christopher D, Lee DS, Morgan B, Pan Z, Singh GJP, Tsong Y, Lyapustina S. *AAPS Pharm Sci Tech.* 2007;8(1):E32-E37. DOI: 10.1208/pt0801004 Product Quality Research Institute evaluation of cascade impactor profiles of pharmaceutical aerosols, part 1: Background for a statistical method (nih.gov)

Part 2 - Evaluation of a Method for Determining Equivalence. Christopher D, Adams WP, Lee DS, Morgan B, Pan Z, Singh GJP, Tsong Y, Lyapustina S.. *AAPS PharmSciTech.* 2007;8(1):E39-E48 DOI: 10.1208/pt0801005 Product Quality Research Institute evaluation of cascade impactor profiles of pharmaceutical aerosols: Part 2—Evaluation of a method for determining equivalence (nih.gov)

Part 3 – Final Report on a Statistical Procedure for Determining Equivalence. Christopher D., Adams W., Amann A., Bertha C., Byron P.R., Doub W., Dunbar C., Hauck W., Lyapustina S., Mitchell J. P., Morgan B., Nichols S., Pan Z., Singh G.J.P., Tougas T., Tsong Y., Wolff R., and Wyka B. *AAPS PharmSciTech.; 2007;8(4):65-74 DOI: 10.1208/pt0804090.* Product quality research institute evaluation of cascade impactor profiles of pharmaceutical aerosols, part 3: Final report on a statistical procedure for determining equivalence (nih.gov)

In Vitro/In Vivo Comparisons In Pulmonary Drug Delivery. Newman, S.P. and Chan, H-K. *J. Aerosol Med. 2007;20(2):211.*

In Vitro and In Vivo Aspects of Cascade Impactor Tests and Inhaler Performance: A Review. Mitchell J, Newman S, Chan H-K. *AAPS PharmSciTech.* 2007; 8(4): Article 110. *DOI: 10.1208/pt0804110* AAPS PharmSciTech | Home (springer.com) (2007)

2006

GMP Guideline for Suppliers of OINDP Device Components. (2006) Subsequently incorporated into **PS 9000:2016,** which is downloadable from https://www.pqg.org/a/product/ps-90002016-downloadable/

Safety Thresholds And Best Practices For Extractables And Leachables In Orally Inhaled And Nasal Drug Products. Daniel Norwood, Timothy McGovern, Douglas Ball, Diane Paskiet, James Blanchard, David Porter, Lidiette Celado, Michael Ruberto, T.J. Deng, Alan Schroeder, Fran DeGrazio, Mark Vogel, Bill Doub, Qingxi Wang, Thomas Feinberg, Ronald Wolff, Alan Hendricker, Melinda Munos, Jeff Hrkach, Lee Nagao, Roger McClellan. *Submitted to FDA* http://pqri.org/pdfs/LE_Recommendations_to_FDA_09-29-06.pdf (2006)

Zero-Tolerance Criteria Do Not Assure Product Quality. Murphy JR, Griffiths KL. *Pharm.Tech*. 2006; 30(1): 52-60. http://www.pharmtech.com/pharmtech/content/printContentPopup.jsp?id=283486.

Addressing Regulatory Issues Through Pharmaceutical Consortia. S. Lyapustina, L. Nagao and M. D. Capizzi *Clinical Research and Regulatory Affairs.* 23 (1): 21-34 (2006).

2005

Aspects of Particle Science and Regulation in Pharmaceutical Inhalation Drug Products. L. M. Nagao, S. Lyapustina, M. K. Munos and M. D. Capizzi. *Crystal Growth and Design. 5 (6): 2261-2267 (2005).*

Microbial Testing for Orally Inhaled and Nasal Drug Products. L. Adjei, A. Amann, J. Blumenstein, P. Byron, R. Dabbah, R. Deschenes, J. Ferguson, E. Fitzgerald, K. Horspool, S. Indelicato, A. Janney, M. Korczynski, B. Layton, S. Lyapustina, R. Malcolmson, D. Mentel, J. Mottishaw, B. Olsson, G. Poochikian, D. Porter, J. Pfeiffer, E. Post, B. Riley, D. Rosario, B. Sawyer, D. Singer, T. Tougas, R. Tracy, P. Valan, and P. Wright, M. J. Brubaker, D. W. Buckmaster, H. Cummings, P. D. Curry, M. T. Riebe, C. G. Thiel and C. Vanneste. *USP Pharmacopeial Forum. 31 (4): 1258-1262 (2005).*

Inhalation Products Expert Groups: Helping to Fill the Gaps, Cover Story. S. Nichols and S. Lyapustina. *Pharmaceutical Technology Electronic Edition. April 2005.* http://electronic.pharmtech.com/041505/Contents.asp *(2005)*

Aerodynamic Particle Size Distribution Profile Comparisons – Considerations for Assessing Statistical Properties of Profile Comparisons Tests. D. Christopher, Z. Pan and S. Lyapustina. *Am. Pharm. Rev. 8 (1): 68-72 (2005).*

Application of Modern Analytical Technologies to the Identification of Extractables and Leachables. D. Norwood, L. Nagao, S. Lyapustina and M. Munos. *Am. Pharm. Rev. 8 (1): 78-87 (2005).*

2004

Foreign Particles Testing in Orally Inhaled and Nasal Drug Products. Blanchard, Coleman, Hayling, Ghaderi, Haeberlin, Hart, Jensen, Malcolmson, Mittelman, Nagao, Sekulic, Snodgrass-Pilla, Sundahl, Thompson, Wolff http://www.aapspharmaceutica.com/publications/toc.asp?vol=21&issue=12&journal=PHAM *Pharmaceutical Research* (Volume 21 Number 12 /December 2004).

Statistical Techniques Used in Simulation of Cascade Impactor Particle Size Distribution Profiles. Z. Pan, J. D. Christopher, S. Lyapustina and E. Chou. *Respiratory Drug Delivery IX,* (VCU/DHI, ISBN 1-930114-65-6) Vol. III, 669-672 (2004).

Debating The Parametric Operating Curves For DDU Tests On Marketed Inhalers. B. Olsson and S. Lyapustina. *Respiratory Drug Delivery IX,* (VCU/DHI, ISBN 1-930114-63-X) Vol. I, 135-141 (2004).

2003

Considerations for the Development and Practice of Cascade Impaction Testing Including a Mass Balance Failure Investigation Tree. D. Christopher, P. Curry, W. Doub, K. Furnkranz, M. Lavery, K. Lin, S. Lyapustina, J. Mitchell, B. Rogers, H. Strickland, T. Tougas, Y. Tsong, B. Wyka. *J. Aer Med* 16 (3): 235-247 (2003). http://www.liebertonline.com/doi/abs/10.1089/089426803769017604

Letter to the Editor. *J Aerosol Medicine*. Jolyon P. Mitchell. December 1, 2003, 16(4): 433-433. doi:10.1089/089426803772455686. http://www.liebertonline.com/doi/abs/10.1089/089426803772455686

2002

Recommendations to the Food and Drug Administration: Metered Dose Inhaler Tests and Methods in the Chemistry, Manufacturing, and Controls Draft Guidances for Meter Dose Inhalers and Dry Powder Inhalers. L. Adjei, V. Chavan, H. Cummings, B. Donovan, C Evans, R. Evans, K. Fitzgerald, B. Gore, K. Griffiths, J. Hart, F. Millar, R. Patel, B. Persson, N. Rajagopalan, F. Schmidt, J. Schuster, C. Sciarra, S. Sultzbaugh, T. West, and B. Wyka. *Drug Information Journal, Vol. 36 (3): 549-556 (2002).*

2001

A Parametric Tolerance Interval Test for Improved Control of Delivered Dose Uniformity of Orally Inhaled and Nasal Drug Products. *Submitted to FDA*. (2001) https://4267f8f9-b688-43d5-b139-33cb56ef9513.usrfiles.com/ugd/4267f8_1dbe8b3743c54efcabcf19f37df0ea75.pdf

Leachables and Extractables Testing: Points to Consider. *Submitted to FDA* (2001) [originally at https://www.fda.gov/ohrms/dockets/ac/00/reports/3657_rpt1.pdf] now at https://wayback.archive-it.org/7993/20170405182132/https://www.fda.gov/ohrms/dockets/ac/00/reports/3657_rpt1.pdf

Recommendations for Tests and Methods. *Submitted to FDA* https://ipacrs.org/assets/uploads/outputs/Recommendations_for.PDF (2001)

Developing Consensus-Based Guidances for Orally Inhaled and Nasal Drug Products: The Work of the ITFG/IPAC-RS Collaboration. G. Hansen, C. Evans and M.D. Capizzi, *American Pharmaceutical Review (Winter 2001 issue)*

JULY 2001 STATEMENT TO ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE AND OINDP SUBCOMMITTEE on the Work of the ITFG/IPAC-RS Collaboration Regarding Chemistry, Manufacturing, and Controls and In Vitro and In Vivo Bioavailability/Bioequivalence Issues in Draft Guidance Documents for Orally Inhaled and Nasal Drug Products. *Submitted to FDA* (2001) https://wayback.archive-it.org/7993/20170405173646/https://www.fda.gov/ohrms/dockets/ac/01/briefing/3764b1_03_ITFG.PDF

2000

Statement to the Advisory Committee *Submitted to FDA* (Nov 2000) https://wayback.archive-it.org/7993/20170405182124/https://www.fda.gov/ohrms/dockets/ac/00/slides/3657s1_09.pdf

Statement of the ITFG/IPAC Collaboration on Chemistry, Manufacturing, and Controls and In Vitro and In Vivo Bioavailability/Bioequivalence Issues in Draft Guidance Documents for Orally Inhaled and Nasal Drug Products. *Submitted to FDA* (April 2000) https://wayback.archive-it.org/7993/20170405182355/https://www.fda.gov/ohrms/dockets/ac/00/slides/3609s1y.pdf

Review of In Vivo and In Vitro Tests in FDA's Draft Guidance on Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action and Anticipated Forthcoming Guidance for Orally Inhaled Drugs (2000) *Submitted to FDA*. https://wayback.archive-it.org/7993/20170405182411/https://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609_rpt3.pdf

Initial Assessment of the ITFG/IPAC Dose Content Uniformity Database by the CMC Specifications Technical Team of the ITFG/IPAC Collaboration. *Submitted to FDA* (2000) [original location http://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609_rpt1.pdf] now at https://wayback.archive-it.org/7993/20170405182405/https://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609_rpt1.pdf

Initial Assessment of the ITFG/IPAC Aerodynamic Particle Size Distribution Database by the CMC Specifications Technical Team of the ITFG/IPAC Collaboration *Submitted to FDA* (2000) [original location: http://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609_rpt2.pdf] Current location: https://wayback.archive-it.org/7993/20170405182408/https://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609_rpt2.pdf (last visited on December 6, 2019)

- 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/7993/20170404224939/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

Note 1: Access to AAPS publications is free for AAPS members. In addition, for AAPS PharmSciTech articles published in 2000-2016, access is free at https://www.ncbi.nlm.nih.gov/pmc/journals/793/

Note 2: 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

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