

IPAC-RS PUBLICATIONS

2000-2025

2025

- February 3, 2025 "Materials Compatibility Considerations for the Transition to Low Global Warming Potential Propellants for Pressurized Metered Dose Inhalers" has been accepted for publication in AAPS PharmSciTech.

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)

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\(SECURED\)\(inhalationmag.com\)](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](#)**

IPAC-RS Posters at RDD 2024

- **[Laser Diffraction Size Analysis of Products for Nasal Inhalation: A Survey of Expert Users](#)**
- **[Regulatory Topics in Nasal Product Development: Pediatrics and Reliability Expectations](#)**

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>

[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>

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 Wiggenghorn, 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 PTTI: 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>

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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>

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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 Wigggenhorn, 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>.

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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

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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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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>

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

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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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