Product Quality Research Institute

Introduction to PQRI

January 2024

MISSION

Established in 1999, the Product Quality Research Institute (PQRI) is a non-profit consortium of organizations, including standard setting and regulatory agencies, working together to generate and share timely, relevant, and impactful information that advances global drug product quality, manufacturing, and regulation.

VISION

Through a unique global collaboration among academia, industry, and regulatory agencies, PQRI will continue to be a leading organization in creating best practices and conducting joint research in support of global pharmaceutical and biopharmaceutical regulation, leveraging its intellectual, scientific, and technical resources to advance drug development and regulation to benefit patients.

Who We Are – Our Members

PQRI
Product Quality Research Institute

FDA U.S. FOOD & DRUG ADMINISTRATION

Health Canada

PDA
Parenteral Drug Association

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

usp™

ELSIE
Extractables and Leachables Safety Information Exchange

INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL
IPEC
AMERICAS

What Does PQRI Do ?

- Unites thought leaders from regulatory agencies, standard setting bodies, industry, and academia to conduct research and share knowledge on emerging scientific and regulatory quality challenges
- Provides a unique, neutral forum to develop common understandings of current scientific, technical, and regulatory challenges among a diverse collection of industry organizations, FDA, and other regulatory bodies
- Creates opportunities to accomplish mutual goals that cannot be achieved by individual organizations.
- Impacts global regulatory guidances and standards, bringing maximum value to members and patients

What Makes PQRI Unique ?

- PQRI's inclusion of regulatory agencies and standard-setting bodies as members as well as its distinct organizational structure, allows for direct connection between regulators, academia, and industry and fosters cross-collaborative pathways between these various stakeholders
- PQRI provides resources to support research projects that serve as stimuli for and help shape global regulatory policies
- PQRI helps its member organizations meet their missions by identifying work of broad interest to those organizations' members
- PQRI provides a platform that encourages and facilitates inter-organizational collaboration

Benefits of PQRI Membership

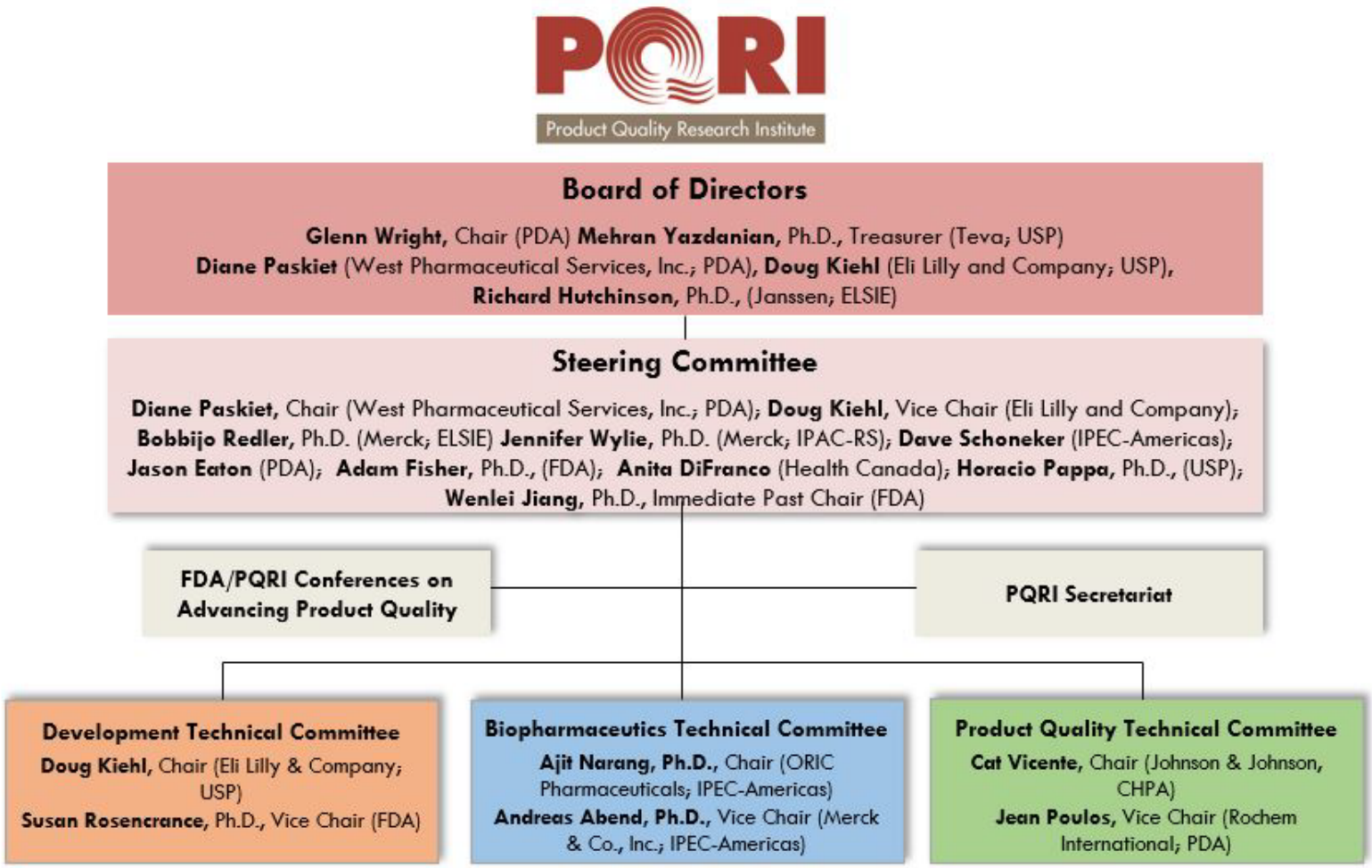
Benefits to member **organizations** include:

- Play a direct role in shaping PQRI's activities and setting its scientific and regulatory priorities.
- Cross-collaborate efficiently among PQRI members to broaden understanding of industry and regulatory concerns, needs and trends.
- Engage with other key stakeholders and impact global regulatory standards and guidance.
- Access to all PQRI technical committees and working groups.

Benefits to **individual members** of PQRI organizations include:

- Collaborate, share knowledge, and work directly with peers in the industry and with regulators. Expand your network.
- Opportunities to participate in leadership roles, present in public forums, and to publish in peer-reviewed scientific journals.
- Develop creative and collaborative approaches to addressing current and emerging challenges related to regulation, development, and quality of drug products.
- Help direct and drive PQRI's technical and scientific activities.

PQRI Organizational Chart 2024



Board and Steering Committee

The Board of Directors and Steering Committee are the dual governing bodies of PQRI.

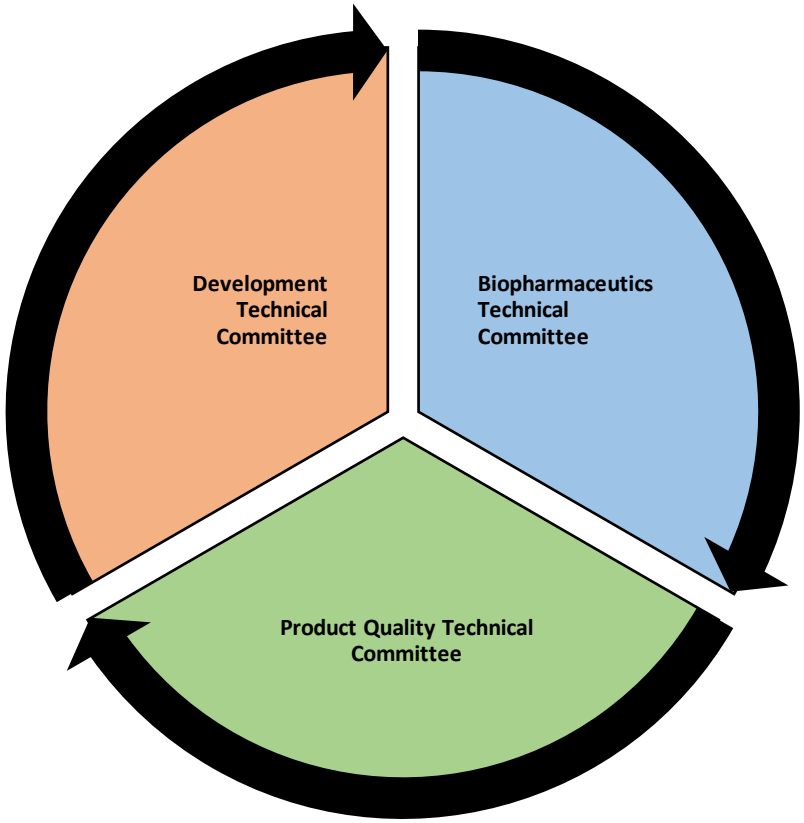
- The **Board of Directors** is vested with the administrative management, growth, and operation of the Institute, except for those activities involving scientific decision making, which are delegated to the PQRI Steering Committee. The Board has authority over the collection and disbursement of funds and the administrative procedures required to ensure the effective operation of the Institute.
  - Each non-governmental member organization is entitled to nominate members to be elected to the Board, which consists of five seats, including the Chair and Treasurer.

- The **Steering Committee** has sole authority over all scientific activities conducted under the auspices of the Institute and is responsible for recommending the disbursement of funds towards those activities, to the Board of Directors.
  - Each member organization is entitled to representation on the Steering Committee and one vote on requiring matters.

Technical Committees

Technical Committees provide scientific guidance, direction, and oversight to the PQRI Working Groups and recommendations to the Steering Committee. PQRI consists of three **Technical Committees**, each with a broad disciplinary focus that collectively spans the drug product regulatory lifecycle.

- The mission of the **Development Technical Committee (DTC)** is to promote scientific studies to engender science-based regulatory policy relating to the development of drugs and drug products, working with industry, academia, pharmacopeias and regulatory agencies.
- The mission of the **Product Quality Technical Committee (PQTC)** is to leverage our regulatory, quality, and manufacturing expertise to define science-based approaches (appropriately integrating an assessment of risk) that encourage innovation and continuous quality improvement in pharmaceutical manufacturing and flexibility in the associated regulatory processes.
- The mission of the **Biopharmaceutics Technical Committee (BTC)** is to identify, disseminate, and facilitate scientific and technical projects to address gaps in biopharmaceutical aspects of drug development and global regulatory guidance. The BTC will translate current and emerging ideas in the pharmaceutical field into proposals for implementing unbiased research projects and delivering results that impact regulatory policies.



Current PQRI Work Groups

Biopharmaceutics Technical Committee (BTC)	Development Technical Committee (DTC)	Product Quality Technical Committee (PQTC)
Biopharmaceutics Classification System for Inhaled Medicines (iBCS) (in progress) • Publications #1 and #2 just published	**Extractables & Leachables in Parenteral Drug Products** - To justify the use of safety thresholds for identification and risk assessment of PODP leachables, the WG conducted and evaluated the results of extraction studies on polymeric materials and evaluated a database of over 600 potential leachables. Based on their findings, the WG developed a set of best practices for parenteral drug products. See publication. • Companion document: Principles for Management of E&L in Ophthalmic Drug Products. • Developing a PDP Training Course	**Elemental Impurities** - Conducted research to investigate variability of ICP-MS analysis of elemental impurities and address key technical challenges in complying with ICH Q3D. (Phase 2 Study completed, papers in progress.) Held four workshops to share industry experiences related to implementation of ICH Q3D. (See website.)
Standardization of an in vivo predictive dissolution methodologies and in silico bioequivalence study (in progress)		
Topical Drugs Classification System (TCS) [joint effort with PQTC] (papers in progress)	**Polymeric Excipient Risk Assessment -** Development of a risk assessment strategy to provide scientific justification for reduced safety testing of new higher molecular weight polymeric excipients for non-parenteral administration.	**Topical Drugs Classification System** (TCS) [joint effort with BTC] (papers in progress)
Evaluate Use of In-silico Crystal Structure Prediction (CSP) in Drug Development and Harmonize on Data Interpretation (Proposal under consideration)		**Workshop on Excipient and API Impact on Continuous Manufacturing** (May 17 – 18) (See website)
Quarterly Webinar Series (see slide in background section) See website for details • May 24th: Approaches to Establishing Bioequivalence Safe Space for Orally Administered Drug Products: Applications and Case Studies	**Guidance for Interconnectivity between Vial Container Closure Systems and Vial Transfer Devices** (survey conducted and paper published) https://journal.pda.org/content/76/2/163	**Artificial Intelligence (AI) Application in Continuous Process Verification (CPV)** (in progress; experiments conducted at UMBC and University of Barcelona) (papers in progress)
	Materials Qualification and Control for Drug (or Biologic)/Device Combination Products (WG being formed)	**Restricted Delivery Systems in Children's OTC Liquid Medications** (in progress)
Hot Topic Discussions: Invite SMEs to BTC calls for Roundtable with interested PQRI members (open to other TCs) • June 24: Challenges in the development of formulations for pediatric patients.	**Webinar on Extractables & Leachables testing for Transdermal Delivery Systems**. (to be held in 2022)	**Use of Recycled Plastics in Pharmaceutical Manufacturing** (Proposal under consideration)

Cross TC Collaboration Focus Groups: Patient Centric Specifications and Drug/Device Combination Products

Looking Forward: Strategic Goals

PQRI Strategic Goals

Promote science-based regulation by developing and delivering a portfolio of projects and public platforms of high value to industry and regulators

- Publish PQRI work in leading peer-reviewed journals.
- Raise awareness of PQRI work by presenting at key conferences and through partnerships with member organizations.
- Hold conferences, workshops, symposia, and webinars to bring together regulators, industry, and academia to address current and emerging regulatory and scientific issues.
- Provide research funds to high priority topics as determined by the membership.
- Establish new projects, based on member input, on high priority regulatory and scientific topics within each discipline-specific Technical Committee – Development, Biopharmaceutics, and Product Quality.
- Create new projects from PQRI conferences, workshops, symposia, and webinar output.

Expand membership and outreach internationally to industry and regulatory agencies, to enhance and further diversify expertise and information sharing

- Add at least one new member organization each year,
- Hold periodic information-sharing summits with potential members to identify areas of mutual interest.
- Proactively highlight PQRI's mission, benefits, and goals to prospective members through brochures, webinars, and presentations.

Enhance member organization benefits through PQRI activities and work product

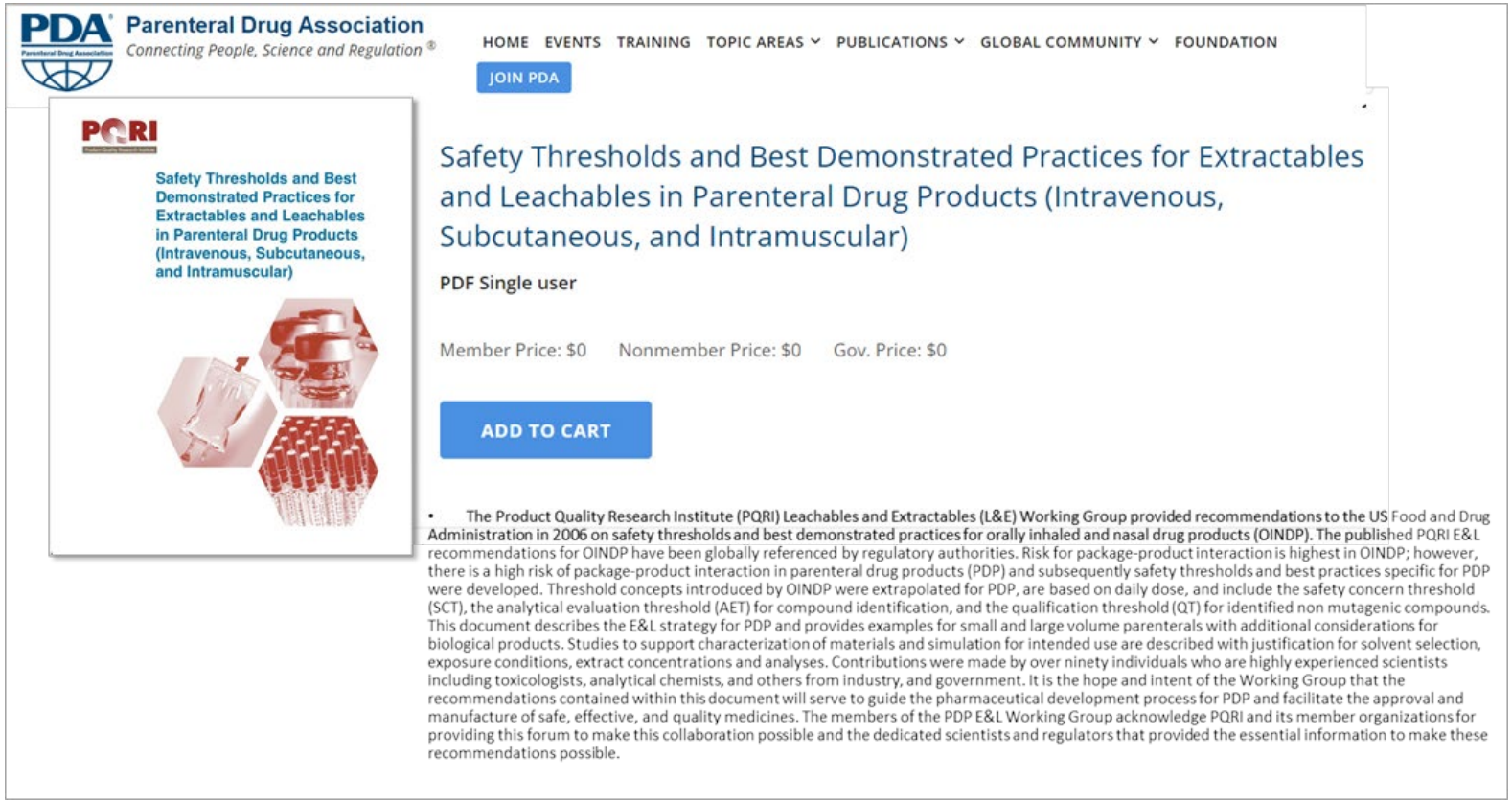
- Provide members with clear benefits to participation and engagement.
- Provide tools to raise awareness of PQRI within member organizations, including the benefits of participation and PQRI work and output.
- Partner with member organizations to highlight PQRI output in member journals, public meeting platforms, and other pathways that will bring benefit to member organizations.
- Build Technical Committee membership and ensure that all Technical Committees have at least one representative from each member organization.
- Support and empower Working Groups by providing a clear understanding of PQRI resources, roles, responsibilities, and expectations.
- Establish an award program to recognize exemplary contributions.

[PQRI 2023-2027 Strategic Plan]

Selected PQRI Publications

Safety Thresholds and Best Practices for E&L in Parenteral DP

– **LinkedIn post:**
https://www.linkedin.com/feed/update/urn:li:activity:6904421989902352384



Selected PQRI Publications

Molecular Pharmaceutics

https://pubs.acs.org/doi/full/10.1021/acs.molpharmaceut.2c00113

https://pubs.acs.org/doi/10.1021/acs.molpharmaceut.2c00112

iBCS: 1. Principles and Framework of an Inhalation-Based Biopharmaceutics Classification System

Jayne E. Hastedt*, Per Bäckman, Antonio Cabal, Andy Clark, Carsten Ehrhardt, Ben Forbes, Anthony J. Hickey, Guenther Hochhaus, Wenlei Jiang, Stavros Kassinos, Philip J. Kuehl, David Prime, Yoen-Ju Son, Simon Teague, Ulrika Tehler, and Jennifer Wylie

Cite this: *Mol. Pharmaceutics* 2022, XXXX, XXX, XXX-XXX
Publication Date: May 16, 2022
https://doi.org/10.1021/acs.molpharmaceut.2c00113
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iBCS: 2. Mechanistic Modeling of Pulmonary Availability of Inhaled Drugs versus Critical Product Attributes

Per Bäckman*, Antonio Cabal, Andy Clark, Carsten Ehrhardt, Ben Forbes, Jayne Hastedt, Anthony Hickey, Guenther Hochhaus, Wenlei Jiang, Stavros Kassinos, Philip J. Kuehl, David Prime, Yoen-Ju Son, Simon P. Teague, Ulrika Tehler, and Jennifer Wylie

Cite this: *Mol. Pharmaceutics* 2022, XXXX, XXX, XXX-XXX
Publication Date: May 24, 2022
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PDA Journal of Pharmaceutical Science and Technology

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Principles for Management of Extractables and Leachables in Ophthalmic Drug Products

Christopher Houston, Andrea Desantis Rodrigues, Brenda Birkestrand Smith, Tao Wang and Mary Richardson

PDA Journal of Pharmaceutical Science and Technology February 2022, pdajpst.2022.012744; DOI: https://doi.o

Article | References | Info & Metrics

Abstract

Ophthalmic solutions and suspensions have long been classified into a high risk category wit
respect to concerns over extractables and leachables (E&L), though specific guidance on the
management of leachables in these products is generally absent from regulatory authorities c
scientific literature. As a result, ophthalmic drug products (ODP) were originally included in th
scope of the Product Quality Research Institute Leachables and Extractables Working Group
Parenteral and Ophthalmic Drug Products (PQRI-PODP). Relative to other high concern dosa
forms such as metered dose inhalers or injectables, ODP possess unique challenges with res
the nature of impactful E&L as well as the safety assessment of leachables. For example, ext
use of semipermeable low density polyethylene primary packaging for ODP necessitates a st
focus on E&L from secondary packaging sources. For safety assessment, a key challenge is
lack of a sufficient database developed on all relevant ophthalmic toxicity endpoints. As result
working group is unable to recommend a Safety Concern Threshold (SCT) for ODP at this tim
Nevertheless, the ophthalmic industry has developed a number of time-tested practices to ma
E&L for ODP. This article describes those science-based practices and key considerations in
analysis, management, and safety assessment of E&L in ODP.

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Survey Report on Complaints Related to the Interconnectivity between Vial Containers and Transfer Devices

Cathy Zhao, Edwin Burnard, Joanne Beyer, Robin Samuel and Naresh Budhavaram

PDA Journal of Pharmaceutical Science and Technology June 2021, pdajpst.2021.012643; DOI: https://doi.org/10.5731/pdajpst.2021.012643

Article | References | Info & Metrics | PDF

Abstract

To address the challenges related to the interconnectivity between vial container closure systems and vial transfer devices, pharmaceutical, elastomer and transfer device manufacturers have formed a working group under the Product Quality Research Institute (PQRI) to establish best practices for the evaluation of the assembly of vial transfer devices and vial systems. As part of the project, the first activity was to quantify the nature and frequency of issues (complaints). To this end, the working group conducted a survey with questionnaires related to categories and numbers of complaints, regions/countries where complaints were received and nature of the manufacturers who received the complaints. The survey was distributed to the sixteen companies participating in the working group and eleven companies submitted a response. Besides quantifying and ranking the frequency of issues, the survey determined what issues are common across all companies and what issues may be product-specific or specific by manufacturer. In this report, the analysis and outcomes of the survey will be presented, and the next steps will be discussed.

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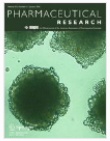


Pharmaceutical Research
January 2016, Volume 33, Issue 1, pp 167–176

The Effect of Excipients on the Permeability of BCS Class III Compounds and Implications for Biowaivers

Authors | Authors and affiliations

Alan Parr, Ismael J. Hidalgo, Chris Bode, William Brown, Mehran Yazdanian, Mario A. Gonzalez, Kazu
Kevin Miller, Wenlei Jiang, Erika S. Stippler

The AAPS Journal
July 2017, Volume 19, Issue 4, pp 989–1001 | Cite as

Evolution of Choice of Solubility and Dissolution Media After Two Decades of Biopharmaceutical Classification System

Authors | Authors and affiliations

Nadia Bou-Chacra, Katherine Jasmine Curo Melo, Ivan Andrés Cordova Morales, Erika S. Stippler, Filippos Kesisoglou, Mehran Yazdanian, Raimar Löbenberg

On the Shelf Life of Pharmaceutical Products

Robert Capen[1, 13], David Christopher[1], Patrick Forenzo[2], Charles Ireland[3], Oscar Liu[4], S
Dennis Sandell[9], James Schwenke[10], Walter Stroup[11] and Terrence Tougas
AAPS PharmSciTech
September 2012, Volume 13, Issue 3, pp 911-918

AAPS PharmSciTech
pp 1–13 | Cite as

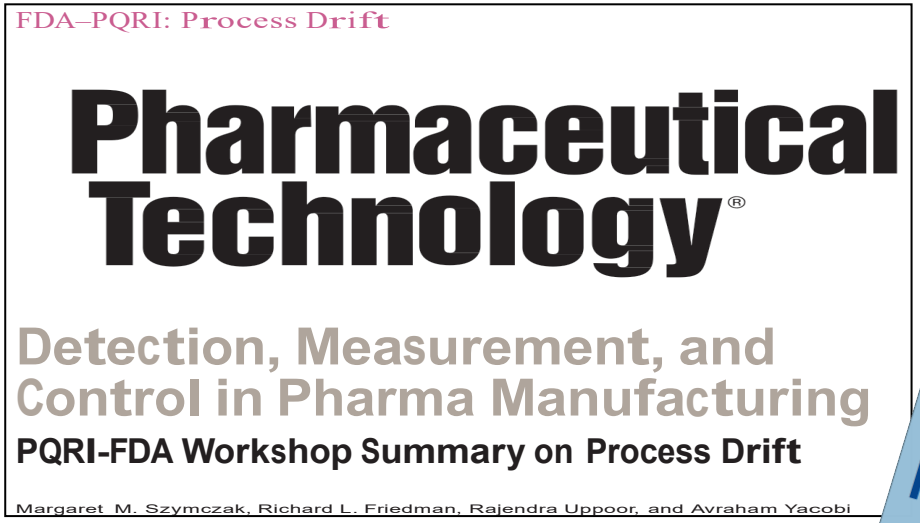
Evaluating Current Practices in Shelf Life Estimation

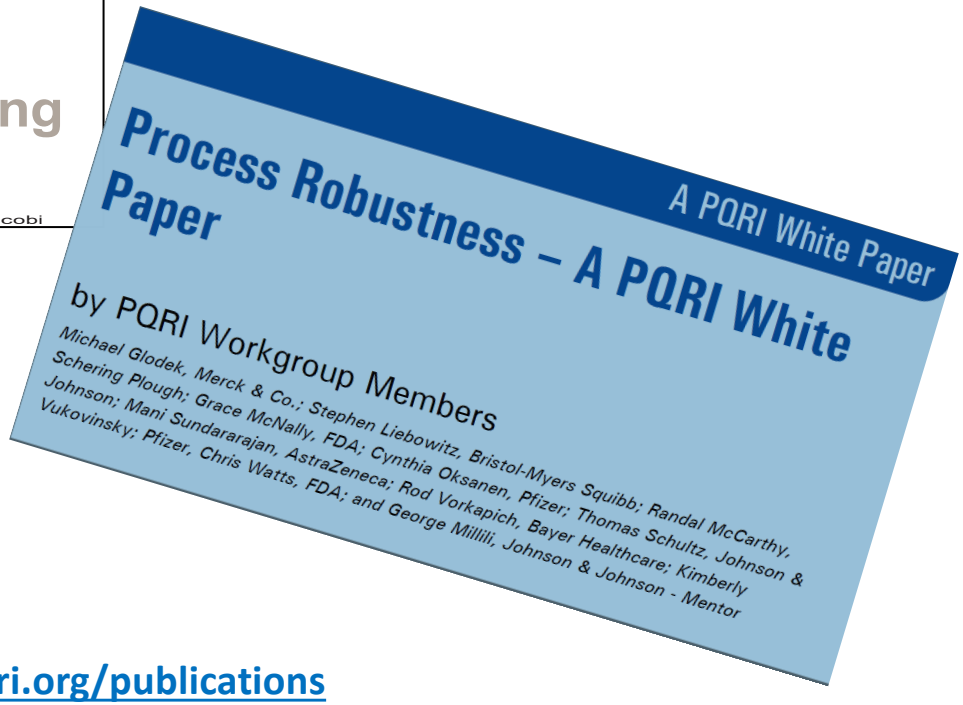
Authors | Authors and affiliations

Robert Capen, David Christopher, Patrick Forenzo, Kim Huynh-Ba, David LeBlond, Oscar Liu, John O'Neill, Nate Patterson, Michelle Quinlan, Radhika Rajagopalan, James Schwenke, Walter Stroup

More available at: **www.pqri.org/publications**

Selected PQRI Publications





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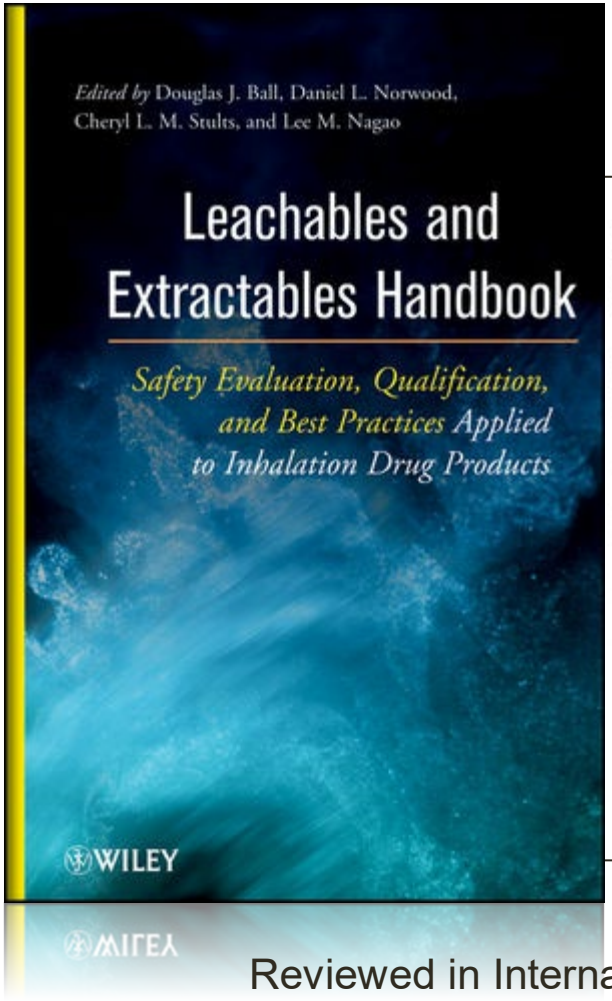
Examples of PQRI Publications



Douglas J. Ball, Daniel L. Norwood, Cheryl L. M. Stults, and Lee M. Nagao, Editors *Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices—Applied to Inhalation Drug Products*. Hoboken, New Jersey: John Wiley & Sons, Inc, 2012. 683 pp. $125.00
ISBN: 978-0-470-17365-7

Reviewed by: John A. Budny, PharmaCal, Ltd., Westlake Village, CA 91362-6700, USA
DOI: 10.1177/1091581812454259

The well-known proverb "Don't judge a book by its cover" is, at first glance, confirmed by *Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products*. The eye-catching phrase, "Leachables and Extractables Handbook" is designed on to the cover to attract attention; however, "Inhalation Drug Products," which is in smaller print and at the end of the long title, identifies the focus and the primary audience for the book. Nonetheless, the book contains information appropriate for toxicologists who are required to conduct toxicological analyses and make risk assessments of trace materials and chemicals associated with manufacturing, transporting, using, and disposing of chemicals not directly associated with medical devices that are specifically used for inhalation therapeutics. The editorial liberty exercised by the editors and publishers for the book's title is not only justified but commendable since human health risk assessments for leachables and extractables span a wide variety of circumstances and products which toxicologists are required to address.

The 4 editors of handbook solicited 49 authors who wrote 21 chapters and 4 appendixes. The 21 chapters are segregated into 2 parts. The first part entitled "Development of Safety Thresholds, Safety Evaluation, and Qualification of Extractables and Leachables in Orally Inhaled and Nasal Drug Products," consists of 9 chapters and constitutes approximately 23% of the handbook. The second part entitled, "Best Practices for Evaluation and Management of Extractables and Leachables in Orally Inhaled and Nasal Drug Products" comprises approximately 69% of the handbook. The remaining 8% of the handbook is devoted to 4 appendixes.

The chapters in both part I and part II have the same basic structure: a brief introduction section or paragraph, the body of the subject material, a concluding section which is, in most cases, a combination of a summary and conclusion and finally a reference list. The sections within the chapters are numbered with appropriately numbered subtopics so as to give the chapters a cohesive outline structure. Unfortunately, the chapters do not have a numbered outline section at the beginning of the chapter and consequently, the reader must search through the chapter, page by page to understand the scope of the chapter's content rather than being able to view the breadth of the treatment at a glance.

The 9 chapters that comprise part I lay the foundation for the handbook's value found in part II. Chapter 1 gives an overview by describing the issues associated with leachables and extractables in orally inhaled and nasal therapeutic delivery systems and how the handbook will address them. The second chapter describes, in a broad way, how and why materials are established as suitable for respiratory delivery devices. Chapters 3 to 7 lay out, principally

Reviewed in International Journal of Toxicology (2012;31[5]:496-7)

PQRI Impact- Regulatory Guideline and Standards

PQRI Project	Supported Guidance and Standards
BCS Class III Biowaivers	FDA Draft Guidance, Waiver of in vivo BA and BE studies for IR solid orals based on BCS
Process Robustness	ICH Q8, Q9
Extractables & Leachables	FDA Draft Guidance, MDIs/DPIs USP 1663 USP 1664
Container Closure	FDA Guidance, Changes to an approved NDA or ANDA

FDA/PQRI Conferences

Past Conferences:

5th PQRI/FDA Conference on Advancing Product Quality: ***Advancing Quality & Technology of Future Pharmaceuticals***

- December 1 -3, 2021 (Virtual Event)

4th PQRI/FDA Conference on Advancing Product Quality: Patient Centric Product Design, Drug Development, and Manufacturing

- April 9-11, 2019
- Presentations

3rd FDA/PQRI Conference on Advancing Product Quality

- March 22-24, 2017
- Presentations

2nd FDA/PQRI Conference on Advancing Product Quality

- October 5-7, 2015
- *A Summary of the Second FDA/PQRI Conference*

1st FDA/PQRI Conference on Evolving Product Quality

- September 16-17, 2014
- *A Summary of the Inaugural FDA/PQRI Conference*

Additional Select PQRI Conferences/Workshops

2024

- FDA/PQRI Workshop: Challenges and Opportunities for Modified Release Oral Drug Product Development – A Forum for Stakeholder Engagement (April 18, 2024) IN PERSON, hosted by USP (Rockville, MD). Registration opening soon!
- PQRI/EUFEPS Global Bioequivalence Harmonisation Initiative (GBHI): 6th International Workshop – GBHI 2024 (April 16-17, 2024) IN PERSON, hosted by USP (Rockville, MD). Registration Open!
- PQRI Workshop: MIDD Approaches in Pediatric Formulation Development (February 28-29, 2024) (VIRTUAL) Registration Open!

2023

- PQRI/FDA Workshop: Workshop on the Regulatory Framework for the Utilization of Artificial Intelligence in Pharmaceutical Manufacturing (September 26-27, 2023) (Virtual)
- PQRI Workshop: TiO2 Use in Pharmaceuticals – Global Regulatory and Technical Challenges (June 13-14, 2023) (Hybrid)

2022

- PQRI/FDA Workshop: Regulatory Framework for Distributed and Point of Care Pharmaceutical Manufacturing: An Opportunity for DM/POC Stakeholder Engagement (November 14 – 16, 2022) VIRTUAL EVENT
- PQRI Workshop: *Managing Excipient and API Impact on Continuous Manufacturing* (May 17 – 18, 2022) VIRTUAL EVENT

Questions

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