

Table of Contents

Features Cvr **Managing Quality Risk Management Implementation**

Coming Next Month
Microbiology
(PDA Annual Meeting
Show Issue)

PDA News & Notes	7	Louise Johnson and Martin Van Trieste Join PDA Board
Science & Technology	8	Recent Sci-Tech Discussions: Pharmaceutical Development Reports and Sterile Filtration vs. Terminal Sterilization
	10	PDA Interest Groups & Leaders
Quality & Regulatory Affairs	16	OOS Final Guidance: What Has Changed?
	18	Regulatory Briefs
Membership Resources	22	A Reinvigorated Membership Department
	23	An Update on North American Chapter Events
	26	New Member List
	28	Chapter Contacts
Programs & Meetings	30	People and Places: Prefilled Syringes Forum, Microbiology Meeting and Asia-Pacific Congress
	32	PDA's Global PAT Conference: <i>Unlocking the Knowledge in Your Process</i>
	32	Quality by Design for Biopharmaceuticals: <i>Concepts and Implementation</i>
	34	2007 PDA Annual Meeting: <i>Putting Science and Technology into Practice</i>
TRI • Education	36	TRI Talk: Happy New Year!
	37	Call for Donations
Professional Resources	11	New Releases from the PDA bookstore
Cover Art	Cover art: Quality risk management will help pharmaceutical experts eliminate unmarked manufacturing obstacles.	

To advertise in next month's issue on Microbiology (PDA Annual Meeting Show Issue) contact **Cindy Tabb** at: +1 (301) 656-5900, ext. 222 tabb@pda.org

Table of Contents

Features Cvr **Review of USP Microbiology Chapters**

Coming Next Month
GMP Enforcement
and Compliance

PDA News & Notes	16	Senior Staff Members Earn Promotions at PDA
Science & Technology	7	Articles of Interest to the Microbiologist
	10	Pharmaceutical Filtration Book is a Must-Read
Quality & Regulatory Affairs	18	Quality Requirements for Clinical Trial Applications in the European Union
	20	First PIC/S Industry Forum: New Opportunity to Discuss Global GMP Issues
	23	PDA Participates in Annex 1 Consultation
	26	ICH Q10 Previewed at PDA Asia-Pacific Congress
	28	PDA Comments on FDA and EMEA Guides
Membership Resources	30	Capital Area Chapter Tailors Events to Members' Needs
	31	PDA Puerto Rico Chapter is Reborn
	31	New England Chapter Tours Applied Biosystems' Facility
	32	Chapter Contacts
	34	Enhance Your Membership at the 2007 Annual Meeting
	36	New Member List
Programs & Meetings	39	Faces and Places: ISPE and PDA Joint Conference on ICH Q8 and Q9
	40	Keynote and Closing Day Speakers Set for Annual Meeting
	41	Expanded Networking Activities You Can't Afford to Miss!
TRI • Education	45	TRI Talk: Gaining Comfort in a Strange Land...or Classroom
Professional Resources	33	PDA Career Center
	35	PDA Bestsellers
	38	PDA Annual Meeting Recommended Reading

Cover art: In late 2006, PDA sponsored a successful meeting on microbiology, a key science for many PDA members. (Image – Lactobacillus bacteria)

To advertise in next month's issue on GMP Enforcement and Compliance contact Cindy Tabb at: +1 (301) 656-5900, ext. 222 tabb@pda.org

Table of Contents

Coming Next Month
ICH Q8/Q9/Q10

Features	Cvr	PIC/S: Why is It Important? What is Its Impact?
	12	Solvents Training Workshop Drums Up Residual Questions
PDA News & Notes	8	President's Message: Strong Showing of Support Strengthens New Facility
	8	Participate in PDA: Write and/or Review Technical Reports; Participate on the Biotechnology Advisory Board
Science & Technology	10	Berlin Workshop on PDA's Technical Report No. 42, Biopharmaceutical Process Validation
	11	PDA Interest Groups & Leaders
Quality & Regulatory Affairs	23	Regulatory Briefs
Membership Resources	24	New Directors Take Familiar Path to Board
	26	Israel Chapter Annual Meeting Draws Fascinating Speakers
	28	Israel Southern California Chapter Hosts Consecutive Dinner Events
	30	New Member List
	32	Chapter Contacts
Programs & Meetings	34	Colorado Springs to Host 2008 Annual Meeting
	34	PAT Team Delivers PDA's First PAT Conference
	36	Faces and Places
TRI • Education	38	TRI Talk: First Steps to Going Global
Professional Resources	7	PDA Bestsellers
	27	PDA New Releases
	33	PDA Web Seminars

Cover art: For most PDA members, successful compliance with regulatory expectations—whether about residual solvents or any other issue—boils down to the results of the next site inspection. Artwork by Bruno Budrovic/www.images.com.

To advertise in next month's issue on ICH Q8/Q9/Q10 contact **Cindy Tabb** at: +1 (301) 656-5900, ext. 222 tabb@pda.org

Table of Contents

Features	Cvr	EMEA's Cooke on the Future of GMPs
	16	Management-Based Regulations New FDA Goal
PDA News & Notes	8	PDA Recognizes Honor Award Winners at Annual Meeting
Science & Technology	10 13	BioAB Drives PDA's Biotech Strategy PDA Interest Groups & Leaders
Quality & Regulatory Affairs	28 30	Quality by Design for Biopharmaceuticals Regulatory Briefs
Membership Resources	32 35 35 36 38	Dedicated Local Leaders Help Grow PDA Chapters Comparability Protocols Discussed at First Midwest Chapter Dinner of 2007 Volunteer with PDA New Member List Chapter Contacts
Programs & Meetings	40 40 42	2007 PDA/FDA Meeting to Address Emerging Regulations PDA's Upcoming Cold Chain Management Meeting Faces and Places: ISPE/PDA Joint Conference, Brussels, Belgium
TRI • Education	46	TRI Talk: Demolition for New TRI Facility Begins
Professional Resources	7 12 22 43	PDA Top 10 Bestsellers PDA New Releases PDA Virtual Career Fair PDA Web Seminars

Coming Next Month
TRI 10th Anniversary
Issue

Cover art: When final, Q10 will complete the trio of guidances that will usher in the GMPs for the 21st century. Artwork by ImageZoo/www.images.com.

To advertise in next month's issue on TRI's 10th Anniversary contact Cindy Tabb at: +1 (301) 656-5900, ext. 222 tabb@pda.org

Table of Contents

Coming Next Month
Hot Topics in
Manufacturing

Features	Cvr	TRI Celebrates 10th Anniversary
	21	TRI's Aseptic Processing is an Industry Standout
	23	Intergenerational Wonder Team Filters Knowledge for TRI Students
PDA News & Notes	8	PDA Chair's Message
Science & Technology	10	Science & Technology Snapshot
	16	Recent Sci-Tech Discussions: Worldwide GMPs?
Quality & Regulatory Affairs	34	Regulatory Briefs
Membership Resources	36	Local PDA Chapters & TRI: Making a Difference Together
	36	Advance Your Career at PDA's Career Fairs
	38	Authors Wanted: Publish Your Research or Article with PDA
	38	2007 Annual Meeting New Member Breakfast
	40	New Member List
Programs & Meetings	5	Call for Papers: PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology
	7	Call for Papers: PDA Visual Inspection Forum
	9	Call for Papers: 2008 PDA Annual Meeting
	37	Call for Papers: PDA Extractables/Leachables Forum
	42	2007 PDA/FDA Conference: Program Chair's Message
	42	2007 PDA Cold Chain Conference: Program Chair's Message
TRI • Education	44	TRI Your Hand at One of Our Training Courses
	45	Why, Yes! TRI Does Offer a Laboratory Course For You!
	46	Ten Great Years—Thanks to Our Sponsors!
Professional Resources	12	April Top 10 Bestsellers
	33	PDA Web Seminars
	35	Recommended Reading
	39	PDA Virtual Career Fair

To advertise in next month's issue on Hot Topics in Manufacturing contact **Cindy Tabb** at: +1 (301) 656-5900, ext. 222 tabb@pda.org

Cover art: Ten years after Past PDA President Ed Fry celebrated TRI's inauguration, the Institute continues to be a leader in hands-on pharmaceutical education and training.

Table of Contents

Features	Cvr	Stainless or Plastic?
	24	Use of Microarrays to Evaluate Cell Culture Processes
PDA News & Notes	8	PDA Saddened by Passing of Vicki Dedrick
Science & Technology	10	Science & Technology Snapshot: From the VP, TR Watch, IG Briefing, Task Force Corner, Leadership Opportunities, Sci-Tech Trends
	12	Recent Sci-Tech Discussions: Cold Chain Distribution and CIP and SIP Cycle
	15	Interest Groups and Leaders
Quality & Regulatory Affairs	30	FDA Warns Drug Manufacturers to Guard against DEG Poisoning
	32	PDA Comments on EMEA GMP Guide
Membership Resources	34	Delaware Valley Chapter Meeting Focuses on QbD
	34	Enrich Your Career – Become a Volunteer
	36	Chapter Contacts
	38	New Member List
Programs & Meetings	40	PDA/FDA Conference Offers Something for Everyone
	42	PDA Presents Technology Transfer Today
	42	PDA/R ³ Nordic Conference: Modern Aseptic Production
	44	Faces and Places: Annual Meeting Sessions Draw Record Crowd
	46	Faces and Places: Not Everything that Happens in Vegas... Stays in Vegas
	48	Faces and Places: Annual Meeting Exhibits Show Off Latest Products, Services and Technologies
TRI • Education	50	TRI Talk: Introducing New Education Advisory Committee
Professional Resources	5	May Top 10 Bestsellers
	9	New Releases from the PDA Bookstore

Coming Next Month
Aseptic Processing/Sterile Products
 (PDA/FDA conference show issue)

Cover art: Various single-use systems by Millipore, Pall Corporation and Sartorius

To advertise in next month's issue on Aseptic Processing/Sterile Products (PDA/FDA conference show issue) contact Cindy Tabb at: +1 (301) 656-5900, ext. 222 tabb@pda.org

Table of Contents

Coming Next Month
Computer Validation

Features	Cvr	New TR-1 Correlates Physical and Bio Principles of Steam Sterilization
PDA News & Notes	8	New TRI Facility Debuts First Course
	8	PDA Member News: Joerg Neuhaus, Kris Evans Join Private Sector
Science & Technology	10	Science & Technology Snapshot: From the VP, TR Watch, Task Force Corner, Journal Preview, Leadership Opportunities, Sci-Tech Trends
	15	Recent Sci-Tech Discussions: ASTM vs. HTM 2010, Temp Limit for Sterilization and Sterilization Cycle Times
	17	Ten PDA Interest Groups to Meet at PDA/FDA Conference
	19	Interest Groups and Leaders
Quality & Regulatory Affairs	26	Review of EMEA Guideline: Limiting Residues of Metal Catalysts
	27	Regulatory Briefs
	31	Know Your Regulators: EMEA Inspections Sector
Membership Resources	34	Tales of the Trail
	38	New Look, New Opportunities: PDA Career Center Gets a Facelift
	39	Puerto Rico Chapter Inaugural Event a Success
	39	Japan Chapter Hosts GMP Training Course
	40	Operational Challenges Discussed at West Coast Chapter Dinner
	42	New Members List
	46	Chapter Contacts
Programs & Meetings	47	2007 Visual Inspection Forum: An Opportunity to Learn
	47	Micro Meeting to Explore International Pharmacopeial Harmonization
	48	Connect with Colleagues New and Old
	48	Extend Your Learning: Attend the Japanese Regulatory Workshop
	49	Exhibitors and Sponsors
	50	PDA Meeting Examines a Changing Environment: Extracables and Leachables
	51	Plant Tour to Follow Pharmaceutical Freeze and Spray Drying Workshop
53	Faces and Places: Spring Conferences	
TRI • Education	54	TRI Inspections Course Caters to Novices and Veterans
	54	PDA Training Courses
Professional Resources	7	June Top 10 Bestsellers

To advertise in next month's issue on Computer Validation contact Cindy Tabb at: +1 (301) 656-5900, ext. 222 tabb@pda.org

Cover art contest: If you can identify the photo and send your answer to lettercontest@pda.org by September 30, 2007, you will be entered into a drawing to win a 1-year membership renewal. The drawing will take place on October 5, 2007. Contest open to PDA members only. In your email, include your member i.d. number and your current contact information to be eligible. PDA staff and those associated with the company that supplied the photo are not eligible. Valid entries must be received via email by 11:59 p.m. Pacific Time, Sunday September 30, 2007.

Table of Contents

Features	Cvr	Method Validation: An Overview of Global Standards
PDA News & Notes	8	Bill Paulson's IPQ: Newest Member Benefit
Science & Technology	10 14 19	Science & Technology Snapshot Recent Sci-Tech Discussions: Software Validation and Reusability of Single-Use Technology Interest Groups and Leaders
Quality & Regulatory Affairs	30 32 34 35	Quality and Regulatory Snapshot ZLG: The Voice of Germany's Inspection Services How Will Inspectors View Risk Management? Quality Systems: An Evolving Environment
Membership Resources	38 40 42 43 44	Membership Committee to Optimize the PDA Member Experience Delaware Valley Chapter Showcases Student Science Projects New England Chapter Meeting Focuses on Filtration Chapter Contacts New member list
Programs & Meetings	46 47	PDA's Prefilled Syringes Universe Expanding Faces and Places: PDA Pharmaceutical Cold Chain Management Conference
TRI • Education	48	TRI Talk: TRI Finalizes Move to Bethesda, Sign Up Now!
Europe	49 50 50	Conference Report Upcoming Meeting Chapters and People
Professional Resources	29 29	July/August Top 10 Bestsellers PDA New Releases

Cover art:
This issue's feature story provides a comprehensive examination of compendial standards for analytical method validation.

Coming Next Month
Next month's issue will contain a comprehensive report from PDA's May workshop on QbD. To advertise, contact Cindy Tabb at +1 (301) 656-5900, ext. 222 or tabb@pda.org.

Table of Contents

Features	Cvr	QbD: Still in Design?
PDA News & Notes	8	Presidents Message: IPQ—New Member Benefit—Mails in October
	9	PDA Revised Technical Report on Cold Shipping Takes Global View
Science & Technology	10	Science & Technology Snapshot: From the VP, Student Programs, In Print, Journal Preview, Technology Trend
	21	PDA Interest Groups and Leaders
Quality & Regulatory Affairs	30	Quality and Regulatory Snapshot: From the VP, Task Force Update, Advisory Board Watch, IG Briefing Regulatory Relations
	32	PDA Submits QP Survey Results
	34	PDA Comments on EMEA Batch Release Certificate
	36	PDA Comments on Q10 Pharmaceutical Quality Systems
Membership Resources	38	Finding Creative Ways to Connect Members: The Southern California Corporate Outreach Program
	39	Volunteer Spotlight: Bob Dana
	40	New member list
	43	Chapter Contacts
Programs & Meetings	44	Programming Department Offers a Full Lineup of Conferences
TRI • Education	46	TRI Talk: Bethesda—We Came, We Saw, We Conquered!
Europe	48	Upcoming Event: Modern Sterile Manufacturing
	49	Chapters and People: Susanne Keitel Named New Director of EDQM
	50	Conference Report: Technology Transfer Today Highlights
Professional Resources	28	PDA Bestsellers
	28	PDA New Releases: <i>Essential Microbiology for QP Candidates</i>

Cover art:
QbD, building a new paradigm for quality?
Artwork
© Bruno Budrovic.

Coming Next Month
Reports from the
2007 PDA/FDA
Joint Regulatory
Conference. To
advertise, contact
Cindy Tabb at
+1 (301) 656-5900,
ext. 222 or
tabb@pda.org.

Table of Contents

Features	Cvr	FDA Reps Present Five-Year Update to GMP Initiative at 2007 PDA/FDA
	27	Foreign Inspection Program Detailed at PDA Japanese Regulatory Workshop
PDA News & Notes	8	The Power of Collaboration: My Welcoming Remarks at the 2007 PDA/FDA conference
	9	TR-43 Announcement: PDA Publishes Glass Defects Technical Report
Science & Technology	10	Science & Technology Snapshot: Chair's Message, Technical Report Watch, Leadership Opportunities, Task Force Update, In Print
	16	PDA Survey on Analytical Methods for Cleaning Validation
	19	PDA Interest Groups and Leaders
Quality & Regulatory Affairs	28	Quality and Regulatory Snapshot: VP Message, Health Authority Spotlight, Health Authority Special Report
Membership Resources	34	Volunteer Spotlight
	35	PDA Puerto Rico Chapter Holds Second Educational Event
	36	Stability, EU GMPs and CAPA on the Marquee at Southeast Chapter Annual Fall Meeting
	38	New England Chapter Talks About Project Portfolio Management
	38	100 New Members Attend PDA/FDA Breakfast
	39	Delaware Valley Chapter Takes a Look at EMEA
	39	New Chapter Websites Up and Running
	40	PDA Welcomes New Members
	44	Chapter Contacts
Programs & Meetings	45	The 2008 Annual Meeting: Science Driven Manufacturing: The Application of Emerging Technologies
	46	Twelve Top Government Speakers Confirmed for 2008 PDA/EMEA Joint Conference
	48	Consider Your Entry for the 2008 Trainers' Choice Award
	50	Faces and Places: PDA/FDA Conference—The Sessions
	52	Faces and Places: PDA/FDA Conference: Exhibits and Networking
	53	Faces and Places: GPP: Good Party Practices
TRI • Education	54	Chair's Message: TRI Officially Opens Doors in Bethesda
	55	TRI Celebrates a New Beginning
Europe	57	Endotoxins: Joint PDA/SFSTP Collaboration Ongoing
	58	Ompi Day
Professional Resources	9	PDA Bestsellers
	36	PDA New Releases

Cover art:
 TRI's new facility
 officially opened
 following the PDA/
 FDA conference

Coming Next Month
Quality Systems &
Compliance. To
advertise, contact
Cindy Tabb at
+1 (301) 656-5900,
ext. 222 or
tabb@pda.org.