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Cover art:

Implementation strategies for EMEA Annex 1 were covered at the workshop for industry and regulators presented by PDA & ISPE with PIC/S. Photo collage by James Austin Spangle.

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Cover art:

Pharma firms are finding that third party audits are one of many ways to secure the supply chain. Photo collage by James Austin Spangle.

Coming Next Issue:

U.S. FDA's New Revised Validation Guidance

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Cover art:

Validation is a critical step in commercializing a drug product and requires careful scrutiny of the manufacturing process.

Coming Next Issue:

Update on Rapid Microbial Methods

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Cover art:

According to some industry experts, the time for implementing Rapid **Microbiological Methods** is now. Cover by James Austin Spangle.

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PDA Journal: New **Editor. New Online Format**

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Cover art:

The appropriate metals to control and at what limits are just two of the problems that industry, the U.S. FDA and USP are trying to solve before a revised general chapter on heavy metals can be implemented.

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The Impact of the Microchip; Reports From the 2009 PDA Annual Meeting

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Futurist lan Morrison predicts a tsunami of chronic care involving cancer, heart disease and depression could overwhelm health care systems worldwide.

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Hot Topics in Sterile Product Manufacturing/ Aseptic Processing

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Cover art:

The 2009 PDA/FDA
Asia-Pacific Pharmaceutical Supply Chain
Conference was the first
meeting under the MOU
between PDA and the
SIFDS.

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A 10 Year View of Harmonized Regulations

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Science & Technology	Science & Technology Snapshot: Journal Editorial Team Now in Place, Journal Preview, InPrint Recent Sci-Tech Discussions: Reporting Injectable Content, Injection Particulate Matter Testing PDA Interest Groups & Leaders
Quality & Regulatory Affairs	Quality & Regulatory Snapshot: International Pharmaceutical Quality WHO Draft Consultation Update: GMP for Sterile Pharmaceutical Products PDA's Comments Address Concerns About Injector Draft Guidance Regulatory Briefs
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Europe	First Public Discussion of EFPIA Mock QbD Submission at PDA Workshop Learn About Sterility Assurance-Boosting Technologies, Practices
Professional Resources	New Releases from the PDA Bookstore Top Ten Bestsellers

Cover art:

A "look back" at ICH Q7 shows that the guidance has had a tremendous positive impact on the API segment of the industry, and, most importantly, has helped align regulatory expectations across the globe.

Coming Next Issue:

PDA's Universe of Pre-filled Syringes: Six Years and Running

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Cover art:

This issue, we carry over artwork we developed for the announcement that Bob Myers was retiring and the search for a new president was on. We use it again here to symbolize the end of the search.

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Hot topics from the PDA/ FDA and PDA/EMEA Conferences

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PDA is dedicated to connecting industry and regulators to advance regulatory science to ensure the safety of patients.

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Pharmaceutical Microbiology: A report from PDA's 4th Annual **Microbiology Meeting**

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