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Anonymous. Standing Tall: Plastic Cooling Towers Capture Metal's Old Territory. *chem.info*

Vol. #:45 Issue:10 Starting Page:16 (2007) Abstract: Factory-assembled cooling towers made of engineered plastics: longevity and savings in maintenance. Data from Delta Cooling Towers, Inc.

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(2007) Abstract: The article is an overview of the implementation of NIR. It also suggests a general approach to system validation and presents data acquisition and interpretation basics for on-line blend monitoring.

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Compton, Bruce Jon and Jensen, Jacob Peter. Tutorial: Use of Perfusion Technology on the Rise. *Genetic Engineering & Biotechnology News* Vol. #:27 Issue:17 Starting Page:48 (2007) Abstract: New modes are beginning to gain ground on fed-batch strategy.

Cook, R. Christopher and Leiken, Jonathan B. Foreign Policy. *Pharmaceutical Executive* Vol. #:27 Issue:6 Starting Page:46 (2007) Abstract: Drug companies doing business abroad- and who isn't- face a special risk of running afoul of stepped-up enforcement of anticorruption laws. Travel alert: When in Rome, don't!!

Curran-Hays, Michael. Industry Outlook: Pharmaceutical Resolutions for 2008: Solve problems before they occur. *Pharmaceutical Processing* Vol. #:24 Issue:1 Starting Page:22 (2008) Abstract: Article looks at hot topics for 2007 and issues of importance for 2008: cost cutting/reduce waste; quality; regulations in a global economy and patent expirations and cost pressures.

Curry, Jim. Simulation Methodology for Facility Design. *BioPharma International* Vol. #:20 Issue:6 Starting Page:58 (2007) Abstract: Find out how simulation software can help ensure proper capacity planning and design.

Daley, Matthew and Aldridge, Susan. Integrity Testing of Large-Size Filter Systems. *Genetic Engineering & Biotechnology News* Vol. #:28 Issue:1 Starting Page:29 (2008) Abstract: Integrity was assessed using oversize volumes to determine accuracy of results. Article by a field marketing specialist and consulting engineer at Millipore.

DePalma,Angelo. Streamlining HPLC in Bioproduction. *Genetic Engineering & Biotechnology News* Vol. #:27 Issue:June Starting Page:48 (2007) Abstract: Customer needs are evolving beyond simple instrument performance and capabilities.

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Dey,Jodi and Sarma,Nagesh. Data Migration Validation. *Drug Discovery & Development* Issue: February Starting Page:28 (2007) Abstract: Why today's practices are no longer best practices. The article presents a methodology for implementing and validating a migration of data or content into a GxP system or application.

Dobiecki,John and Mello,Alex. Where and What to Test: From Purified Bulk Drug Substance to Sterile Liquid Final Drug Product. *Controlled Environments* Vol. #:11 Issue:2 Starting Page:10 (2008) Abstract: Short review by principals from a contract testing laboratory.

Dott,Mark. Steam sterilizer validation requirements per the New Standard ISO 17665-1:2006. *Controlled Environments* Vol. #:10 Issue:10 Starting Page:11 (2007) Abstract: Nice review article with pre- and postvalidation issues noted. Few selected references.

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Forsyth,Richard. Test method validation for cleaning validation samples. *American Pharmaceutical Reviewer* Vol. #:10 Issue:5 Starting Page:74 (2007) Abstract: A number of test methods options are reviewed for their analytical capabilities along with their method validation parameters.

Gane,Scott R. Security Compliance at Chemical Facilities. *Security* Vol. #:44 Issue:7 Starting Page:32 (2007) Abstract: The game has changed since 9/11 when securing infrastructure was simple. Now higher-level technology, better officer training and more industry rules and government regulations need to be taken into consideration.

Glaser,Vicki. Complex Peptides Challenge Manufacturers. *Genetic Engineering & Biotechnology News* Vol. #:28 Issue:1 Starting Page:26 (2008) Abstract: Novel molecules require improvements in synthesis, scale-up, and purification. Nice review with overview of efforts by Merck, Zelos Therapeutics, Merck KGaA, AplaGen.

Gombar,Charles and Loh,Evan. Learn & Confirm. *Drug Discovery & Development* Issue: February Starting Page:23 (2007) Abstract: A new approach to drug development at Wyeth based upon the work of Lewis Sheiner (Clin. Pharm. Therapeutics 61 (5): 275-291. Wyeth feels this will not result in incremental improvements but new paradigms for industrial drug development.

Hallworth,Mark. An Analysis of Acceptable Particle Losses in Tubing. *Controlled Environments* Vol. #:11 Issue:2 Starting Page:16 (2008) Abstract: Brief review with nice explanations of sampling and various forces at work in tubing as various types of fluids move and the forces that impact them.

Harclerode,William and Moualhaf,Christophe. Risk Management for Pharmaceutical Change Control. *Pharmaceutical Review* Vol. #:10 Issue:6 Starting Page:74 (2007) Abstract: The purpose of their article is to present a risk management tool that can be used for change control at a pharma plant. Case studies are presented.

Hindo,Brian. At 3M, A Struggle Between Efficiency and Creativity. *BusinessWeek* Issue:11 June Starting Page:8 (2007) Abstract: Review of the impact of new management from GE and the consequences of the deployment of Six Sigma on creativity at 3M.

Hoover,J. Nicholas. Next-Gen Data Centers. *Information Week* Issue:1175 Starting Page:38 (2008) Abstract: Secure and operationally and energy efficient, these facilities provide a glimpse into practical, state-of-the-art design.

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Laskey,Keith. The Issues and Benefits of Non-Metallic Pump Bearing Design. *chem.info* Vol. #:45 Issue:10 Starting Page:24 (2007) Abstract: A review on non-metallic vertical pump bearings, how they can help and what they might do especially with regard to preventing contaminants from infiltrating pumped fluids.

Lipp,Elizabeth. Personalized Medicine Seeks Mainstream. *Genetic Engineering & Biotechnology News* Vol. #:27 Issue:17 Starting Page:32 (2007) Abstract: Reeducating medical professionals and public is mandatory to overcome substantial obstacles.

Malhortra,Girish. Implementing QbD: A Step-By-Step Approach. *Pharmaceutical Processing*

Vol. #:23 Issue:2 Starting Page:16 (2008) Abstract: An in-depth look at Quality by Design and how it can help the industry.

Mentesana,Mike. Pharmacovigilance Impacts Drug Safety. *Genetic Engineering &*

*Biotechnology News* Vol. #:10 Starting Page:50 (2007) Abstract: Creating a flexible and proactive approach to patient protection.

Miller,Henry I. Risk-Averse Behavior Entrenched at FDA. *Genetic Engineering & Biotechnology*

*News* Vol. #:27 Issue:17 Starting Page:6 (2007) Abstract: Tactics increasingly worrisome, and firms should be outraged according to author, a fellow at the Stanford University Hoover Institution.

Netterwald,James. Where's the Virus. *Drug Discovery & Development* Issue: June Starting

Page:24 (2007) Abstract: DNA vaccine manufacturers look to take over the market aimed at protecting against viral pathogens.

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Issue:5 Starting Page:22 (2007) Abstract: Emerging pathogens are still a threat, but their lack of staying power has caused big drug companies to lose interest in combating them.

Neway,Justin O. Moving PAT Forward: A focus on quality will enable transformation.

*Pharmaceutical Processing* Vol. #:23 Issue:2 Starting Page:26 (2008) Abstract: A short review article by the Exec. VP and CSO of Aegis Analytical Corp. It has a brief boxed commentary on PAT Terms and Advice: Straight from the FDA.

Ninawe,A. A. Gone Fishin'. *Drug Discovery & Development* Issue: February Starting Page:46

(2007) Abstract: Marine organisms are a promising new source of bioactive substances.

Some examples are provided of deep sea compounds in development are provided.

Pearson,Sue. Producing Biologics Less Expensively. *Genetic Engineering & Biotechnology News*

Vol. #:27 Issue:17 Starting Page:36 (2007) Abstract: Gleaning greater yields with novel approaches and fine-tuned tools is one solution.

Perciali,Michael. Pharmaceutical Lab Construction. *Controlled Environments* Vol. #:10 Issue:6

Starting Page:18 (2007) Abstract: A Case Study.

Phillips,Dave. Ergonomics and safety in biological research cabinets. *Bioscience Technology*

Vol. #:31 Issue:9 Starting Page:44 (2007) Abstract: Good overview of biosafety cabinets from a technical applications specialist for Thermo Fisher Scientific.

Poonai,Tej and Chatterjee,Bikash. The Impact of the FDA's Adoption of Risk Management on

the Design and Qualification of Aseptic Facilities. *Controlled Environments* Vol. #:10

Issue:9 Starting Page:23 (2007) Abstract: This article addresses the issues in developing

one of the most rigorous of controlled environments in light of the FDA's new

expectations and their risk-based approach.

Railkar,Aniruddha. Anticounterfeiting Measures for Pharmaceutical Products. *American*

*Pharmaceutical Review* Vol. #:10 Issue:4 Starting Page:15 (2007) Abstract: Review of

various measures such as RFID, Taggants, molecular markers, holograms.

Rhoden,Alan. The Need for PAT During Freeze-Drying. *Pharmaceutical Review* Vol. #:10

Issue:6 Starting Page:28 (2007) Abstract: Author is from Pfizer and has global

responsibility for implementing PAT throughout Pfizer.

Sava,Tuna. Breakthrough Insulation for Tubing in Controlled Environments. *Controlled Environments* Vol. #:11 Issue:1 Starting Page:17 (2008) Abstract: Article by a product manager at UFP Technologies. Discussed new PVDF foam insulation as a new material for cleanroom insulation.

Segalstad,Siri H. Validating Quality. *Drug Discovery & Development* Vol. #:10 Issue:7 Starting Page:32 (2007) Abstract: Quality standards help pharma and biotech labs stay within regulatory guidelines. Discussion of the various GxP standards, LIMS validation. Nice short review to hand out to a new staff member.

Sekulic,S. Sonja. Is PAT changing product/process development. *American Pharmaceutical Review* Vol. #:10 Issue:5 Starting Page:30 (2007) Abstract: This paper takes a look at PAT from the R&D perspective to see where impacts of PAT are being felt while also trying to identify opportunities that could extend the impact of PAT even further.

Shaidani,Hamid. Vibration Isolation in Cleanrooms: A system for virtually every application. *Controlled Environments* Vol. #:11 Issue:1 Starting Page:20 (2008) Abstract: Article by the director of engineering for Kinetic Systems. They are involved in the design and manufacture of standard and custom-designed vibration isolation equipment. Some good pointers such as "... the weight of your typical load should be no more than 80% of the equipment's rated load capacity."

Sharma,Bhanu P. Computer Systems Validation for US FDA's 21 CFR Part 11 Compliance: A Risk-based Approach to Pharmaceutical Good Manufacturing Practices (cGMP). *American Pharmaceutical Review* Vol. #:10 Issue:4 Starting Page:96 (2007) Abstract: The risk-based approach has been a challenge as firms modernize and integrate their IT systems to meet cGMP compliance requirements.

Shaw,Gina. Growing Fierce. *Drug Discovery & Development* Issue:June Starting Page:28

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Shortening the Path to Acceptance. *Pharmaceutical Processing* Vol. #:23 Issue:2

Starting Page:20 (2008) Abstract: A quick tutorial with some references to works by the authors who are consultants from Tunnell Consulting.

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Biopharmaceutical Purification Strategies: Tutorial. *Genetic Engineering & Biotechnology News* Vol. #:27 Issue:1 Starting Page:52 (2007) Abstract: Bed-height optimization can reduce cost and increase speed of production.

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*Buildings* Vol. #:102 Issue:1 Starting Page:50 (2008) Abstract: Water systems: many of the well-publicized cases of Legionnaire's disease have had their origins in cooling towers; sporadic cases are coming from domestic building water systems. Authors are from Healthy Buildings International, Inc. Article provides elements of a risk assessment.

Tustin,Wayne. Why is Random Vibration Quantified in Strange  $g^2/Hz$  Units? *Controlled*

*Environments* Vol. #:1 Issue:7 Starting Page:12 (2007) Abstract: How do you measure vibration and what do the units mean.

Various Authors. Expanding Research Facilities: Supplement to Laboratory Equipment.

*Laboratory Equipment* Vol. #:44 Issue:1 (Supplement) Starting Page:1 (2007) Abstract: Lab construction/renovation trends report for 2007.

Ward,Chris and Menighan,Thomas. Auditing: Resources for Managing Vendor Oversight.

*Controlled Environments* Vol. #:10 Issue:10 Starting Page:17 (2007) Abstract: The authors looked at audits of vendors from software developers and distributor audits to distributor audits for supply chain integrity. A common thread was identified in successful audits which are sound audit practices, standards and guidelines.

Watson,Scott. The Inevitability of Conflict. *Security* Vol. #:44 Issue:8 Starting Page:32

(2007) Abstract: How to deal with conflict in the workplace. Rivalries and how to manage them from a security manager's standpoint.

Zu,Yanming, Luo,Yi and Aldridge,Susan. PAT Initiative in Generic Product Development.

*American Pharmaceutical Review* Vol. #:10 Issue:7 Starting Page:10 (2007) Abstract: Short review of PAT implementation and its benefits in generic product development by staff from the R&D group at Barr Labs.