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Featured Whitepaper

[Semisolid Formulation Development: The CRO Approach](#)

Author: Nicole Krilla, Debanjan Das and John G. Augustine, Ph.D.; Sponsored By: SP Formulations
Medicated cream and lotion development can be challenging as these are often complex mixtures with sophisticated requirements achieved via successful execution of a meticulous formulation program. Physicochemical characterization is often limited or incomplete, which is an additional challenge in the development of an effective formulation. This white paper presents strategies for developing a formulation more rapidly.

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Manufacturing

[Humidity Measurement in Cleanrooms](#)

Author: Daisuke Fujisawa; Sponsored by: Valisala
When considering humidity measurement in cleanrooms, choosing the right type of measurement instrumentation is important in order to reach the best humidity measurement results. Calibration should also be carried out regularly, and to traceable standards. Products manufactured in cleanrooms cover a wide range, including pharmaceuticals and semiconductors. Humidity, temperature, particles and pressure are often controlled, as these parameters can have serious effects on product quality and production efficiency.

[Seven Plant-Closing Mistakes & How to Avoid Them](#)

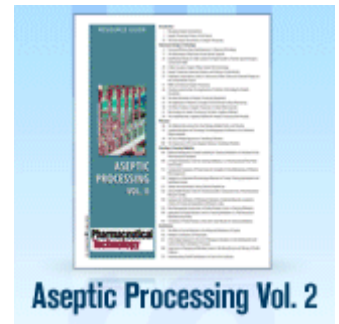
Sponsored by: Equipnet
Find out more on maximizing returns and minimizing damage when closing a facility.

[ADVANTAGES OF COLLECTING PM2.5 PARTICULATE TODAY](#)

Author: Tom Anderson; Sponsored by: Midwesco
Scientific studies have suggested that long term exposure to fine particulate matter may be associated with increased rates of chronic bronchitis, reduced lung function and increased mortality from lung cancer and heart disease. Thus



the EPA is setting standards for fine particulates: an annual standard (yearly) and a 24-hour standard, designed to provide additional protection on days with high peak PM2.5 concentrations. Earlier this year, the EPA has enacted industrial manufacturing plants to become PM2.5 compliant within 24 months, so why do so now?



Regulation

Outsourcing: A Rapid, Cost-Effective Option for Electronic (eCTD) Submissions

Sponsored By: Beckloff

Pharmaceutical and biotech sponsor organizations are in increasing numbers making the switch from paper to electronic (eCTD) format for their marketing applications to FDA. Given the current difficult economic environment, sponsors, especially those with modest submission volumes, should consider outsourcing as a great option to enable the strategic benefits of eCTD while significantly reducing the barriers.

Risk Evaluation and Mitigation Strategies (REMS) Under FDAAA

Sponsored By: Beckloff

The highly publicized withdrawal of a number of unsafe drugs from the market over the last several years has led to strong criticism of FDA's ability to protect the public health, resulting in a call for fundamental changes in the United States drug safety system. On March 25, 2008, new legislation designated as the Food and Drug Administration Amendments Act of 2007 (FDAAA; "the Act") took effect, which directed FDA to develop a systematic, scientifically sound approach to managing the risk-benefit ratio of a drug throughout its lifecycle, with an explicit focus on postapproval safety.



Information Technology

Technology Approaches to Quality Management

Author: Mike Jovanis; Sponsored By: Sparta Systems Europe, Ltd.

Organizations in highly regulated industries continue to face pressure to maintain the highest level of quality in every facet of their operations. These pressures stem from a number of different areas including a wide range of international regulatory authorities, global customers and other key stakeholders.

Protect Your Intellectual Property: Proof of

Authenticity is Your Best Defense

Author: Tom Klaff, CEO; Sponsored By: Surety, LLC

In today's digital world, altering an electronic document or record containing critical formulas or data takes nothing more than motive and a keystroke - forcing R&D organizations to rely on the trustworthiness of their people, processes and technology to vouch for the authenticity of their records. You insure your employees, your buildings, your products and your systems against unforeseen trouble, why wouldn't you protect the integrity of your organization's critical electronic content the same way?

Bulk Inspection of Tablets: Assuring Product Quality at Manufacturing and Packaging

Sponsored By: Symetix

Achieve new levels of product quality and inspection efficiency in the manufacturing and packaging of tablets. Learn the pros and cons of manual inspection, mechanical sorting, blistering, single-file optical systems and a new class of automated, bulk vision inspection systems. The latest technology is keeping pace with the increasing demand for top-quality products. Learn how it helps minimize risk, increase throughput and contain costs.

Survey Finds Life Sciences Manufacturers Face Data Challenge Despite Significant IT Investments

Author: Justin Neway, Vice President and Chief Science Officer; Sponsored By: Aegis Analytical Corp.

Aegis recently conducted a survey with PharmaceuticalManufacturing.com of 538 life science professionals to understand current trends associated with collecting and managing manufacturing data. The survey showed: The biggest challenges are the amount of time spent gathering data from multiple sources, followed by analyzing data once it has been gathered. More than 24% of large life sciences companies store manufacturing data on paper, resulting in additional challenges with data analysis. Large companies have invested more heavily in IT Infrastructure – systems such as LIMS, MES, ERP – yet they still feel they spend too much time collecting data for analysis.

The Executive Guide to Contracts & Chargebacks Management

Sponsored By: CDC Ross Enterprise

When it comes to Contracts and Chargebacks – the stakes are high – as credits for chargebacks can often exceed millions of dollars each month. If you find yourself faced with addressing changing regulatory requirements, managing hundreds of

contracts, and validating and processing chargeback submissions, we encourage you to learn more in this white paper.



Packaging

TECHNICAL TRANSFER DOCUMENTATION IS KEY FOR SUCCESS

Author: Tom Hughes; Sponsored by: Carton

Clearly defined objectives and project requirements between the pharmaceutical company and their contract packager need to be spelled out – in writing – in a Technical Transfer Document prior to any pharma packaging project. A published report documenting details for the customer and the packager is a critical component for success.

Achieving a Perfect Induction Seal Every Time

Author: Ryan Schuelke; Sponsored by: Enercon

Inspired by the rave reviews of Enercon's webinar: "Achieve a Perfect Seal Every Time". This graphically rich whitepaper provides all the basic and advanced setup, operating, and troubleshooting techniques required to ensure a perfect seal every time.



Outsourcing

Topical Dermatological Formulation Development - "Things You Should Know"

Author: Vanlee Waters M.B.A., Marketing Manager; Sponsored By: Dow Pharmaceutical Sciences, inc.

"Things You Should Know" will answer many of your questions and will provide insight into issues you may not have considered -- but should be aware when developing a topical formulation. The target product profile, dosage form selection, reasons for multiple excipients, the formulation development process, prototype screening, and lead formulation selection are discussed.

A New Option in Prefilled Syringe Filling

Author: Jeanne Lawson; Sponsored by: Hylauron

Hyaluron Contract Manufacturing (HCM) offers solutions for your aseptic parenteral drug formulation and filling needs. Currently only HCM is able to fill prefilled syringes with "no" bubble through our BUBBLE-FREE FILLING® technology. We have conducted a number of studies to confirm the advantages of eliminating the bubble inside a prefilled syringe.



Analytics

Reducing the Limitations of HPLC/UFLC Analysis

Sponsored By: Shimadzu

Use of MS as an LC detector can significantly enhance LC analysis, and the new LCMS-2020 is ideally suited for this purpose, delivering the speed and quality researchers require.
