

PARCS (Pacific Region Clinical Supplies)

Friday, April 24, 2009

The Westgate Hotel, San Diego, CA

8:30 AM - 5:00 PM

Sponsor's Welcome

Lisa Soliz, Account Manager, Aptuit

Regulatory Update

David Bernstein, Ph.D., Bernstein CMC Regulatory Consulting

The recent FDA Process Validation Guidance and ICH Q4 Harmonization of tests for Uniformity of Dosage Units, Sterility Testing and Dissolution Testing will be discussed.

The Top Game-Changers for Improving Operational Excellence in the Clinical Supply Chain

RS Kumar, Senior Manager, Life Sciences, BearingPoint

This session will explore the global results of a recent Clinical Trial Supply Chain benchmark study conducted by BearingPoint and AMR Research. We will share the five game-changers that can help pharmaceutical companies identify clinical supply chain issues and adopt a new, integrated approach to accelerate time to market, reduce costs and mitigate drug development risks that adversely affect the drug pipeline. Additionally, during the afternoon breakout session, we will conduct a detailed workshop, where we will expand on these five solutions to cover aspects of implementation, business benefits, and tools needed for measuring the key metrics and ROI from this approach.

Visualization Technology for Communicating Clinical Packaging Design

Doug Murphy, EZpak Project Manager, EZpak Division, Analytical Mechanics Associates, Inc.

As clinical trials become increasingly complex and more global, the need to create and disseminate quality information about the package design and clinical supply story becomes more critical. Traditional ways of creating packaging diagrams and related graphical content can be improved upon by borrowing techniques from the aerospace and other high-tech manufacturing industries, where visualization technologies are widely used. This talk describes using these technologies to build realistic, dynamic, interactive three-dimensional models and web-compatible content to improve communication in clinical supplies.

Development and Validation of In-Vitro Release Tests for Solid and Semi-solid Dosage Forms

Kailas Thakker, Ph. D., President and CEO, Analytical Solutions Inc.

Dissolution [USP <711>] is the traditional in-vitro technique used during development to screen, select and control solid dosage forms. However, for semi-solid topical dosage forms, release of the API is based on passive diffusion of the API out of the vehicle and thermodynamic issues. The use of Franz diffusion cells for the early development of an investigational drug product and utilization of the concepts of Quality-by-Design and design space will be described. The challenges of developing meaningful test methods for oral solid and topical semi-solid dosage forms will be discussed.

Successfully Outsourcing Your Clinical Supply Project [Client Perspective]

Robert Silber, Director Supply Chain Management, Fibrogen

The selection of a clinical supply contract organization can make or break the quality and timelines for a clinical study. Various success factors based on actual experiences and case studies will outline the concepts of value versus cost and differences among quality, technical and master service agreements. This presentation will include several “Beware of” and describe the key questions to ask when in the due diligence stage of selecting a contractor.

Outsourcing Clinical Packaging, Labeling and Distribution – An Insider’s Guide to Auditing Suppliers

Christi Gimber, Director of Quality, Almac Clinical Services Division

The discussion will focus on the key concepts involved with auditing packaging, labeling and distribution contract organizations. The session will specifically address the unique challenges presented in packaging and labeling clinical supplies and identify how to avoid potential pitfalls which may be overlooked in a general GMP audit. For example, in blinded trials, control of all packaging materials, random numbers and labels is essential – yet these areas are seldom scrutinized as thoroughly as they should be. We will also cover how GCP related pieces of the clinical puzzle fit within the GMP packaging operations and are often overlooked during most audits.

Regulatory and Best Practices Impacting Temperature Controlled Drug Shipments

Kevin O'Donnell, Director and Chief Technical Advisor, Tegrant Corporation

Recent changes in regulations have made temperature controlled and cold chain shipments of drug products a dynamic consideration in investigational drug supply chain planning. This presentation will include the use of Mean Kinetic Temperature to determine if a real out-of-specification temperature event has occurred; the development of standard packaging-time protocols by the ISTA [International Safe Transit Association and PDA]; USP <1079> Good Storage and Shipping Practices.

Taking the Mystery out of Media Fills

Bob Pallo, Manager, PSO Fill and Finish Operations, Allergan, Inc.

A media run is a simulation of the aseptic process used to manufacture an ophthalmic or injectable drug product without using valuable drug. This presentation will discuss several aspects of this ‘final exam’; media run frequency, fill volumes, line speeds, interventions and how to handle media fill failures.

Workshops (from 3:00 - 5:00 PM)

attendees will be able to attend any two workshops

Wading Through the New Airline Logistics Regulations* [Kevin O'Donnell]

New IATA [International Air Transport Association] and TSA Regulations and Labeling Requirements [effective July 2009]

Visualization Tools for Clinical Supplies* [Doug Murphy]

A live demo of a 3-D modeling system for clinical packaging design will be demonstrated. Web-compatible formats for deploying multimedia content [JAVA 3D, Adobe Flash, Adobe PDF] will be reviewed in the context of creating improved clinical packaging documentation.

Best Practices for Outsourcing Clinical Supply Projects [Christi Gimber and Robert Silber]

Clinical Trial Supply Benchmarking Study* [RS Kumar]

Solutions to the top five slow spots in the clinical supply chain

- **new topic – has not been discussed in the morning presentations**



Aptuit is a pharmaceutical service company that conducts research, development and manufacturing on a contract basis for both large and small innovators. Our mission is to *engineer a better drug development process through scientific excellence* to serve these two very different clients equally well but in very different ways.

First, we are assembling a complete suite of services from discovery to proof-of-concept and constructing the related manufacturing services from discovery to launch. Along the way, we are opportunistically inventing and acquiring novel technologies and services that allow our clients to differentiate their drug development programs. Today, Aptuit has approximately 750 clients and employs over 2,750 individuals in 17 global facilities.

Aptuit's Scientific Operations segment delivers a unique global supply chain where small scale development and formulation occurs in the US and Europe with commercial scale undertaken in Aptuit Laurus' new state-of-the-art facilities in India. Aptuit Consulting overlays these capabilities with highly experienced scientists based throughout the US and Europe, each with successful track records managing multiple aspects of pharmaceutical R&D.

Aptuit's Clinical Operations segment is the second largest global provider of clinical packaging and logistics services by capacity, with over 600,000 square feet in 30 international clinical distribution sites. Within Clinical Operations, Aptuit Informatics develops, markets, and services best-of-breed, mission-critical information systems to support customers throughout the entire drug development continuum.

About the Venue, the Westgate Hotel

The Westgate, San Diego's finest premiere hotel continues to deliver on its original vision of classic luxury. The Westgate is beautifully appointed with exquisite European luxuries throughout and located in the heart of downtown San Diego, steps away from the trendy Gaslamp Quarter, fashionable shopping and historic Balboa Park. Discounted parking available.

Other Clinical Supply Events

Comparator Studies: Regulatory Compliance and Competitive Strategies for Acquisition and Use of Comparator Products in Global Clinical Trials

March 26-27, 2009, Philadelphia, PA [www.cbinet.com] For discount, contact David Bernstein

GMPs for Investigational Medicinal Products and Clinical Trial Materials

This 2-day program explains global GMP guidance and regulations and interprets them from the clinical supply perspective. Both US and EU regulatory issues are covered. June 2009 in Prague, Czech Republic. www.key2compliance.com. Available in US as an in house course.

Clinical Trial Supply USA 2009, June 3-4, 2009, San Francisco, CA, USA
For more information visit; www.clinicaltrialevents.com/usa2009

PARCS fall 2009 meeting

Friday, October 2, 2009 in San Francisco