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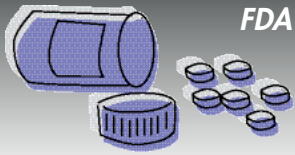
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FDA Warning Letter Excerpt: "... will not be granted until the violations related to the subject devices have been corrected ..."

**DAY ONE
MONDAY, NOVEMBER 10, 2008**

7:30 REGISTRATION AND BREAKFAST

**8:45 CHAIRPERSON'S WELCOME AND
OPENING REMARKS**

CASE STUDY

**9:00 CREATING PARTNERSHIPS FOR SUCCESSFUL
COMBINATION PRODUCT DEVELOPMENT**

*Stuart Madden PhD, Senior Vice President, Non
Clinical Services*

ICON DEVELOPMENT SOLUTIONS

Combination products are themselves a partnership between drugs and devices. To maximize the opportunity that combination products present, new partnerships between organisations and functions within organisations are vital.

The following areas will be considered in terms of forming business effective partnerships through the practical consideration of the following areas:

- Intellectual property and ownership retention
- Organisational structures, cultures, and synergy
- Cross boundary multidisciplinary team formation
- Organisational intersection management – 3 way, 2 way
- Post market surveillance issues over multiple organisations
- System, versus component, management
- Development Management System integration – pipeline filter versus evolution
- Positioning for the regulator
- Integrating competitive positioning
- Taking the high ground for business effective compliance

10:00 MID-MORNING BREAK

IN-DEPTH REGULATORY GUIDANCE

**10:15 COMBINATION PRODUCTS:
DRUG - DEVICE AND DRUG - BIOLOGIC
PRODUCTS AND THE FDA APPROACH TO
THEIR REGULATION**

Steven Kuwahara, Founder

GXP BIOTECHNOLOGY LLC.

Combination products often result in confusing and conflicting regulatory needs. Yet these products are becoming more

common and offer therapeutic advantages not seen with either type of product alone. FDA has attempted to cope with these needs by issuing guidance documents to the industry. This talk will discuss:

- The existing state of the regulations that have an impact on combination products.
- The contents of the recent guidance documents.

The participant will:

- Gain a better understanding of the regulatory environment for combination products.
- Understand the current regulatory requirements for combination products.
- Learn what constitutes a combination product as opposed to separate products.

**11:15 THE FDA AND INNOVATIVE PRODUCTS -
REGULATORY ISSUES FOR NEW IN VITRO
DIAGNOSTICS AND COMBINATION
PRODUCTS**

Richard Lowenthal, Founder

PACIFIC LINK CONSULTING

Drug/device combination products and In-Vitro Diagnostics are increasingly the focus of device companies seeking to find additional utility for their products. Pharmaceutical companies are also looking to combination products or synergistic drug and device usages as a way of extending the life-cycle of drugs or biologics. The regulatory considerations for drug/device combinations take into account both drug and device requirements as well as some unique considerations due to the nature of combination product. Novel In-Vitro Diagnostics and Combination product require careful evaluation and strategic planning to ensure that the regulatory pathway for these products is properly defined and executed. This seminar will review the regulatory requirements and strategy for drug/device combination products and the unique issues faced by companies in managing health authority requirements.

12:15 LUNCHEON

CASE STUDY

**1:15 DRUG DELIVERY: CHALLENGES,
OPPORTUNITIES, AND MECHANISMS**

Vishal K. Gupta, PhD, Director, Pharmaceutical R&D

COVIDIEN

Innovations in the field of drug delivery present both new opportunities and challenges. In this talk, therapeutic and pharmacokinetic fundamentals will be discussed. Various drug delivery concepts such as sustained release, controlled release,

delayed release, zero order release, and Higuchi's square-root kinetics will be explored. Focus will be on the mechanistic understanding of physico-chemical considerations for drug delivery.

Mechanism of drug release from matrix, reservoir, osmotic, and coated systems will be described along with common methods of fabricating such systems.

- Learn fundamental therapeutic and pharmacokinetic considerations for drug delivery
- Various drug release profiles and how to obtain them
- Gain an understanding of various mechanisms of drug release and fabrication of drug delivery devices

2:15 HIGH-PERFORMANCE DISSOLUTION: THE ROLE OF CONVECTIVE DIFFUSION AND CONTROLLED HYDRODYNAMICS FOR OPTIMAL PHARMACEUTICAL RELEVANCE

Larry Stevens, Senior Scientist
ALCON RESEARCH LTD.

It is necessary for optimal and efficient product development to have a precise and meaningful characterization of product performance. This is especially true for drug and device combination products with extended release of low drug levels. The dissolution measurement remains significantly important in characterizing such drug releasing systems minimizing the need for costly time consuming in vivo measurements. Such measurements, however, have lacked physicochemical and biological relevance and have been subject to wide analytical system variations often resulting in less than desired outcomes.

Improvements in the dissolution measurement through the control of hydrodynamics and convective diffusion have been described. These factors have been emerging as critical, and perhaps key in obtaining appropriately responsive, relevant and reliable measurements. Important to all types of dissolution, these factors are especially relevant to flow-through techniques optimally recommended for device measurements. This session will focus on better understanding and controlling these factors along with the resulting analytical and product development advantages. Among these include improved formulation and device sensitivity, reliability, physicochemical and biological relevance. Also discussed will be the improved mathematically modeling of kinetics and device designs.

- Understanding the Role of Convective Diffusion and Hydrodynamics
- Optimized Instrument and Method Considerations
- Improved Physicochemical and Biological Relevance
- Kinetics and Mathematical Modeling
- Combination Product Opportunities

3:15 AFTERNOON BREAK - 7TH INNING STRETCH

CASE STUDY

3:30 EFFECTIVE CLINICAL TRIAL STRATEGIES FOR COMBINATION PRODUCTS

Linda S. Alexander, CEO, Founder
ALQUEST INC.

This presentation will be based on years of experience working on combination product strategies and clinical trials. The presentation will provide an overview of clinical conduct including budgets, subject enrollment, and special challenges for combination product clinical trials including strategies for communicating with FDA. Ms. Alexander will offer ideas for reducing clinical trial time and costs and managing internal and external expectations about the process.

4:15 INTERACTIVE PANEL DISCUSSION:

INCLUDING ALL DAY ONE SPEAKERS

- Current trends in combination drug development
- Variations in international acceptance of combination products
- How to determine the commercial scope for combination products, which two products are market compatible?
- Why are combination products the future of drug formulation in the 21st Century?
- Questions and answers

5:00 END OF DAY ONE

DAY TWO

TUESDAY, NOVEMBER 11, 2008

7:45 BREAKFAST

7:55 CHAIRPERSON'S OPENING REMARKS

CASE STUDY

8:00 DRUG-ELUTING STENTS: DOES THE STATUS QUO MAKE SENSE? WHAT MORE CAN THEY DO?

Michael Drues, PhD, President
VASCULAR SCIENCES

The focus of this session will be on one of the most commonly used and controversial products in medicine today – the drug-eluting stent. This session will provide a critical look at the drug-eluting stent as it exists today. What are they supposed to do? What do they really do? Does what we do today make sense? Are problems like chronic in-stent thrombosis really “unexpected?” The better we understand the advantages and

limitations of current technologies, the better poised we will be to move intelligently into the future.

This session will conclude with a view into the future of the drug-eluting stent. What we have today is child's play by comparison! Why do we think of a drug-eluting stent as a stent? By incorporating multiple drugs, biologics and a wide range of biotherapeutics into a single device, a.k.a. a "multiple combination product" or better a biotherapeutic carrying vehicle, we can use a drug-eluting stent as a syringe to treat far more than simply atherosclerosis. Potential applications include diabetes, cancer, Alzheimer's, gene therapy and angiogenesis, just to name a few!

9:00 OPTIMAL LABORATORY PRACTICES FOR THERMAL GEL DESIGN AND SPECIFICATION FOR TEMPERATURE CONTROLLED PACKAGING OF COMBINATION PRODUCTS

Karen Greene, Technical Director

DDL

The significant development of the biotechnology market sector, specifically for the treatment of human health, has expanded the need to ship temperature sensitive protein based biotechnology and biopharmaceutical combination products globally. This sector growth and its temperature controlled packaging requirements have focused the business need for cost effective, targeted, high performance thermal packaging. The engineering sophistication of these temperature controlled products demand greater thermal performance protection than frozen water in a bag.

This presentation will outline well reasoned and laboratory challenged practices for optimal thermal gel design and specification. The presentation will provide laboratory studies which illustrate the thermal performance of critical design inputs for gel refrigerants. The presentation will educate the audience to the important design considerations when evaluating competing refrigerant designs and will provide you with information on how to set up laboratory studies which can more precisely demonstrate temperature controlled packaging performance in the field.

10:00 MORNING BREAK

10:15 PARENTERAL DRUG DELIVERY SYSTEMS AND THE IMPORTANCE OF A PROTECTOR SAFETY SHIELD SYSTEM™ WITH PRE-FILLED SYRINGES

Mico Holquin, MBA, Director, Business Development, Sterile Technologies Group
CATALENT

Simon Cohen, MD, Managing Director
INNOVATE UK

This presentation will contribute to understanding the challenges and decision making process regarding the

development, and outsourcing of drug delivery systems with emphasis on pre-filled syringes with a safety device.

The most prominent trend in the pharmaceutical industry in the past few years has been the change in the pipeline portfolio from small molecule to large molecule compounds.

Large pharmaceutical companies are generally capacity constrained to support various drug delivery systems and biotechnology companies typically lack the manufacturing infrastructure/operations to support their needs for their expanding portfolio and are looking to various outsourcing networks to provide various drug delivery systems to support clinical trials and/or new indications.

Pre-filled syringes are the most preferred option of delivery of vaccines and/or biologics based drugs for several reasons. In addition, the recent changes in the health care reimbursements etc are forcing companies to find ways by which patients rely more on self injectable drugs/ in home medication vs. going to a hospital.

This has resulted in driving the outsourcing market for the most efficient and safe system to deliver the drug to the patient as well as prevent injury. When vials or IV bags do not support marketing or patient requirements, a pre-filled syringe and device injectable combination product is the preferred alternative. Subsequently, needlestick injuries are of increasing concern to Caretakers and healthcare workers. Estimates suggest that in the United States, between 380,000 and 800,000 hospital-based health care providers sustain sharps injuries annually

Whilst all practices should have a policy for sharps injuries, prevention of needle stick injuries remains the best policy. Recent regulations establish the parameters of using safety shield in order to minimize needle stick injuries.

This presentation will focus on understanding the challenges and key drivers in the development and outsourcing of drug delivery systems with emphasis on pre-filled syringes. In addition, device combination product such as needle safety devices to prevent needle stick injury will be discussed.

11:15 ADVANCES IN BIOMEDICAL ENGINEERING: A VIEW TO THE FUTURE

Michael Drues PhD, President

VASCULAR SCIENCES

This session will explore the dynamic world of biomedical engineering and the extraordinary potential for the future of the medical device industry. Case studies from a variety of clinical specialties will be discussed to provide attendees insight into the convergence of the life science industries and explore the innovations and opportunities currently available for furthering product development. It will provide an overall perspective on current advances in biomedical engineering and the impact they will have on technology. The presentation concludes with a look at the future of medical device industry including combination products, tissue engineering, nanotechnology and beyond!

12:15 LUNCHEON

1:15 THE ROLE OF SYSTEMS INTEGRATION IN THE COMMERCIAL PRODUCTION OF MEDICAL DEVICES

*Tom Graves, Business Development,,
Mikron Corporation Denver*
MIKRON ASSEMBLY TECHNOLOGY

A Systems Integrator typically provides production equipment for the controlled manufacture, assembly, test, inspection and packaging of medical devices. This presentation will include a discussion on the following topics:

- Design for manufacturability and assembly
- Production scale-up considerations - manual, semiautomatic, fully automatic
- Business considerations - cost, schedule, facilities
- FDA equipment validation
- Why, when and how to select a systems integration partner? Benefits to be expected from this partnership
- How to manage manufacturer and integrator expectations

2:15 AFTERNOON BREAK - 7TH INNING STRETCH

CASE STUDY

3:30 UNDERSTANDING THE COMMON AND CONFLICTING REQUIREMENTS OF CGMP AND QSR WITH COMBINATION PRODUCTS

Steven Kuwahara, Founder
GXP BIOTECHNOLOGY LLC.

The session will cover the common and conflicting regulatory requirements between drug and device GMPs as applied to combination products. The problems often arise because of the application of different areas of the GMPs and also the definitions related to the “primary mode of action.” In some cases such as with OOS test results these differences lead to differences in the approach taken to dealing with the problems. In other cases conflicts arise because different groups have different ideas regarding the mode of action of the combination product.

The audience will learn about:

- The FDA and other regulatory requirements
- Requesting the FDA’s help in defining the combination product
- The particular parts of the GMP that lead to conflicts
- Conflicts that have arisen in the past and their resolution

4:15 CLOSE OF CONFERENCE



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