

FDA Warning Letter Excerpt: "... failure to have written procedures for stability testing and to perform stability testing for drug products ..."

STABILITY TESTING

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LILLY RESEARCH LABORATORIES Stability Indicating Methods in the Pharmaceutical Industry: Regulatory Expectations and Strategies	CARDINAL HEALTH Strategies for International Product Registrations

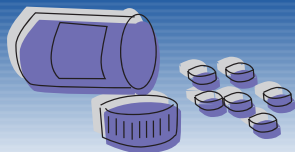
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DAY ONE
THURSDAY, OCTOBER 19, 2006

7:30 REGISTRATION AND BREAKFAST

8:30 CHAIRPERSON'S WELCOME AND OPENING REMARKS

MEETING REGULATORY REQUIREMENTS FOR STABILITY DATA

8:45 SCIENTIFIC BASIS OF PHARMACEUTICAL STABILITY AND GLOBAL REGULATORY REQUIREMENTS

Prabu Nambiar, Ph.D. MBA, RAC Sr. Director, CMC Regulatory Affairs
CUBIST PHARMACEUTICALS

Stability is one of the critical quality attributes of any pharmaceutical product and any deviation from the defined limits might affect the safety and/or efficacy of the product and render it unsuitable for the intended purpose. Establishing the stability profile of pharmaceutical product is a key CMC development activity that involves a number of systematic studies on the active pharmaceutical ingredient, intermediates, and the finished product under various conditions and configurations. It is important to keep in mind of all the possible environmental conditions the product could be exposed to, starting from manufacturing throughout the supply chain. The ICH guidances Q1A, Q1B, Q1C, Q1D, Q1E, Q1F and Q5C define various aspects of stability data package required for registering a new drug substance or drug product. This seminar presentation will cover the scientific basis of pharmaceutical stability and its connection to safety and efficacy of the product, and highlight the regulatory requirements for generating the appropriate stability data for filing new drug applications.

CASE STUDY

9:45 COMPONENTS OF STABILITY PROTOCOLS, SUMMARY REPORTS, AND ANNUAL PRODUCT EVALUATION REPORTS

Pat Bell, Manager, Stability
WYETH

This session will examine various components of stability testing by analyzing stability protocols for marketed products, stability summary reports and annual product evaluation reports. Attendees will gain insight into what FDA inspectors are looking for when conducting inspections regarding stability programs, protocols and summary reports.

- I. Stability Protocols for Marketed Products
 - Learn the components and commitments that need to be included in the Post-Marketed Protocols
 - Gain insight on the design and format of protocols
 - Receive examples of protocols for the CMC submission vs. abbreviated protocols that Stability Supervisors can use to implement new and ongoing studies
 - Understand how revisions and change control affect stability programs and protocols
- II. Stability Summary Reports
 - Learn how to design and format summary reports to satisfy FDA guidelines and pass inspections
 - Gain insight on how to cross-reference OOS results and special studies within the summary reports
 - Learn what FDA Inspectors often ask while conducting inspections regarding stability programs, protocols, and summary reports
- III. Annual Product Evaluation Reports
 - Learn the scope and components of Annual Product Evaluation Reports (APER)
 - Receive advice on the details to be included within the stability section of the APER
 - Gain knowledge and an example of a statistical analysis program used for evaluating data and trends for the APER

10:45 MID-MORNING BREAK

IN-DEPTH COVERAGE ON BRACKETING AND MATRIXING

CASE STUDY

EX-FDA

11:00 COST EFFICIENT DESIGN OF STABILITY STUDIES

David Lin, Senior Consultant,
BIOLOGICS CONSULTING GROUP
Former Chemistry Division Director, CDER, FDA

A drug stability program can include multiple packaging configurations and even multiple dosage strengths. The simplest program design would be to include all packaging configurations and dosage strengths. However, this design results in wasted resources and does not necessarily yield additional useful data. This presentation will discuss the concept and implementation of bracketing and matrixing design for stability testing.

- Understand the concept of bracketing and matrixing
- Bracketing and matrixing designs
- Applying designs with examples

12:00 LUNCHEON

EXTENDED SESSION

CASE STUDY

1:00 DEVELOPING OPERATIONAL EXCELLENCE IN STABILITY STORAGE OPERATIONS

Michael Barron, MBA, Director of Stability Services
CARDINAL HEALTH

This interactive session will cover the most pressing issues for implementing mistake-proof and fail-safe operations. Sample traceability is the theme and there are many functional and procedural aspects for consideration.

I. What To Expect During Regulatory Inspections

- Questions to expect
- Common areas of concern
- Things inspectors like to hear and see
- Preparing for inspections

II. Zero Tolerance for Errors

- Content of SOPs for critical functions
- Protocol generation
- Sample set-up and pulls
- Stability calendar maintenance
- Inventory
- Storage condition monitoring

III. Storage Chambers

- Qualification overview
- Monitoring systems
- Disaster recovery plans

2:45 AFTERNOON BREAK - 7TH INNING STRETCH

CASE STUDY

3:00 UTILIZING CONTRACT LABS TO MAXIMIZE STABILITY PROGRAMS

Gregory Kupp, Director of Pharmaceutical Chemistry and Client Services
LANCASTER LABORATORIES

Collaborating with contract laboratories as a means to assist with stability testing has proven to be advantageous to firms in a variety of ways. The use of contract laboratories allows firms to focus their resources on core competencies, limits the investment on expanding overall capacity in terms of both capital equipment and personnel, and enables firms to keep more projects moving simultaneously. Outsourcing also presents some challenges that firms can effectively plan for in advance such as effective transfer of analytical methods, effective communication, and handling of out-of-trend (OOT) or out-of-specification (OOS) results. During this session, the following topics regarding the use of contract laboratories for stability testing will be presented and discussed.

- Advantages of outsourcing stability study testing to a contract laboratory
- Challenges of outsourcing that can be addressed with appropriate planning and communication
- Expectations of a contract laboratory and what to look for during a vendor audit
- Best practices and examples of successful outsourcing relationships in the contract laboratory environment
- How to manage and achieve effective investigation and deviation procedures with a contract laboratory

4:00 CONSIDERATIONS AND CHALLENGES WHEN IMPLEMENTING A STABILITY MANAGEMENT SYSTEM

Parsa Famili, President
Susan Cleary, Director
NOVATEK INTERNATIONAL

During this comprehensive session, attendees will learn what criteria should be evaluated when selecting, implementing and validating a stability system. Reporting of stability study data will also be addressed. Attendees will learn:

- How to select the right Stability System
 - Software (OTS, Configurable OTS, Customized)
 - GAMP Validation approach based on software type
 - Vendor Audit
- How to pilot Stability System
 - Training
 - Configuration requests
 - Control logs
 - User acceptance testing
- How to Validate the Stability System, meeting 21 CFR part 11
 - Documentation
 - SOPs
 - IQ/OQ/PQ
 - Risk Assessment
- How to apply the EM system to assist in reporting Stability study data
 - Reports
 - Statistics
 - What makes a complete report package

5:15 INTERACTIVE PANEL DISCUSSION STABILITY ISSUES

INCLUDING ALL DAY ONE SPEAKERS

- Current Stability Issues
- ICH/FDA Guidelines for Stability Testing
- Discuss Advances and Efficiency in Stability Programs
- Question and Answer

5:45 END OF DAY ONE

DAY TWO
FRIDAY, OCTOBER 20, 2006

7:30 BREAKFAST

8:15 CHAIRPERSON'S OPENING REMARKS

8:30 **IN-USE TESTING OF BIOTECHNOLOGICAL AND BIOLOGIC PRODUCTS**

David Lin, Senior Consultant
BIOLOGICS CONSULTING GROUP

EX-FDA *Former Chemistry Division Director, CDER, FDA*

It is well understood that the storage conditions can have an adverse effect on the quality of a biologic product. Stability studies can be designed and conducted to understand these adverse effects and also mitigate the risk during storage. One aspect that is less understood and planned is the adverse effect on quality once in possession by the end-user. This presentation will discuss the need and relevance for in-use stability studies and what to consider when setting up this testing program.

- The need and relevance for in-use stability studies
- Stability under handling and administration conditions:
- In use shelf life
- Compatibility with administration material
- Points to consider from manufacturing to administration
- Guidelines and requirements

CASE STUDY

9:15 **HOW TO INTEGRATE LIMS TO OPTIMIZE STABILITY PROGRAMS**

Pat Bell, Manager, Stability
WYETH

Pharmaceutical companies are overwhelmed by the amount of data that needs to be gathered during their stability testing studies. This data has to be documented, validated, analyzed, reported and archived. Many companies have implemented Laboratory Information Management Systems (LIMS) in an effort to save time and money. This session will explore how to integrate LIMS into your stability program while remaining in compliance.

- Choose the system that fits best with your stability program
- Write "good" functional requirements
- Determine which variables to include when customizing your LIMS
- Validate new systems and processes
- DQ, IQ, OQ and PQ
- Ensure fast and easy access to stored stability data – Data warehousing and retrieval
- Create contingency plans

10:15 MID-MORNING BREAK

EXTENDED SESSION ON
STABILITY PROTOCOL DEVELOPMENT

CASE STUDY

10:30 **STRATEGIES FOR INTERNATIONAL PRODUCT REGISTRATIONS**

Michael Barron, MBA, Director of Stability Services
CARDINAL HEALTH

In this interactive session we'll canvas both universal protocol requirements and provide updates for published guidances on a global basis. Learn ideas for being a stability thought leader in your company.

I. Regulatory Guidance Updates

- ICH
- US, EU, and Japan
- WHO
- China
- Southeast Asia
- Australia
- South Africa
- Brazil

II. Stability Protocol Requirements

- Regulatory status
- Batch selection
- Storage conditions and timepoints
- Test methods and specifications

III. Benefit vs. Risk

- Safety/efficacy/elegance
- Manufacturing issues
- Packaging considerations
- Distribution challenges

IV. Storage conditions and timepoints to satisfy various regulatory filing

- Which long term storage condition(s) for testing?
- Which, if any, intermediate storage conditions?
- Which accelerated conditions?
- Which stress conditions?

12:00 LUNCHEON

CASE STUDY

1:00 STABILITY INDICATING METHODS IN THE PHARMACEUTICAL INDUSTRY: REGULATORY EXPECTATIONS AND STRATEGIES

Dr. Stefan Adam - Teamleader, Analytical Product Research and Development,
LILLY RESEARCH LABORATORIES

Stability indicating methods are required for submission to the authorities. With the end in mind, development of stability indicating methods for API's and DP's should occur in early phase development. This presentation focuses on regulatory expectations for stability indicating ability of methods and strategies to develop those methods.

- What stability indicating testing means?
- What methods need to be stability indicating
- How to develop stability indicating methods?
- How to prove stability indicating ability of the method?

INCLUSIVE WORKSHOP

2:00 IMPROVED LAB EFFICIENCY TO ENSURE FDA COMPLIANCE FOR STABILITY TESTING RECORDS

Charles Sodano, PhD, Manager, Information Services
BERLEX LABORATORIES

A rigorous records management program is essential for laboratory data, documents, and records. Records help meet current operational needs; provide legal and regulatory accountability and provide a memory to build on.

I. Records Essentials

- What are records?
- What is the purpose of records?
- Appreciate how records management can improve the efficiency of laboratories
- Learn how to categorize records based on business and regulatory needs
- Learn how to manage the life cycle of your records

II. Compliance to FDA requirements

- Understand current FDA requirements for record retention
- Learn about recommendations from FDA sources about managing stability testing records
- Gain insight into future regulatory requirements

III. Records Archiving to assure future usability and compliance

- Learn about International models and standards for archiving
- Review options for long term preservation
- Consider the choices for hardware and software that will be most efficient

About the workshop leader: **Charlie Sodano** is an experienced information management professional within the research and development field. He began his career as a research chemist at Pfizer and served as Information Services Manager at Nabisco, Inc. He is currently at Berlex Biosciences in Richmond California where he has responsibility for electronic and paper records management, the technical library and administration of global research electronic information systems. He holds baccalaureate and masters degrees in Chemistry from Seton Hall University and earned a Ph.D. in organic chemistry from Arizona State University

5:15 CLOSE OF CONFERENCE



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