Supplemental USP <797> Background Information

Implementing a Regional Compounding Program for Compounded Sterile Preparations:

Practical strategies, a USP <797> approach.

Lou Diorio, RPh

Principal

LDT Health Solutions, Inc.

2010 IDN Summit and Expo
April 20, 2010
Walt Disney World Swan, Orlando FL

IDN SUMMIT AND EXPO

The Objective of USP <797>…

- "…is to describe conditions and practices to prevent harm, including death, to patients…"*

* Introduction: USP <797> Pharmaceutical Compounding- Sterile Preparations © USP

IDN SUMMIT AND EXPO

USP Chapter <797> Sections:

- Definitions
- Responsibilities of compounding personnel
- CSP microbial contamination risk levels
- Personnel training and evaluation in aseptic manipulation skills
- Immediate use CSPs
- Single-dose and Multiple-dose containers
- Hazardous drugs as CSPs
- Radiopharmaceuticals as CSPs
- Allergen Extracts as CSPs
- Verification of Compounding Accuracy and Sterility
- Environmental Quality and Control
- Suggested Standard Operating Procedures (SOPs)
- Elements of Quality Control
- Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding
- Finished preparation release checks and tests
- Storage and beyond-use-dating
- Maintaining Sterility, Purity, and stability of Dispensed and Distributed CSPs
- Patient or Caregiver training
- Patient monitoring and adverse event reporting
- The Quality Assurance (QA) Program
- Abbreviations and Acronyms
- Appendices I-V

IDN SUMMIT AND EXPO

Responsibilities of Compounding Personnel-

- Personnel are adequately educated, instructed, and skilled to perform their functions
- Ingredients have correct identity, quantity, amount
- Open/partial containers are properly stored
- Minimize bacterial endotoxins
- Proper and adequate sterilization is used
- Equipment is clean, accurate, appropriate
- Potential harm from added substances considered
- Packaging is appropriate for sterility, stability
- Compounding environment maintains the sterility of pre-sterilized items
- Labels are appropriate and complete
- Beyond-use-dates are appropriate and based on valid scientific criteria
- Correct compounding procedures are used
- Deficiencies in compounding can be rapidly identified and corrected
- Separate compounding from quality evaluation

IDN SUMMIT AND EXPO

Verification of Compounding Accuracy and Sterility

- Compounding procedures and sterilization methods correspond to correctly designed and verified written documentation.
- Verification requires-
  - Planned testing
  - Monitoring
  - Documentation
    - Sterility Testing USP <71> [Low & Medium Risk]
    - Use of Biological Indicators [High Risk]

IDN SUMMIT AND EXPO

Verification of Compounding Accuracy and Sterility

- What this means is a review of…
  - (for) Visual examination for particulates
  - The prescription order
  - The written compounding procedures
  - The preparation records
  - The expended materials
- What you are looking for is…
  - Accuracy and correctness of identities and amounts of ingredients
  - Aseptic mixing
  - Proper sterilization, packing and labeling
  - …the expected physical appearance of the CSP before dispensing or administration.

IDN SUMMIT AND EXPO

Standard Operating Procedures-

- Each compounding site shall have written, properly approved SOPs designed to ensure the quality of the environment in which the CSP is prepared.
  - There are 23 recommendations within the chapter.
  - This list is obviously not all-inclusive!

IDN SUMMIT AND EXPO

Standard Operating Procedures-

- SOPs:
  - Must reflect current practices.
  - Available to all employees.
  - Must tie to any forms or documents in use.
  - Must be consistent throughout the organization.
  - Must be reviewed and updated regularly.
  - Must be the basis of any “controlled processes” developed for the organization.

IDN SUMMIT AND EXPO

Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding

BBraun Pinnacle™ Device

Baxa EM-2400™ Device

IDN SUMMIT AND EXPO

Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding

- If used and maintained properly ACDs can provide improved accuracy and precision of the compounding process over traditional manual compounding methods.
  - Personnel must maintain daily records and review these records over time for device accuracy.
  - Follow manufacturer's recommendations for the device and its software.

IDN SUMMIT AND EXPO

Finished Preparation Release Checks and Tests

- Physical Inspection
- Compounding Accuracy Checks
- Sterility Testing
- Bacterial Endotoxin (Pyrogen) Testing
- Identify and Strength Verification of Ingredients

IDN SUMMIT AND EXPO

Storage and Beyond-Use Dating

"USP <797> Matrix"

Low Risk Level CSPs	Low risk Level CSPs w/ 12hr or Less BUD	Medium Risk Level CSPs	High Risk Level CSPs
48 Hours Room Temperature	12 Hours Room Temperature	30 Hours Room Temperature	24 Hours Room Temperature
14 Days Refrigerated	N/A	9 Days Refrigerated	3 Days Refrigerated
45 Days Frozen	N/A	45 Frozen	45 days Frozen

IDN SUMMIT AND EXPO

Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs

- The compounding facility is responsible for the proper packaging, handling, transport, and storage of CSPs.
- This includes the appropriate education, training, and supervision of the compounding personnel assigned to these functions.
  - Cold chain transport
  - Tamper evident packaging
  - Redispensed CSP policies

Quality Assurance Program

- Requires formalized policies, controlled processes and clear procedures used in preparing CSPs
- One element of quality that is not routinely performed in pharmacies is documentation, or “written proof” that compounding is occurring properly.

IDN SUMMIT AND EXPO

“Controlled Process”-

- “A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products must be developed for each site.” [1]
- “Controlled processes” are based upon best practices and have been analyzed for possible points of failure. They are not based upon oral history or perceived “*Secundum Artum.*”

- 1- USP General Chapter <797> Elements of Quality Control –pg 35

IDN SUMMIT AND EXPO

The Objective of USP <797>…

Review

- "…is to describe conditions and practices to prevent harm, including death, to patients…"*

* Introduction: USP <797> Pharmaceutical Compounding- Sterile Preparations © USP

IDN SUMMIT AND EXPO

Bibliography-

- General Chapter USP <797> - www.usp.org
- Controlled Environmental Testing Association (CETA) – www.CETAinternational.org
- Pharmacy Purchasing and Products Magazine- www.pppmag.org
- Impact of USP Chapter <797>: Results of a National Survey Am J of Health Syst Pharm 2006;63(14):1336-1343 (Candy TA, Schneider PJ, Pedersen CA.)
- Blueprint for implementing USP <797> for compounding sterile preparations Am J of Health Syst Pharm 2005;61(18):1928-1938 (E. Kastango)
- Pharmacy Practice News-Special Report (Oct 2008) Outsourcing Compounding Services to meet USP <797> Requirements: An Overview (M. Sanborn)
- ASHP / Baxter discussion guide on USP Chapter <797> for Compounding Sterile Preparations- (Buchanan et.al.)

IDN SUMMIT AND EXPO

QUESTIONS?

- Lsdiorio@LDTRx.com

THANK YOU!

www.LDTRx.com