



## Gap Analysis USP 797 Check List

**Facility Name:**

**Date of Assessment:**

### Assessment Team:

This gap analysis looks at each of the individual components to determine existing conditions in the facility and compares the existing conditions to requirements to be compliant with USP 797 revisions effective June 2008.

USP 797 has many facets that can be broken down into three major sections for reviewed. Each section will be reviewed in this document to determine the current conditions. The current conditions will be evaluated against USP 797 requirements and gaps will be identified. The second phase will be to develop an action plan for compliance.

Method: Materials entering the facility will be tracked from receipt to use to determine the current facilities and practices used in the handling of the materials. The tracking will consider facilities, documentation and personnel factors.

Facility and equipment considerations will include receiving, storage, and preparation.

Documentation will include policies, procedures, logs and training records

Personnel will include qualifications and training

USP 797 criteria:

#### Facilities and equipment

- Environmental quality and control during the processing of Compounded Sterile Products.
- Equipment used in the preparation of Compounded Sterile Products.
- Verification of automated compounding devices. Includes pumps and compounders.
- Storage both pre and post preparations

#### Documentation

- Basis of classification of risk level. ( low – medium – high)
- Procedures for verification of compounding accuracy
- Procedure for in process checks
- Finished preparation release checks and tests



- Beyond use dating procedure
- Procedure for quality and control after the product leaves the pharmacy
- Procedure for determining handling, storage and transport of compounded sterile products
- Patient and caregiver training
- Procedure for patient monitoring and adverse events reporting

Personnel

- Procedures for training pharmacy personnel
- Procedures for evaluation of pharmacy personnel preparing Compounded Sterile Products

**Evaluation: Facility and equipment-** The facility design and environmental controls are in place and functioning correctly.

**Incoming materials storage -** The incoming materials are logged into the pharmacy and placed into a storage area that is temperature controlled. The controlled environment that is to be monitored and results documented for temperature.

<b>Existing condition ( Indicate if Gap)</b>	<b>Expectation</b>	<b>Gap</b>
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Controlled Environment	Controlled Environment*	
Environment not Monitored	Environment Monitored	
Temperature documented	Temperature documented	

**Pre preparation area –** The pre preparation area is used for preparing material for use in the compounding of sterile products. The are is temperature controlled and contains storage and preparation surfaces for the products to be processed prior to entry into the compounding area. The area has proper lighting and ceiling, walls and floor are cleanable surfaces.

<b>Existing condition</b>	<b>Expectation</b>	<b>Gap</b>
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Controlled Environment	Controlled Environment*	
Environment not monitored	Environment Monitored	
Surfaces cleanable	Surfaces cleanable	





Pressurization verification    semi annually

Viabile air sampling            semi annually

**After preparation storage** – After preparation the compounded sterile produces are placed into a storage environment of either room conditions, refrigeration or freezer depending on product and dating requirements.

**Microbiological Beyond Use Dating**

<u>Risk Level</u>	<u>Room Temperature</u>	<u>Refrigeration</u>	<u>Freezer</u>
			<b>&lt;-20 C</b>
Low	48 hours	14 days	45 days
Medium	30 hours	9 days	45 days
High	24 hours	3 days	45 days

**Existing condition  
Gap**

**Expectation**

Storage to meet requirements    Yes \_\_\_\_\_ No \_\_\_\_\_

**Verification of automated compounding devices**

Automated compounding devices used in the facility?    Yes \_\_\_\_ No \_\_\_\_\_

If yes attach verification procedures

\* Controlled Environment – Maintain manufacturers temperature and humidity requirements that will allow the products to retain the manufacturers expiration date.

**Evaluation of Documentation**

**Basis of classification of risk level. ( low – medium – high)**

**Low Risk Conditions**



1. Compounder with aseptic manipulations entirely within ISO class 5 or better air quality using only sterile ingredients, product components and devices
2. The compounding involves only transfer, measuring and mixing manipulations with closed and sealed packing systems. Operations performed promptly and attentively.
3. Manipulations are limited to aseptically openings ampoules, penetrating sterile stoppers on vials with sterile needles and syringes and transferring sterile liquids.
4. For low risk preparations, in the absence of passing a sterility test, the storage periods cannot exceed storage requirements ( 48 hours at room temperature – 9 days for refrigeration and forty five days for frozen)

#### Quality Assurance measures for low risk

- Routine disinfection and air quality testing of the direct compounding environment
- Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles
- Review of orders and packages of ingredients to assure the correct identity and amounts of ingredients are compounded
- Annual media fill – See UPS 797 example

#### **Medium Risk Conditions**

1. Compounder with aseptic manipulations entirely within ISO class 5 or better air quality using only sterile ingredients, product components and devices
2. The compounding involves only transfer, measuring and mixing manipulations with closed and sealed packing systems. Operations performed promptly and attentively.
3. Manipulations are limited to aseptically openings ampoules, penetrating sterile stoppers on vials with sterile needles and syringes and transferring sterile liquids.
4. For low risk preparations, in the absence of passing a sterility test, the storage periods cannot exceed storage requirements ( 30 hours at room temperature – 9 days for refrigeration and forty five days for frozen)
5. Multiple individual or small doses of sterile products are combined or pooled to prepare compounded sterile products that are administered either to multiple patients or to one patient on multiple occasions.
6. The compounding process includes complex aseptic manipulations other than a single volume transfer.
7. The product does not contain broad spectrum bacteriostatic substances and they are administered over several days.



#### Quality Assurance measures for medium risk

- Routine disinfection and air quality testing of the direct compounding environment
- Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles
  
- Review of orders and packages of ingredients to assure the correct identity and amounts of ingredients are compounded
- Annual media fill more challenging – See UPS 797 example

#### High Risk Conditions

1. Non sterile ingredients, including manufactured products for routes of administrations (see USP 797 p-3124) are incorporated or a non sterile devices are employed before terminal sterilization.
2. Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to ISO class 5. This includes storage in environments inferior to ISO class 5 or opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives.
3. Non sterilized preparations are exposed for at least six hours before being sterilized.
4. It is assumed but not verified by examination of labeling and documentation from suppliers or by direct determination that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened packages of bulk ingredients.
5. For high risk preparations in the absence of passing a sterility test the storage periods cannot exceed 24 hours at controlled room conditions, 3 days at refrigerated temperatures or 45 days at frozen temperature.

#### Quality Assurance measures for high risk

- Routine disinfection and air quality testing of the direct compounding environment
- Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles
- Review of orders and packages of ingredients to assure the correct identity and amounts of ingredients are compounded
- Semi annually media fill – See UPS 797 example



**Existing condition  
Gap**

**Expectation**

Low and Medium Risk

Based on operations

**Procedure for verification of compounding accuracy**

Written procedures for double checking compounding accuracy must be followed for every product during preparation and immediately prior to release. Compounding personnel must visually confirm that ingredients measured in syringes match the written order being compounded.

**Existing condition  
Gap**

**Expectation**

Procedure Exist?

Procedure Exist Yes \_\_\_\_ No \_\_\_\_

**Procedure for in process checks**

Compounding personnel must visually confirm that ingredients measured in syringes match the written order being compounded.

**Existing condition  
Gap**

**Expectation**

Procedure Exist?

Procedure Exist

**Beyond use dating procedure**

Beyond use dating is determined by two factors:

1. The manufacturers expiration date
2. The storage dating based on USP recommendation or sterility testing data

**Microbiological Beyond Use Dating**



<u>Risk Level</u>	<u>Room Temperature</u>	<u>Refrigeration</u>	<u>Freezer</u>
Low	48 hours	14 days	<-20 C 45 days
Medium	30 hours	9 days	45 days
High	24 hours	3 days	45 days

### Existing condition Gap

### Expectation

Procedure Exist?

Procedure Exist

Procedure for quality and control after the product leaves the pharmacy

Compounding personnel must include specific handling instructions. Temperatures of the products should be ascertained during transport to determine that they do not exceed the warmest temperature specified on the storage temperature range on the compounded sterile products label. Periodic review of the routes and duration of transport should be conducted.

### Existing condition Gap

### Expectation

Procedure Exist?

Procedure Exist

### Patient and caregiver training

A formal training program training program is provided as a means to ensure understanding and compliance with the many special and complex responsibilities placed on the patient or caregiver for the storage, handling and administration of compounding sterile products.

Upon conclusion of the training program the patient or caregiver should correctly and consistently be able to do the following: (See expectations USP 797 revision 12/07 Page 45 )



## **Existing condition Gap**

Training Exist?

## **Expectation**

Training Exist

### **Procedure for patient monitoring and adverse events reporting**

The standard operating procedures of compounding facilities must describe specific instructions for receiving, acknowledging and dating receipts for recording or evaluating reports of adverse events. This is to include the quality of preparations claimed to be associated with compounded sterile products. Reports of adverse events with compounded sterile products must be reviewed promptly and thoroughly.

## **Existing condition Gap**

Training Exist?

## **Expectation**

Training Exist

### **Evaluation - Personnel**

## **Procedures for training pharmacy personnel - Testing for evaluation of pharmacy personnel**

Personnel who prepare compounded sterile products must be provided with appropriate training from expert personnel, audio-video instructional sources, and professional publications.

Personnel shall perform didactic review, pass written testing and perform media testing of aseptic manipulative skills. Frequency of testing is based on the risk level of manipulations performed in the preparation area.

- Low Risk - Annually
- Medium Risk - Annually
- High Risk - Semi Annually

Training includes hand washing, gowning and aseptic technique



Testing includes finger tip after gloving and media testing

**Existing condition  
Gap**

**Expectation**

Training exist hand washing      Training Exist  
Training exist gowning              Testing Exist  
Training exist aseptic technique    Training Exist

Testing exist finger tip              Testing procedures exist  
Testing exist media fill              Testing materials and procures exist

**Summary of Gap Analysis**

**Evaluation: Facility and equipment**

**Incoming materials storage**

**Existing condition  
Gap**

**Expectation**

Controlled Environment      Controlled Environment\*  
Environment not monitored    Environment Monitored

**Pre preparation area**

**Existing condition  
Gap**

**Expectation**

Controlled Environment      Controlled Environment\*  
Environment not monitored    Environment Monitored  
Surfaces cleanable              Surfaces cleanable



**Preparation area**

**Existing condition  
Gap**

**Expectation**

Barrier Isolator	Procedures Exists
Room – clean and un trafficked	Clean and un trafficked
Particulate verification	semi annually
Pressurization verification	semi annually
Viable air sampling	semi annually

**After preparation storage**

**Existing condition  
Gap**

**Expectation**

Storage to meet requirements	Storage to meet requirements
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**Verification of automated compounding devices**

Automated compounding devices used in the facility?

**Evaluation: Documentation**

**Basis of classification of risk level. ( low – medium – high)**

**Existing condition  
Gap**

**Expectation**

Low and Medium Risk	Based on operations
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**Procedure for verification of compounding accuracy**



**Existing condition  
Gap**

**Expectation**

Procedure Exist?

Procedure Exist

**Procedure for in process checks**

**Existing condition  
Gap**

**Expectation**

Procedure Exist?

Procedure Exist

**Beyond use dating procedure**

**Existing condition  
Gap**

**Expectation**

Procedure Exist?

Procedure Exist

Procedure for quality and control after the product leaves the pharmacy

**Existing condition  
Gap**

**Expectation**

Procedure Exist?

Procedure Exist

**Patient and caregiver training**

**Existing condition  
Gap**

**Expectation**

Training Exist?

Training Exist



**Procedure for patient monitoring and adverse events reporting**

**Existing condition  
Gap**

**Expectation**

Training Exist?

Training Exist

**Evaluation - Personnel**

**Procedures for training pharmacy personnel - Testing for  
evaluation of pharmacy personnel**

**Existing condition  
Gap**

**Expectation**

Training exist hand washing

Training Exist

Training exist gowning

Testing Exist

Training exist aseptic technique

Training Exist

Testing exist finger tip

Testing procedures exist

Testing exist media fill

Testing materials and procures exist