

The Top 10 Gaps in USP 797 Compliance



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Disclaimer

“Although I am a member of the USP Sterile Compounding Expert Committee, I am speaking today in my individual capacity and not as a member of the Committee or as a USP representative.

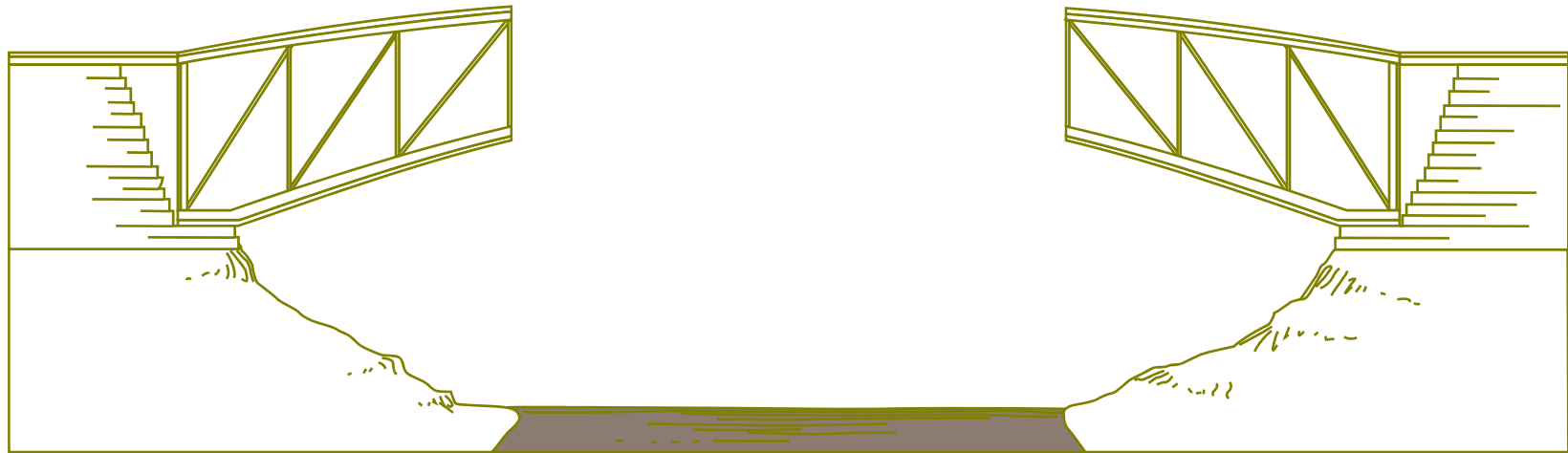
The views and opinions presented are entirely my own. They do not necessarily reflect the views of USP, nor should they be construed as an official explanation or interpretation of <797>.”

Hell's Cleanroom!



Gap Analysis

- What is a gap?
- How do you identify it?
- How do you correct it?
- How do you make sure nothing becomes a gap?
- How often do you perform a gap analysis?



Top 10 Gaps in USP 797 Compliance

- Understanding USP 797 and knowing how to comply
- State Board of Pharmacy position re: USP 797
- Facility meets design requirements
- Caulked Ceiling Tiles
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- Personnel training in hand hygiene, media fill, surface sampling and gloved fingertip sampling
- Personnel equipment training
- Properly documenting temperatures and reporting excursions
- Having a properly tested and certified facility
- Complying with BUDs

Understanding USP<797>

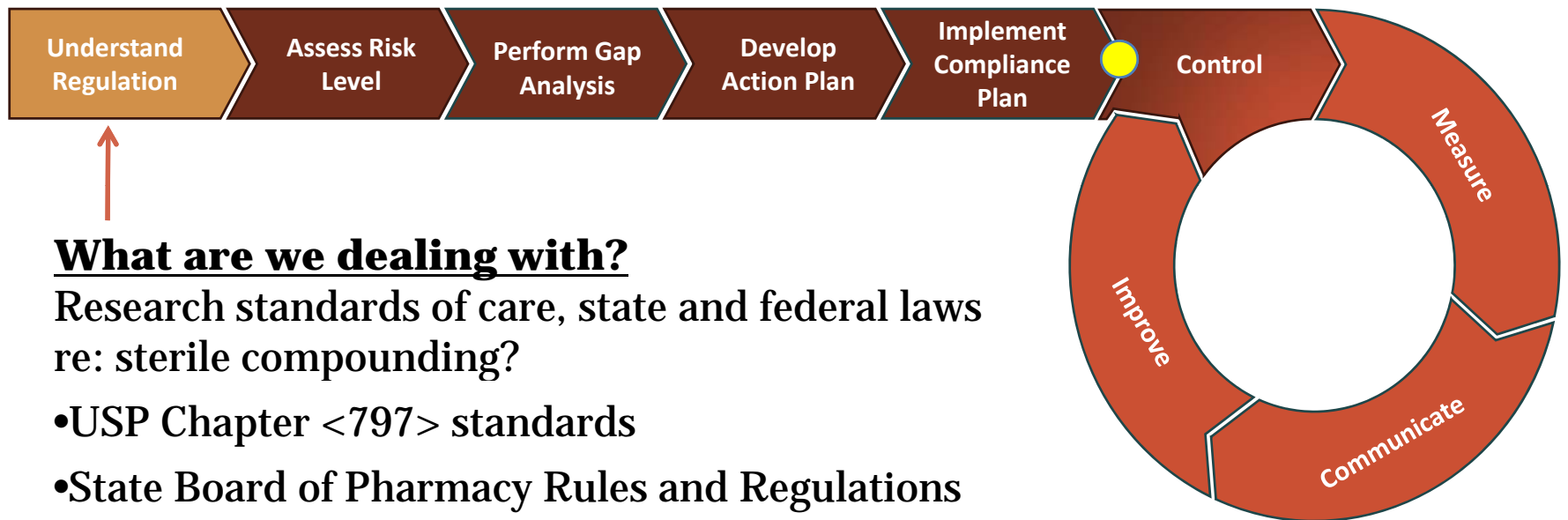
- **USP Home Page for Compounding**

- <http://www.usp.org/products/797Guidebook/>
- <http://www.usp.org/audiences/pharmacist/797FAQs.html>
- <http://www.usp.org/audiences/healthcarePro/pharmacists>

- **ASHP Compounding Resource Center**

- <http://www.ashp.org/compounding>
 - ASHP Discussion Guide for Compounding Sterile Preparations-2004
 - ASHP Discussion Guide for Compounding Sterile Preparations - Summary of revisions to USP Chapter <797>-2008

Understanding USP<797>



What are we dealing with?

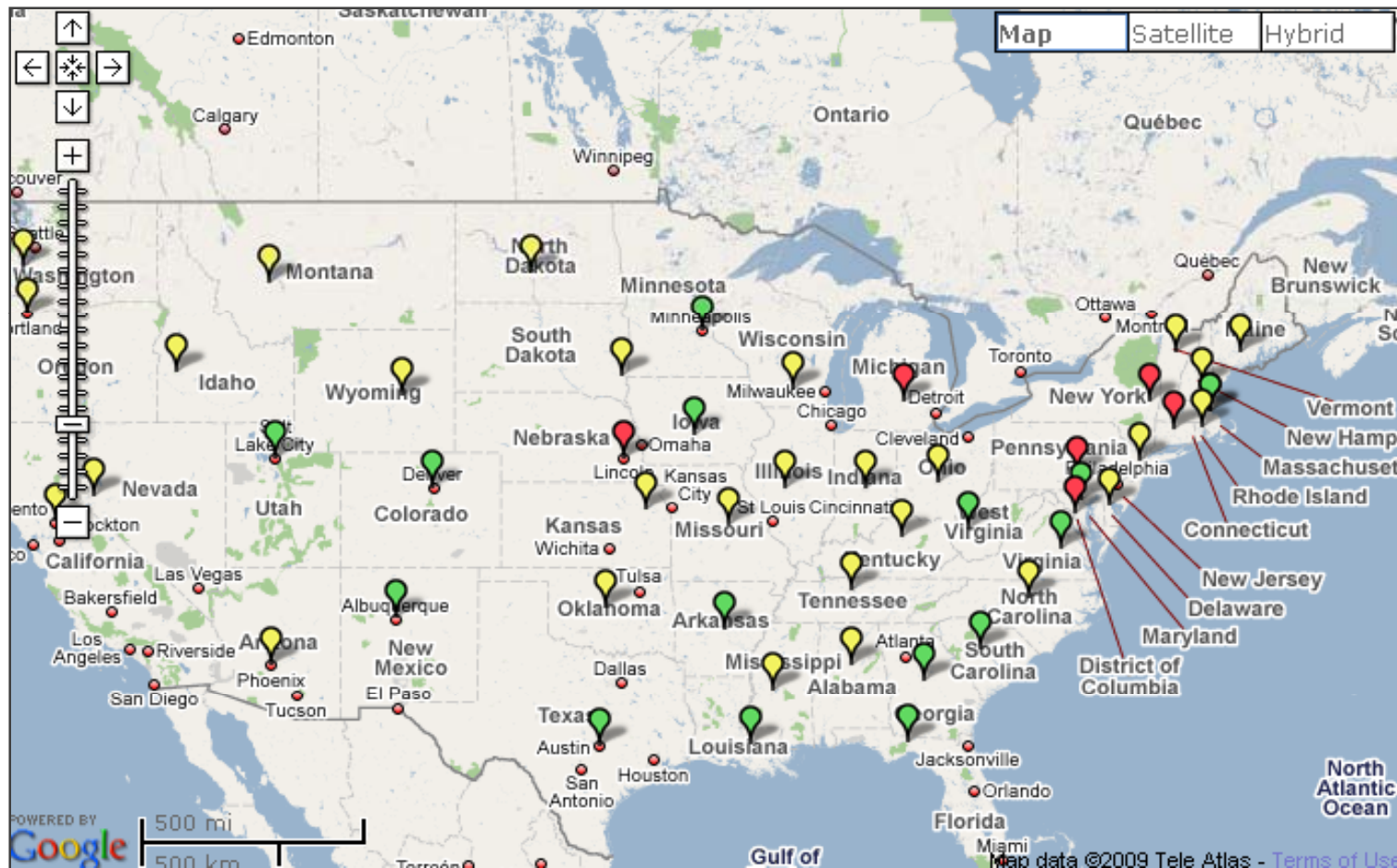
Research standards of care, state and federal laws re: sterile compounding?

- USP Chapter <797> standards
- State Board of Pharmacy Rules and Regulations
- State Department of Health
- Drug Enforcement Agency

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State Board of Pharmacy Position USP <797>



http://www.clinicaliq.com/component/option,com_google_maps/Itemid,111/

State Board of Pharmacy Position USP <797>

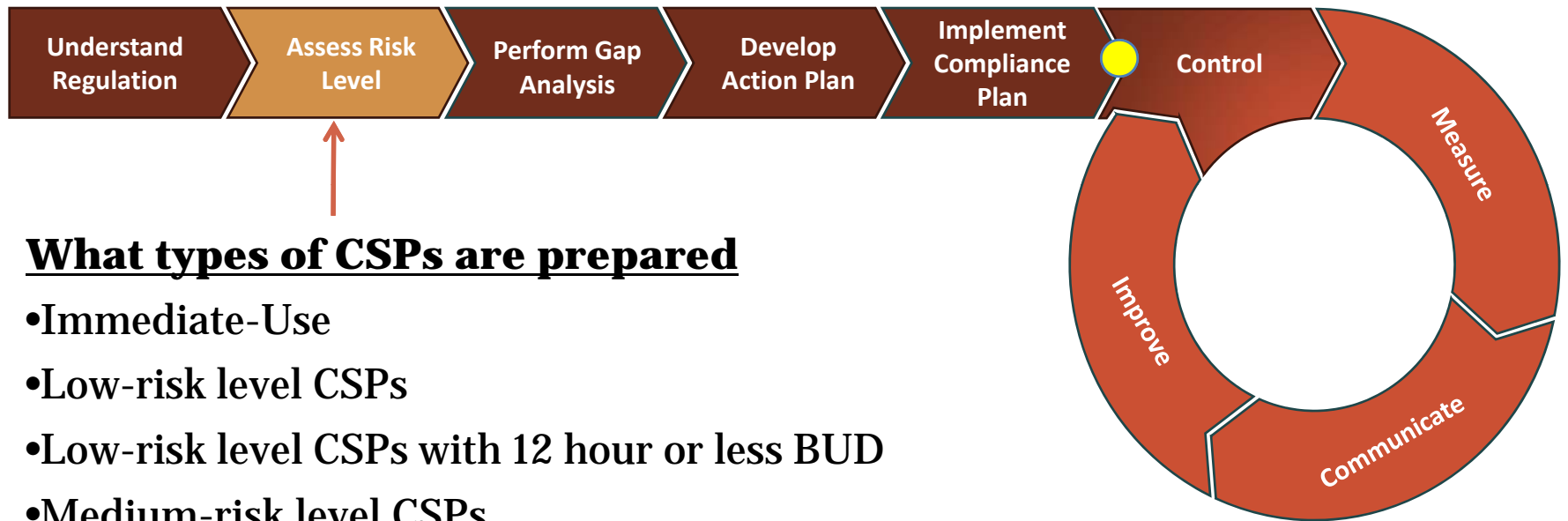
Actual note from State Board of Pharmacy Inspector addressed to the Hospital Pharmacy Director

A note on your pharmacy Inspections last week:

“Your hospital” has not initiated changes in your physical spaces used for Sterile Compounding. The changes in the Administrative Code were added to the Board of Pharmacy regulations in June 2009. The pharmacy inspectors are to note progress on compliance, and initiate deficiencies in January 2010. I have attached a copy of the new administrative code, and a summary of the administrative code that I have simplified.

As you can see, the new administrative code contains a number of issues requiring major changes in the physical space (e.g., ante rooms, buffer space, positive pressure room for intravenous admixtures, and negative pressure for chemotherapy). In addition, the new administrative code has considerable changes in training, testing, and verification of the capabilities of the individuals working in the area. Non-compliance will result in disciplinary action.

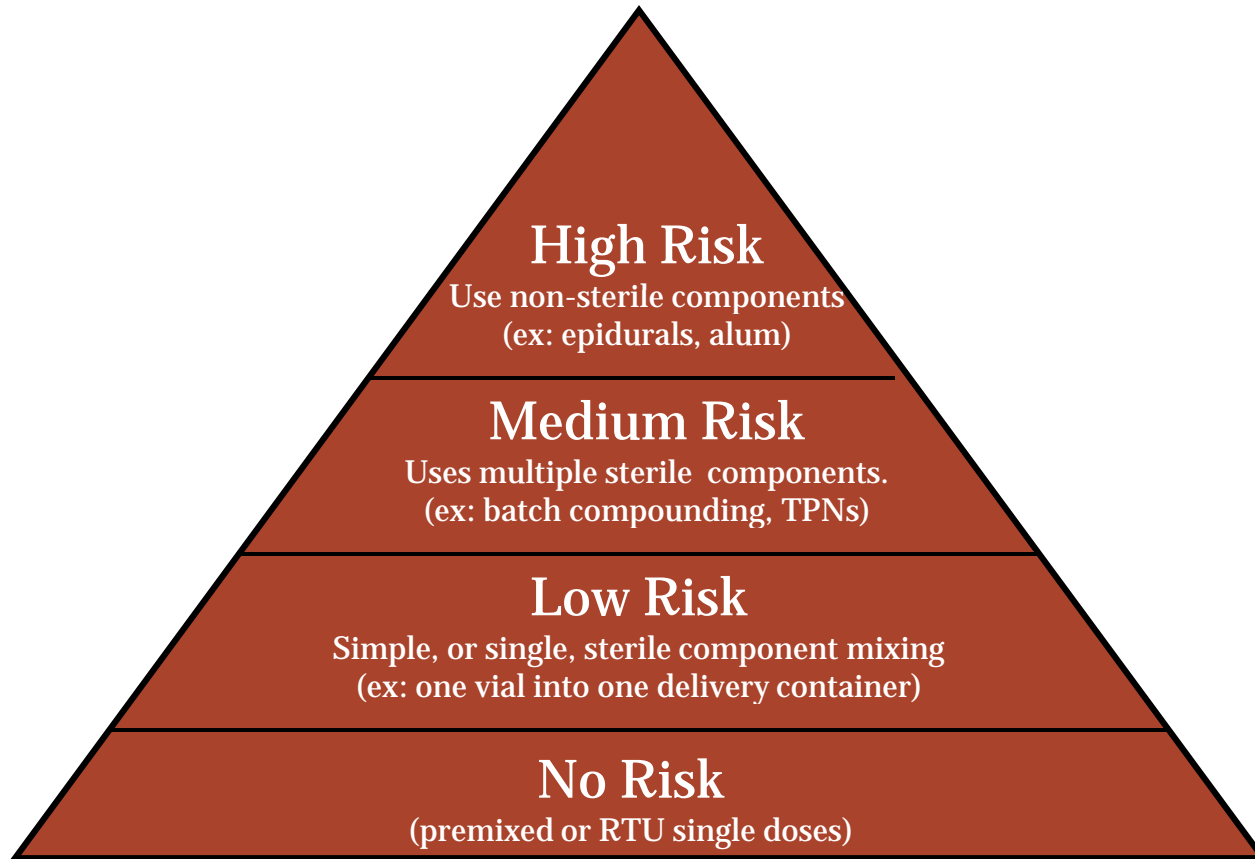
Assess Risk Level



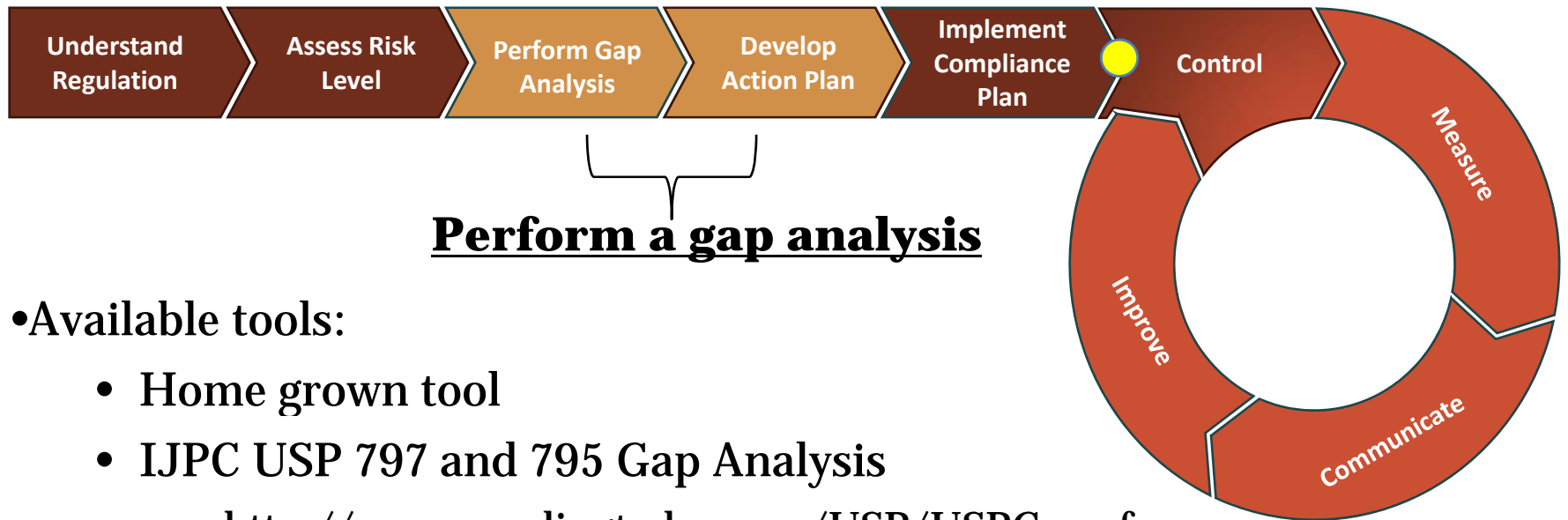
What types of CSPs are prepared

- Immediate-Use
- Low-risk level CSPs
- Low-risk level CSPs with 12 hour or less BUD
- Medium-risk level CSPs
- High-risk level CSPs

Top 10 Gaps in USP 797 Compliance



Gap Analysis



• Available tools:

- Home grown tool
- IJPC USP 797 and 795 Gap Analysis
 - <http://compoundingtoday.com/USP/USPGap.cfm>
- **CriticalPoint, LLC 797 Gap Analysis**
 - <http://797gaptool.797compoundingiq.com>
- ASHP-no tool

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Facility meets design requirements

**Primary
Engineering
Control**



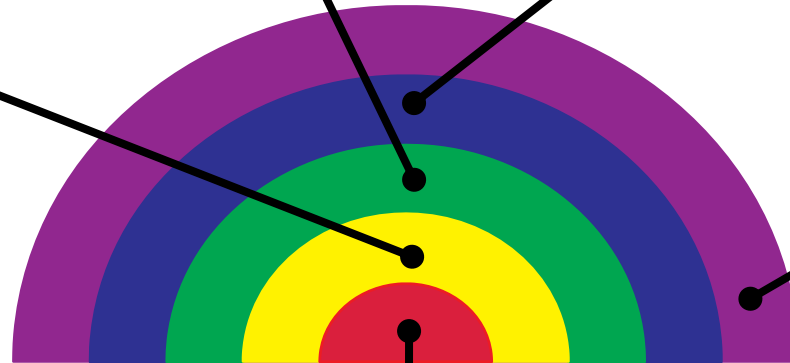
Buffer Area



Ante Area

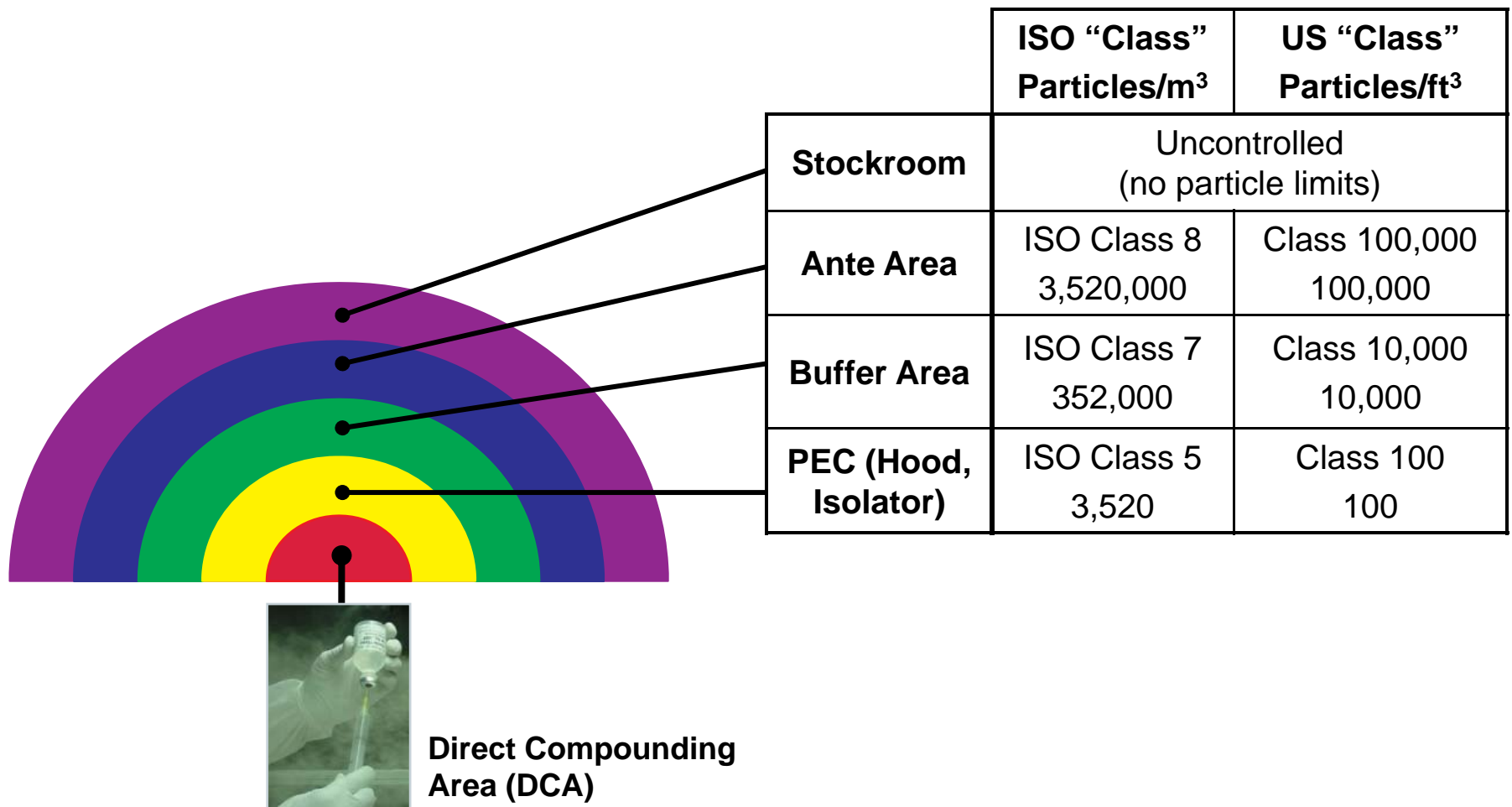


Stockroom



**Direct Compounding
Area (DCA)**

Facility meets design requirements



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Caulked Ceiling Tiles

- Tiles caulked in place
- Work with facility engineering or cleanroom vendor to resolve matter
 - Caulk can be removed by certifier as needed
- Caulked tiles keep tiles in place when cleaning
- Most important in negative-pressure buffer areas
- Caulk can easily be removed if tile change/repair needed
- An easily identified design feature that State Boards of Pharmacy can cite as a deficiency



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Dating of MDVs (Vaccines)

- Interpreted by TJC and SBOP as a gap or deficiency
- CDC states:
 - The vaccine or diluent may be used up to and including this date unless otherwise stated in the product package insert.
- Consult Product Package Insert
- Refer to USP Chapter <797>
 - Single-dose and Multiple-dose Containers

The screenshot shows the 'Vaccine Storage and Handling Toolkit' website. The main heading is 'Vaccine Storage and Handling Toolkit' with the subtitle 'National Center for Immunization and Respiratory Diseases'. Below this is a navigation bar with links for 'Home', 'Site Map', 'Videos', 'Resources', 'Challenge Game', and 'Contact', along with a 'Printable PDF' icon. The current page is titled 'Vaccine Inventory Management'. A table of contents on the left lists various topics: Introduction, Cold Chain, Storage and Handling Plans, Vaccine Personnel, Storage Equipment, Storage Practices, Temperature Monitoring, Storage Troubleshooting, Selected Biologicals, Inventory Management, Vaccine Shipments, and Preparation and Disposal. The main content area is divided into sections: 'Vaccine Access' (with a blue box stating 'Limit access to the vaccine supply to authorized personnel only'), 'Expiration Dates', and 'Interpreting Expiration Dates'. The 'Interpreting Expiration Dates' section explains that all vaccines and diluents have expiration dates and provides instructions on how to use them. Below this text are two images of vaccine vials. The first image shows a vial with an expiration date of 1/15/08 and a note: 'Note: Use through January 15, 2008. Do NOT use on or after January 16, 2008.' The second image shows a vial with an expiration date of 1/08 and a note: 'Note: Use through January 31, 2008. Do NOT use on or after February 1, 2008.' A caption below the images states: 'Vaccine may be used up to and including the expiration date.' The final section is 'What to Do with Expired and Mishandled Vaccine or Diluent', which states: 'Expired vaccine and diluent, even if they are only 1 day past the expiration date, should'.

http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/inventory_management.htm

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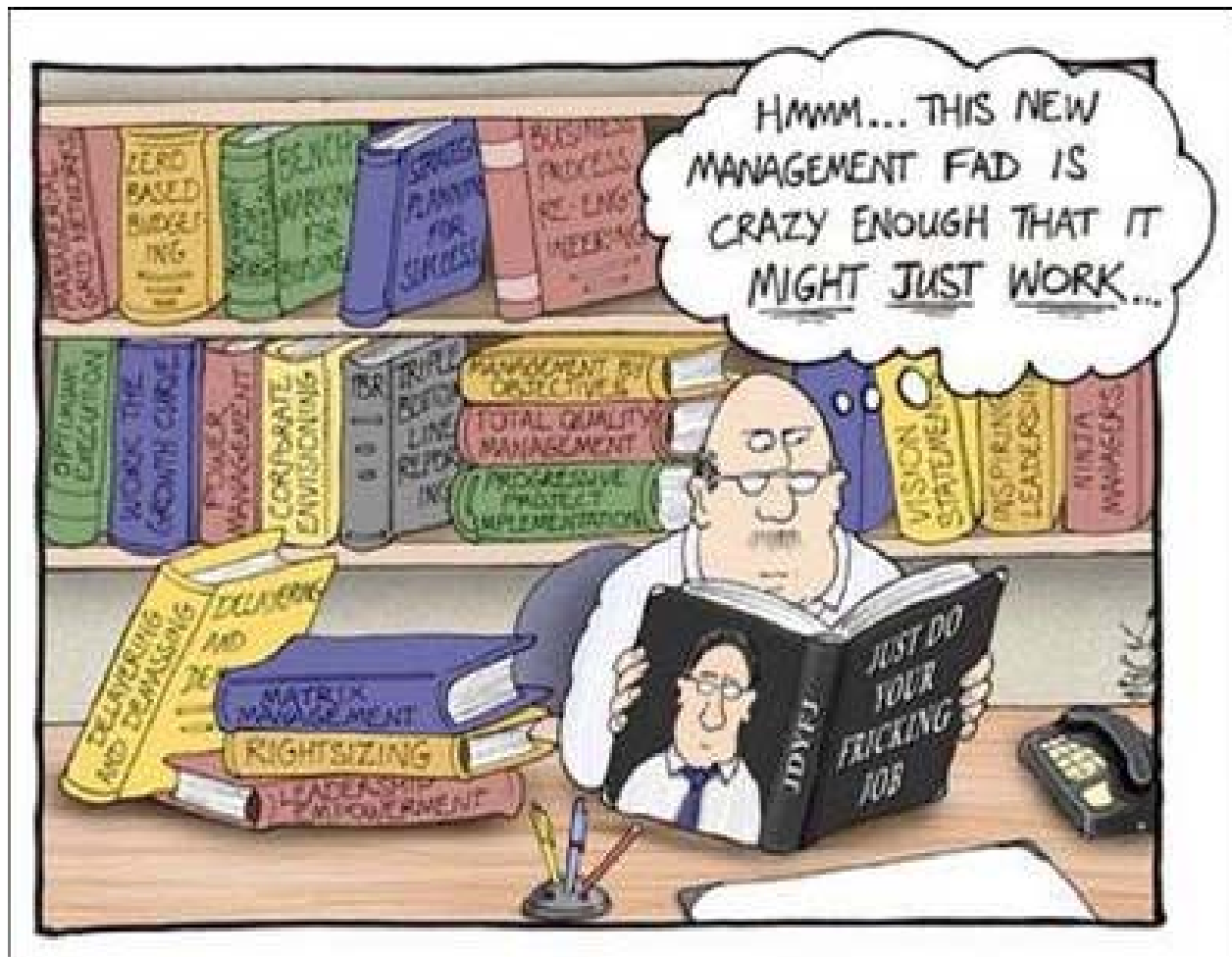
Personnel Training Gaps

- Personnel training-Hand Hygiene
 - Frequency-initially for all personnel
 - Annually for low and medium-risk level operations
 - Semi-annually for high-risk level operation
 - Hand Hygiene
 - Hospital Infection Preventionists
 - CDC Website
 - <http://www.cdc.gov/Handhygiene/>
 - CDC Interactive Training
 - <http://www.cdc.gov/handhygiene/training/interactiveEducation/>
 - CriticalPoint, LLC (www.criticalpoint.info)
 - Virtual Compounder™

Personnel Training Gaps

- Personnel Training: Media Fills (Aseptic Technique Assessment)
 - Frequency-initially for all personnel
 - Annually for low and medium-risk level operations
 - Semi-annually for high-risk level operation
 - Media Fill Supplies (S) and Training (T)
 - Valiteq www.valiteq.com (S)(T)
 - QI Medical www.qimedical.com (S)(T)
 - CriticalPoint, LLC www.criticalpoint.info (T)
 - bioMérieux, Inc <http://www.pmlmicro.com/our-products/new-products> (S)

Top 10 Gaps in USP 797 Compliance



Personnel Training Gaps

- Personnel training-Gloved Fingertip sampling
 - Frequency-initially for all personnel (x 3)
 - Annually for low and medium-risk level operations
 - Semi-annually for high-risk level operation
 - Gloved Fingertip Supplies (S) and Training (T)
 - QI Medical: www.qimedical.com (S)
 - bioMérieux, Inc: www.pmlmicro.com/our-products/new-products (S)
 - CriticalPoint, LLC: www.criticalpoint.info (T)

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Personnel Equipment Training

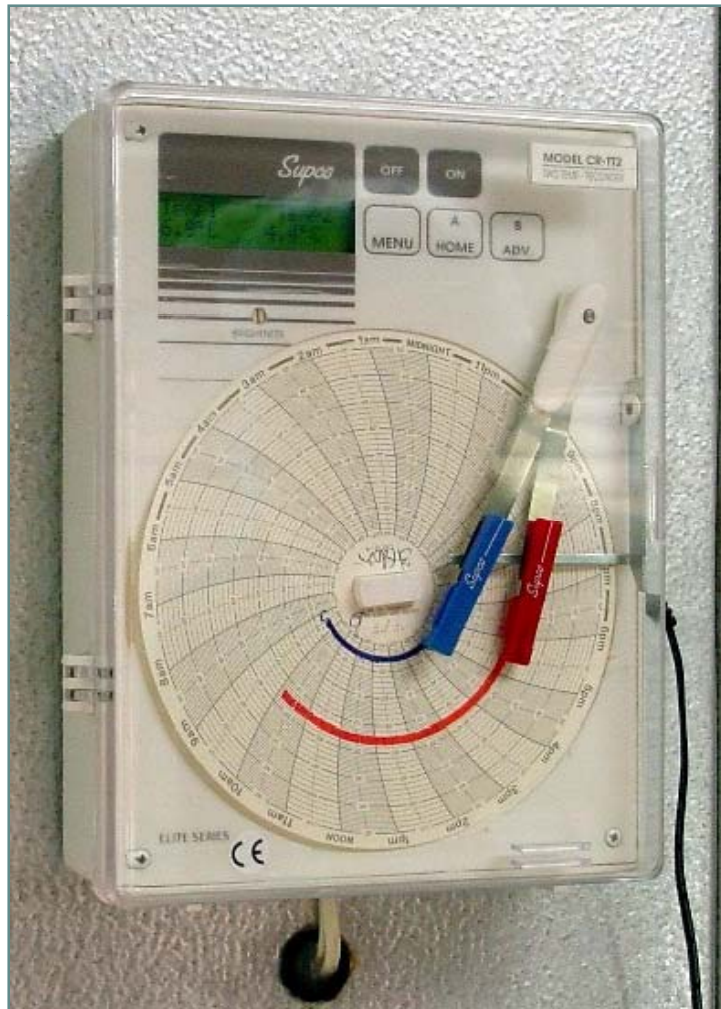


- **Personnel who use equipment:**
 - have received training
 - demonstrated the ability to use the equipment properly
 - can troubleshoot the equipment in the event of malfunction.

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Properly Documenting Temperatures



REFRIGERATOR/FREEZER Temperature Log Sheet

Temperatures will be recorded with the initials of the person performing the check.

Refrigerator temperature should be between 2 and 8° C (36 and 46° F).

Freezer temperature should be between -20 and -10° C (-4 and 14° F).

Refrigerator #1 (Anteroom)

OPEN 7 DAYS/WEEK
MISSING TEMPERATURES

Month: March 2008

1	<u>34</u> F	<u>AW</u> initials	17	→ <u>34</u> F	<u>AW</u> initials
2	<u>34</u> F	<u>AW</u> initials	18	→ <u>34</u> F	<u>AW</u> initials
3	<u>36</u> F	<u>AW</u> initials	19	→ <u>35</u> F	<u>AW</u> initials
4	<u>36</u> F	<u>AW</u> initials	20	→ <u>34</u> F	<u>AW</u> initials
5	→ <u>34</u> F	<u>AW</u> initials	21	→ <u>34</u> F	<u>AW</u> initials
6	→ <u>32</u> F	<u>AW</u> initials	22	→ <u>34</u> F	<u>AW</u> initials
7	→ <u>32</u> F	<u>AW</u> initials	23	<u>34</u> F	<u>AW</u> initials
8	→ <u>32</u> F	<u>AW</u> initials	24	→ <u>34</u> F	<u>AW</u> initials
9	<u>32</u> F	<u>AW</u> initials	25	→ <u>32</u> F	<u>AW</u> initials
10	→ <u>32</u> F	<u>AW</u> initials	26	→ <u>32</u> F	<u>AW</u> initials
11	→ <u>33</u> F	<u>AW</u> initials	27	→ <u>32</u> F	<u>AW</u> initials
12	→ <u>34</u> F	<u>AW</u> initials	28	→ <u>32</u> F	<u>AW</u> initials
13	→ <u>32</u> F	<u>AW</u> initials	29	<u>34</u> F	<u>AW</u> initials
14	→ <u>32</u> F	<u>AW</u> initials	30	<u>34</u> F	<u>AW</u> initials
15	→ <u>34</u> F	<u>AW</u> initials	31	<u>34</u> F	<u>AW</u> initials
16	<u>34</u> F	<u>AW</u> initials			

8/31 DAYS MISSING DATA

2/23 DAYS TEMPERATURE IN RANGE

21/23 DAYS TEMPERATURE OUT OF RANGE

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Properly Tested and Certified Facility

- USP Chapter <797> has specific requirements
- There is currently no industry based accreditation program for certifiers of sterile compounding facilities.
- NSF International has an accreditation program for certifiers of BSC.
 - For now that program is the best barometer of whether or not an individual has demonstrated an ability to certify this type of equipment.

Properly Tested and Certified Facility



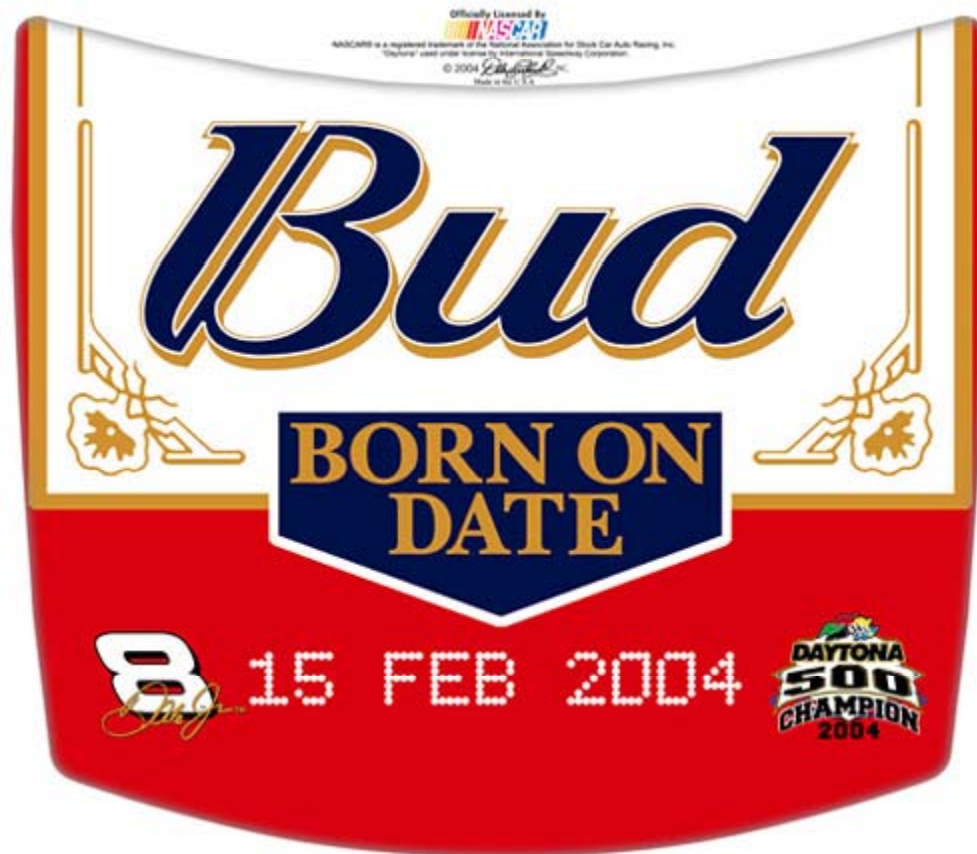
Properly Tested and Certified Facility

- **Certification reference material**
 - **Controlled Environment Testing Association (CETA)**
 - <http://www.cetainternational.org>
 - CETA has established an application guides (CAG-003-200X) detailing procedures for certification of sterile compounding facilities
 - **Choosing a Certification Professional to Evaluate Your Cleanroom and Engineering Control-James T. Wagner. Published in Pharmacy, Purchasing and Products Magazine (www.pppmag.com)**
 - http://pppmag.com/documents/V6N7/p8_9_10_12.pdf
 - <http://pppmag.com/documents/V6N7/matrix1.pdf>

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Complying with BUDs



Complying with BUDs

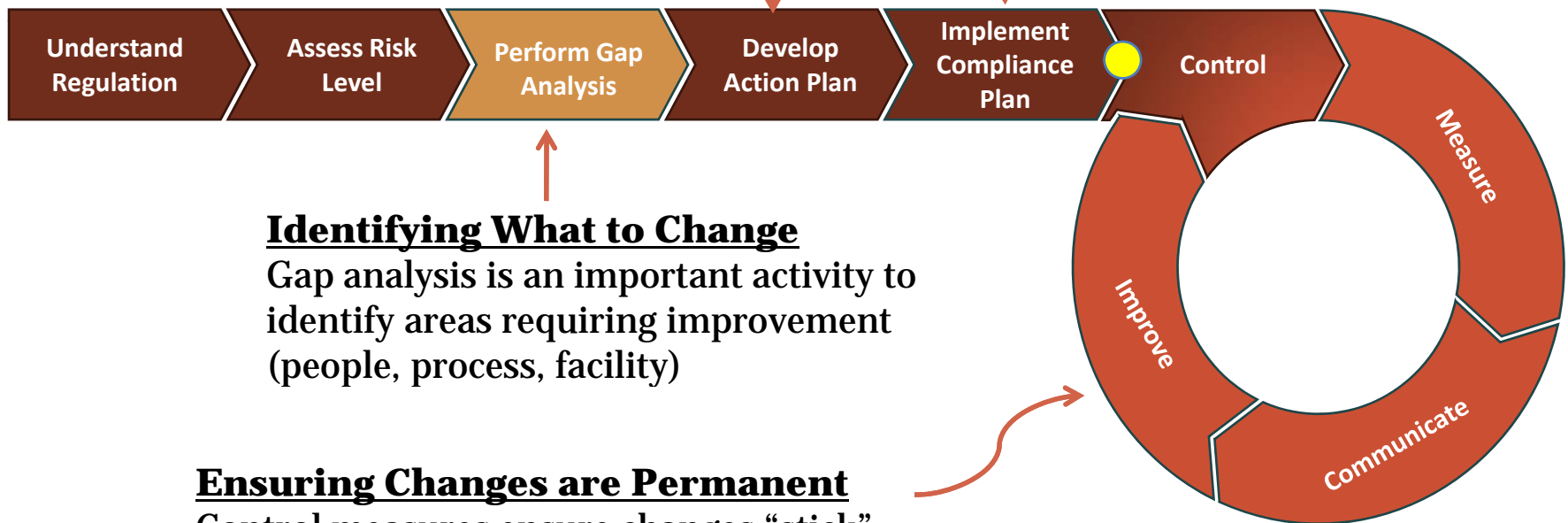
- A CSPs beyond-use date identifies the time by which the preparation – once mixed – must be used before it is at risk for chemical degradation, contamination, and permeability of the packaging.
- In other words, the beyond-use date serves to alert pharmacists and caregivers to the time after which a CSP cannot be administered.
- Understanding Beyond-Use Dating for Compounded Sterile Preparations by Patricia Kienle published by Pharmacy, Purchasing and Products Magazine
 - www.pppmag.com/documents/V4N3/p2_4_5.pdf

Putting All Together

Planning to Change and Changing

Action planning and implementation against identified gaps bring compliance!

State of Compliance
(point in time)



Identifying What to Change

Gap analysis is an important activity to identify areas requiring improvement (people, process, facility)

Ensuring Changes are Permanent

Control measures ensure changes “stick” and help identify further improvements.

“Simplifi 797 Software”

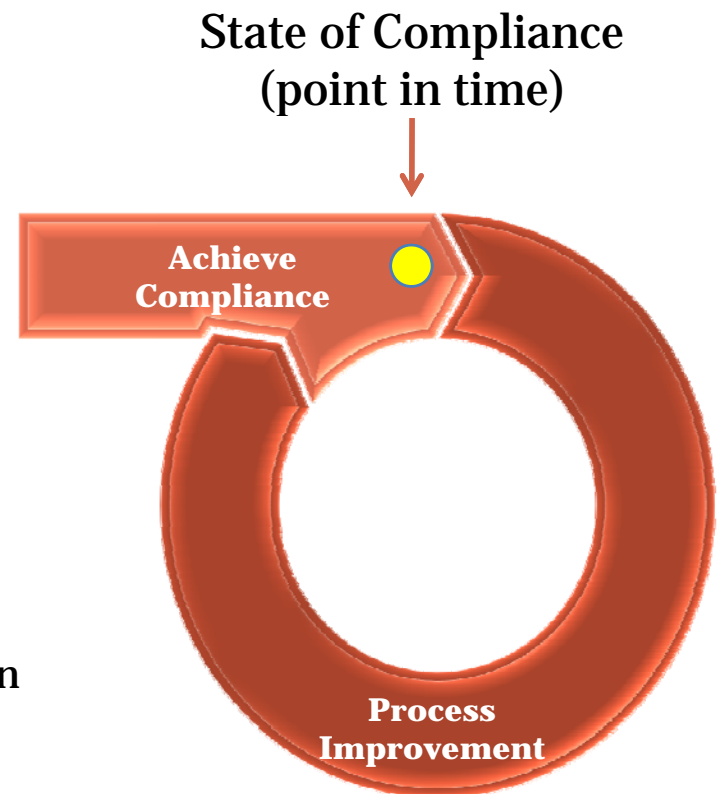
Compliance is an endpoint?

Think about compliance as a 3-step process:

- Identify gaps and action plan
- Achieve compliance
- Maintain compliance: requires constant monitoring and measurement

Consider:

- Linear process of achieving compliance (get to a point in time)
- Cyclical aspect of process improvement: maintain a state of compliance
- “Compliance” isn’t an endpoint or a finish line



Close the Gap



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