Section 17. SOPs

Facilities that prepare CSPs must develop SOPs for the compounding process and other support activities.

- A designated person must ensure that SOPs are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function.
- A designated person must follow up to ensure that corrective actions are taken if problems, deviations, failures, or errors are identified.
- The corrective action must be documented.
Section 17. SOPs

All personnel who perform or oversee compounding or support activities must be trained in the SOPs. All compounding personnel must:

1) Be able to recognize potential
   • problems, • failures, or
   • deviations, • errors
   associated with preparing a CSP (e.g., those related to
   • equipment, • personnel,
   • facilities, • the compounding process, or
   • materials, • testing)
   that could potentially result in contamination or other adverse impact on CSP quality

2) Report any problems, deviations, failures or errors to the designated person(s).

Section 17. SOPs

• SOPs must be reviewed at least every 12 months by the designated person(s) to ensure that they reflect current practices, and the review must be documented.

• Any changes or alterations to an SOP must be made only by a designated person and must be documented.

• Revisions to SOPs must be communicated to all personnel involved in these processes and procedures, and personnel should document acknowledgment of the communication.
What are Standard Operating Procedures?

- Are itemized instructions that describe
  - How a task will be performed – the procedure
  - Who will perform the task (including eligibility to perform the task)
  - Why the task is necessary
  - Any limitations in performing the task
  - What action to take when unacceptable deviations or discrepancies occur.

Benefits of an SOP

Ideally, an SOP
- Establishes and maintains a standard of practice
- Ensures consistency
- Allows delegation of tasks
- Sets out clear lines of accountability
- Provides useful template for training new staff
Areas which should have SOPs

- Beyond-Use dating
- Chemical and physical stability
- Cleaning and disinfecting
- Component quality evaluation
- Compounding methods
- Dispensing
- Documentation
- Environmental quality and maintenance
- Equipment maintenance, calibration, and operation
- Formulation development
- Labeling
- Materials and final compounded preparation handling and storage
- Measuring and weighing
- Packaging and repackaging
- Patient monitoring, complaints, and adverse event reporting
- Patient or caregiver education and training
- Personnel cleanliness and garb
- Purchasing
- Quality Assurance and Continuous Quality Monitoring
- Safety
- Shipping
- Testing
- Training and retraining

Per USP<1163> Quality Assurance in Pharmaceutical Compounding

Sections of an SOP

<table>
<thead>
<tr>
<th>Royal Pharmaceutical Society of Great Britain</th>
<th>Example #2</th>
<th>Example #3</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Objectives</td>
<td>• Purpose</td>
<td>• Definition and Purpose</td>
</tr>
<tr>
<td>• Scope</td>
<td>• Equipment and Material</td>
<td>• Policy</td>
</tr>
<tr>
<td>• Stage of the process</td>
<td>• Responsibility</td>
<td>• Equipment and Material</td>
</tr>
<tr>
<td>• Responsibility</td>
<td>• Background</td>
<td>• Procedure</td>
</tr>
<tr>
<td>• Other</td>
<td>• Frequency</td>
<td></td>
</tr>
<tr>
<td>• Audit process</td>
<td>• Procedure</td>
<td></td>
</tr>
<tr>
<td>• Review frequency</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Distinguish the following documents:

- **Policy** – overarching document
- **Standard Operating Procedure** – from the policy, but more specific
- **Training Document(s)** – more explanatory and detailed; include testing
- **Check list** – for use to remember steps or order of steps
- **Documentation logbooks or electronic logs**

All five documents must match.

Changes to one document should accompany review of the corresponding documents.
How to develop an SOP?

- From the bottom up – development by the people doing the procedure on a regular basis
- Upper level dictate – the word comes down from on high (corporate).
- Committee – everybody gets a say

How are SOPs and changes communicated?

- By email → please read and sign that you understand
- Training program
- Word of mouth