

ASHP 2006 Midyear Clinical Meeting  
Anaheim, California  
Tuesday, December 5, 2004

Management Pearls



***Me,***  
***CSP-APV,***  
***&***  
***3-For-3***  
***Competency!***

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## Background

- USP-797 Intent: “Gold Standard” For Compounded Sterile Preparations (CSP)
- Greater Emphasis on Annual Process Validation (APV)
- Competency Assessment
- Promotion of Continued Competence

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## Annual Process Validation (APV) Methods

- Didactic Examination
- Media Fill Test
- Direct Observation Assessment

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## Progressive Action

[Progressive Action includes both **Intervention and Disciplinary Actions**]

An employee has a total of three (3) opportunities to pass each component of the APV Method.

Disciplinary Action occurs after each failed attempt.

Intervention Action occurs after each first and second failed attempt.

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## Didactic Examination:

Benchmark Passing Rate =75% or higher.

An employee has a total of three (3) opportunities to pass the Didactic Examination.

- An employee who fails any section of the Didactic Examination (Math or General Practice) shall meet with his/her supervisor to discuss Intervention Actions and Re-testing Options.
- Failure in any section of the Didactic Examination shall result in Progressive Action as follows:
  - First Failure – Verbal Warning
  - Second Failure – Written Warning, 3-day suspension without pay, and 90-days probation
  - Third Failure – Termination

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## Media Fill Test:

Benchmark Passing Rate = 100%

An employee has a total of three (3) opportunities to pass the Media Fill Test regardless of Progressive Action evoked for the first and/or second failure of the Didactic Examination.

- An employee who fails the Media Fill Test shall meet with his/her supervisor to discuss Intervention Actions and Retesting Options.
- Failure of the Media Fill Test shall result in subsequent Progressive Action as outlined up to Second Failure Disciplinary Action.
- An employee must fail the Media Fill Test three (3) times before termination action is taken.

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## Direct Observation Assessment:

Benchmark Passing Rate = 100%

An employee has a total of three (3) opportunities to pass the Direct Observation Assessment regardless of Progressive Action evoked for the first and second failure of the Didactic Examination and/or Media Fill Challenge Test.

- An employee who fails the Direct Observation Assessment shall meet with his/her supervisor to discuss Intervention Actions and Retesting Options.
- Failure of the Direct Observation Assessment shall result in subsequent Progressive Action taken as outlined up to Second Failure Disciplinary Action.
- An employee must fail the Direct Observation Assessment three (3) times before termination action is taken.

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## Competency Assessment & Progressive Action Didactic Examination

- Employee successful 1<sup>st</sup> Attempt; proceeds to Media Fill.
- Employee fails 1<sup>st</sup> Attempt; Verbal Warning & Intervention I
  
- Employee successful 2<sup>nd</sup> Attempt; proceeds to Media Fill.
- Employee fails 2<sup>nd</sup> Attempt; Written Warning & Intervention II
  
- Employee successful 3<sup>rd</sup> Attempt; proceeds to Media Fill.
- Employee fails 3<sup>rd</sup> Attempt; Terminated.

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## Competency Assessment & Progressive Action Media Fill Testing

- Employee successful 1<sup>st</sup> Attempt; proceeds to Direct Observation.
- Employee fails 1<sup>st</sup> Attempt; Verbal Warning & Intervention I
  
- Employee successful 2<sup>nd</sup> Attempt; proceeds to Direct Observation.
- Employee fails 2<sup>nd</sup> Attempt; Written Warning & Intervention II
  
- Employee successful 3<sup>rd</sup> Attempt; proceeds to Direct Observation.
- Employee fails 3<sup>rd</sup> Attempt; Terminated.

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## Competency Assessment & Progressive Action Direct Observation

- Employee successful 1<sup>st</sup> Attempt; employee is Process Validated.
- Employee fails 1<sup>st</sup> Attempt; Verbal Warning & Intervention I
  
- Employee successful 2<sup>nd</sup> Attempt; employee is Process Validated.
- Employee fails 2<sup>nd</sup> Attempt; Written Warning & Intervention II
  
- Employee successful 3<sup>rd</sup> Attempt; employee is Process Validated.
- Employee fails 3<sup>rd</sup> Attempt; Terminated.