



Aseptic Processing Technology – Techniques and Behaviors

KRIS EVANS

EXECUTIVE DIRECTOR, QUALITY SCIENCES

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AMGEN[®]



Standardizing requirements, processes and *behaviors* will Control and Prevent potential contamination in our manufacturing facilities





WARNING LETTER

Operator dropped sterilized component on the floor, picked it up and used it

Operators' behaviors should be consistent with smoke studies and media fills (speed, technique)

During set up operators wore goggles on their foreheads and exposed skin

Operators crawled on the floor on their hands and knees under the filling line during routine aseptic filling operations

Operators opened barrier to adjust or remove vials from line with bare hands



Humans are not Robots

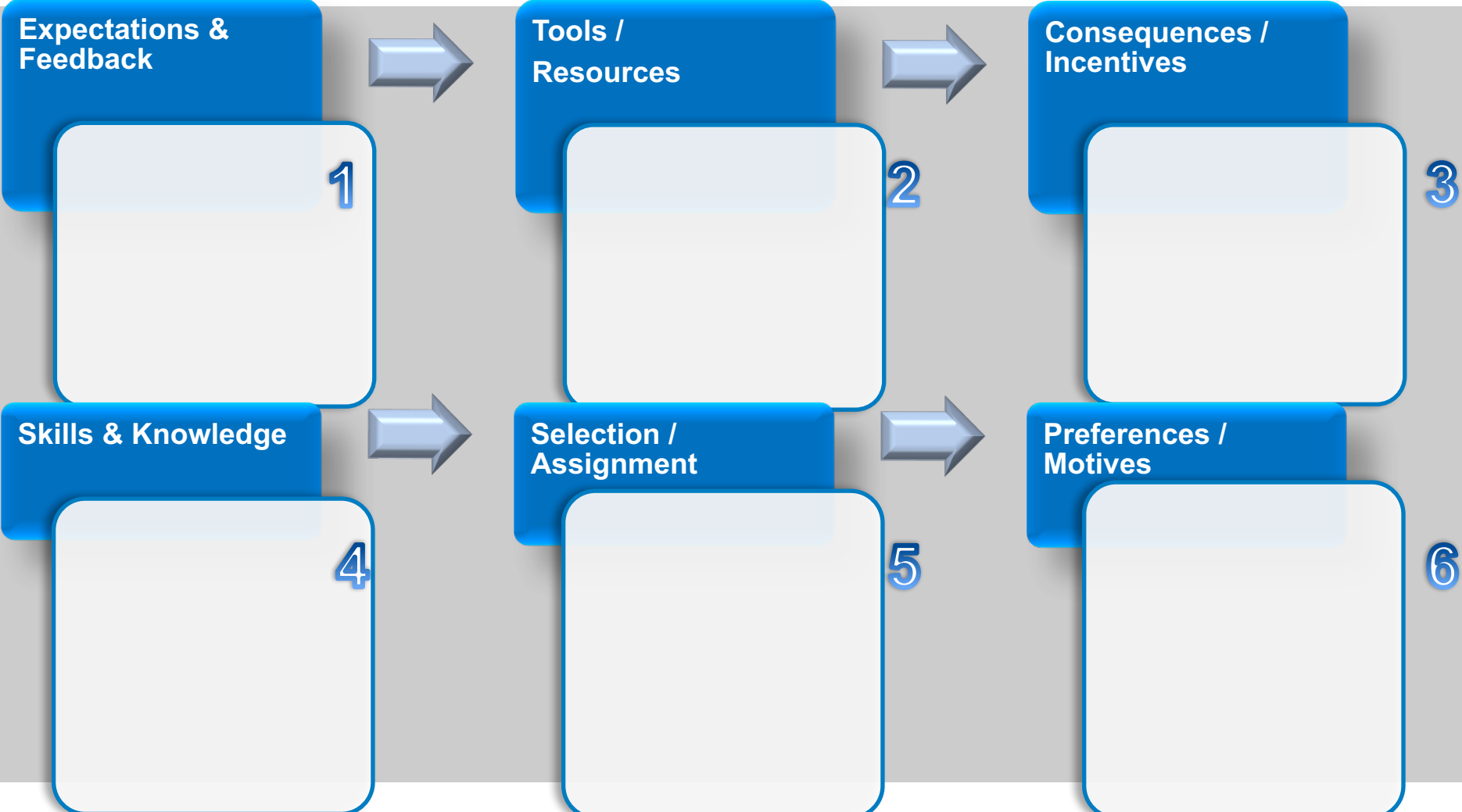


“I fear the day that technology will surpass our human interaction. The world will have a generation of idiots.”

Albert Einstein



Utilization of the Six Boxes[®] Approach Helped Identify Factors that Impact Individual Performance



EVERY VOICE IS IMPORTANT

Amgen is Dedicated to Continuous Improvement of Aseptic Processing Operations

AMGEN'S ASEPTIC
PROCESSING
PROGRAM

*Aseptic
Manufacturing
Requirements*

Amgen recently launched a holistic behavior Program to enhance aseptic behaviors.

The Program utilizes multiple components to ensure continual and sustainable improvements in the aseptic processing environment.

Critical Aseptic Behaviors

**Move Slowly and
Deliberately**

**Protect Sterility of
Equipment,
Components and
Product**

**Maintain Gowning
Control**

**Be Aware of Body
Positioning**

**Practice Good
Hygiene**

***Example:
Move Slowly and Deliberately***

- Think before acting.
- Quick and sudden movements can create turbulence in Grade 5 areas.
- Such movements disrupt the unidirectional airflow, presenting a challenge beyond design and control parameters.
- Keep unnecessary movement to a minimum and when not performing tasks, stand or sit still, with hands up and above waist level.

Improved Training Program



Aseptic Processing Coaching Program to Increase Aseptic Awareness

- Aseptic Processing Coach
 - Front Line Managers
 - Plant Quality Assurance
 - Aseptic Processing Subject Matter Experts
- Aseptic Processing Coaches must include:
 - Enhanced Aseptic Processing Training
 - Effective Coaching Training
 - Participate in, or Lead, Learning Groups

Aseptic Processing Program Oversight

In order to provide standardized and consistent feedback and real-time evaluation, we established a global scoring system.

- Behavior Evaluation Tool (BET): Plants use the Aseptic Processing Behavior Evaluation Tool (BET) for tracking adherence to defined aseptic behaviors

Aseptic Processing Program Tools

Human Performance Tools improve focus for critical tasks and reduce the occurrence of mistakes. Understanding and evaluating human errors for reduction/elimination of latent conditions is a key improvement opportunity.

The Behavior Observation Program (BOP) is focused on positive, *peer-to-peer* feedback and builds on things done correctly.

Aseptic Processing Program Metrics

- Adherence to the Aseptic Processing Program must be tracked as part of plant performance and management oversight.
- Review of behavior information should be included in existing forums including:
 - Daily work team meetings
 - Front line management meetings
 - Plant/Building metric reviews
 - Site Management Review (MR)

Final Thought...

We Really need to Provide Tangible Benefits to
Ensure Long-term Sustainability...

