Chief Quality Officer Forum

Metrics that Matter -

Putting the V-Model Approach into Motion

Proprietary

Scenario 1: Right First Time

- On April 25, 2019, a Quality Assurance inspector (Gerry Smith) was performing a post-production quality inspection of a batch of filled TRIDADA 100mg sterile vials from fill line WIL-2256.

- Gerry noticed that a few vials had yellow caps instead of blue caps. Blue caps are the correct cap for the 100mg dose of lot #2019-APR25-100MG that Gerry was inspecting.
  - The vials are produced in batches of 35,000 units.
  - The acceptable defect rate for a wrong cap color is ≤ 1 unit of the sample set inspected per the standard operating procedure (SOP).
  - Gerry found 5 units with the wrong cap color, which exceeds the acceptable defect rate.

- Gerry knows the yellow cap is for the 50mg dose of TRIDADA.

Correct
100MG

Incorrect
50MG

Scenario 1: The Investigation Begins

- The production schedule indicated that the 50 mg dose had been filled earlier in the day on the same fill line (WIL-2256) and room.

- The operations team was performing some training for new operators on April 25, 2019, prior to the fill of #2019-APR25-100MG.
  - They were learning how to clear the equipment and clean the room after a fill event, and how to properly do component inventory reconciliation (caps and vials used, not used, rejected or damaged) at the end of each lot.

- The yellow caps (50mg) from the previous fill lot had not been counted yet.
  - Due to the training, the team was behind, so they just moved to the next fill.
  - They were going to make sure all the caps were accounted for later in the week.

Correct 100MG

Incorrect 50MG

Likely Root Cause: Human Error – Poor Line Clearance by trainees

Typical Metrics: % Human Error, and Track Poor Line Clearance. Impact to RFT

Scenario 1: The Investigation Continues

- The new trainees (Jeff Zimmerman and Lucy Star) had a conversation about who was going to clear the equipment of all unused components and sweep up the floor.
  - Lucy thought Jeff was going to do it, and Jeff thought Lucy did it already.
  - Since the training was taking longer than planned, the team had not completed all the sections of the batch record.
  - No one had made an entry yet on that specific cleaning step.

- The training leader (Mark Anderson) was working to complete the training records for Jeff and Lucy.
  - He was trying to find out if they had completed all the required sections of the training so they could be qualified as fill operators.
  - Mark did not go into the fill area, but instead, he relied on the Production Floor Leader (Carrie Butler) to tell him which activities the trainees performed.

Correct
100MG

Incorrect
50MG

Confirmed Root Cause: Human Error – Poor Line Clearance. Also identify corrective actions related to documentation practices, and training process failures

Still Measure % Human Error.
Track Poor Line Clearance.
Impact to RFT.

Scenario 1: 5 Why's

The technicians-in-training did not properly clear the yellow caps from the line

- **Why?** They were not sure what they needed to do
- **Why?** They did not have documentation with them to follow procedures and document the work they were doing. This led to confusion on what was and what was not completed.
- **Why?** The lead trainer was not in the room with them
- **Why?** The lead trainer was too busy with other work
- **Why?** The training was squeezed in-between the production of lots
- **Why?** There was not enough time in the production schedule to train new employees
- **Why?** No one communicated to the production planner that training was needed
- **Why?** This has never been part of the training process

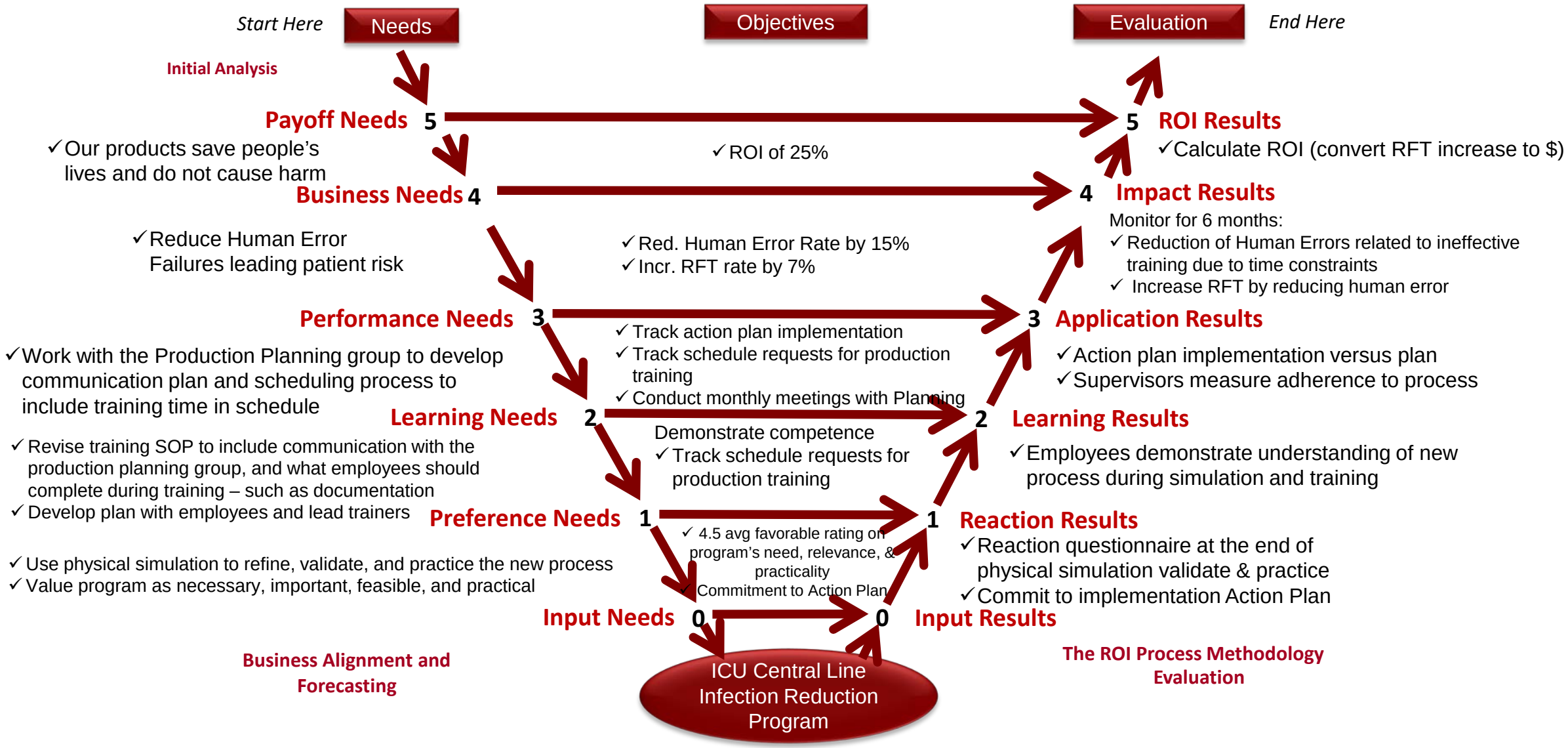
Outcome = fewer human errors and fewer line clearance errors = Increased RFT

New Root Cause: Training time is not being included in the production plan so as to provide enough time and resources to properly train new employees.

Perhaps Measure % Time Training is included in Production Plan

Value Alignment Planning Model

Scenario 1: V-Model for Right First Time

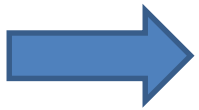


Scenario 1 – Digging Deeper

- A thorough review of production records included maintenance events. You find the following entry related to maintenance during the production of lot #2109-APR25-100MG:
  - The Maintenance team addressed a clogging issue in the cap hopper, WIL-450 (the hopper feeds caps to the capping machine).
  - Matt Sullivan entered a note into the maintenance logbook for the cap hopper WIL-450 that stated *"Work Order 2019-123 was closed – Maintenance Technician fixed clogging issue by realigned the feed shoot line from the hopper to the capper. Maintenance Technician opened Work Order 2019-124 to request a modification to hopper WIL-450 to address an ongoing issue – caps are getting stuck in the corners of the hopper"*.
  - Completion of Work Order 124 was scheduled to be completed in the future, since it was not marked as CRITICAL, so the fill team continued with production once Work Order 123 was closed.

- Matt knew the hopper would work better if the corners were made smooth – that way caps would not get stuck in the corners.

Actual Root Cause: New entrapment area in equipment



Address the failure through improved process, employee awareness of criticality, etc.

Outcome: reduced risk to product and patient, and increased RFT

Key Takeaway

High Level metrics don’t drive the desired outcome, because they are too far removed from the cause

- Focus on the cause
- Measure the cause
- Employees can rally around the solution
- Your typical business metric improvement will be the natural outcome