Ensuring Compliance, Building Capability

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Objectives

At the completion of this session participants will be able to:

- Describe the challenges of addressing the need to comply with regulations and also enable employees to perform
- Describe the impact of requiring fair, objective assessments as a means for qualifying employees to perform specific duties
- Describe how Lilly devices met the requirements above while minimizing cost and cycle time
- See and discuss examples of the key characteristics of effective overviews and performance assessments

Speaker Background

Craig Burton, PhD
Eli Lilly and Company

Burton is a Team Leader at Eli Lilly and Company in the global medical device function. He holds three degrees, including a doctorate in Instructional Systems Technology from Indiana University. He's worked in both start-up boutiques interfacing with clients to turn ideas into solutions as well large global organizations working to build effectiveness and efficiency.

Pete Hybert
www.prhconsulting.com

- Worked in the human performance improvement industry since 1984; external consultant since 1989
- Authored more than thirty articles on a variety of HPT-related topics
- Presented multiple times at ISPI, CISPI (Chicago Chapter of ISPI), ASQ, and ASTD
- Served as a volunteer
  - ISPI Chicago Chapter Past-President
  - ISPI Awards Committee Chair
  - ISPI Nominations Committee Chair
- CPT since 2003, Lifetime ISPI member since 2007

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SURVEY

Please take a moment to complete and hand-in the brief survey about training and qualification in regulated environments.

We will provide a summary of the results at the end of the session.

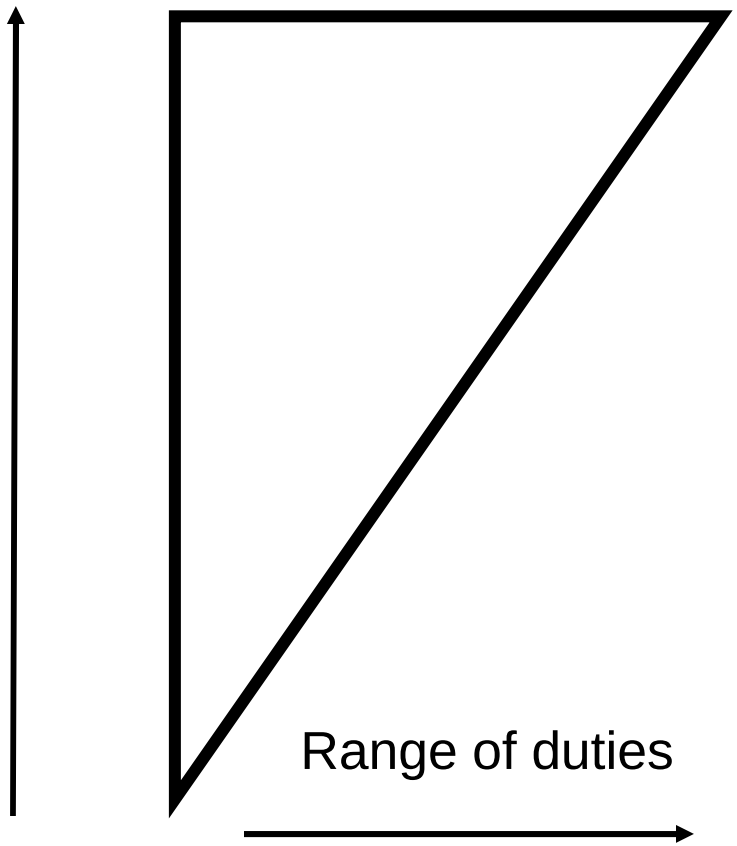
Business Challenge

- Stable pharmaceutical. Regulated. Compliance is ever-present.
- The device enterprise is growing. Four lines launched in one year.
- Other manufacturing areas are able to contribute (sometimes) senior personnel.
- Onboarding and integrating new team members is a continuous challenge.
- Meeting demand for recently-launched and launching devices is a challenge.

How can we integrate new team members and have an equitable assignment of duties?

- Duties have a range of complexity: from loading material to inspecting materials and output through managing a lot.
- Team members vary in terms of commitment.
- Long/slow learning curve to bring new operators up to speed (even if they are experienced).
  - •Training requirements and grouping
  - •Unclear steps and timeframe for “sign-off”

Growth in New Area, Shrink in Mature Businesses—Inherited Highly Paid Employees



Level 3: Deep technical expertise

Level 2: Able to understand the system

Level 1: Able to execute

No Flexibility

- Difficult to shift resources as workload fluctuates
  - Between areas
  - Between shifts
  - Between lines

Current Practice and Why it Wasn't Good Enough

Training—Largely Paper Exercise

- The pursuit of compliance is implicitly equated with training
- SOP-Based Training— Ensure we have signatures in place
- Focus on Compliance versus Capability
  (Tail Wagging the Dog)
- Team members vary in terms of commitment.

On-The-Job Training

- The bar to become an OJT instructor is low.
- OJT instructors not qualified – nor held accountable or rewarded.
- The system promoting six OJT sessions in one day – some conducted in a conference room.
- No objective evidence of capability – only the instructor's signature.

No Big Picture—People Don't Know Why

- On-boarding is characterized by people being asked to read through a stack of 15-20 SOPs. Alone in a cube.
- New team members are not receiving advanced organizers through which to assimilate new knowledge
  - how devices impact patients' lives.
  - the objectives of device manufacturing.
- The respect for people is not reflected in the on-boarding.
- Individuals being asked to contribute with context.

Regulator Requirement of Evidence

- The FDA requires evidence of qualification
- Signatures do not provide objective evidence

Solution Overview

O T A

Training at DDAO: OTA

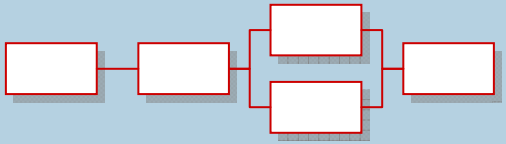
Answers That Matter.

O T A

Training at DDAO is based on an **OTA** model, which stands for **O**verview, **T**raining, and **A**ssessment.

Overview
The Big Picture

The Overview will provide you with a framework that is designed to help you understand the details you get in the Training.



Training
The Details

The Training gives you all the skills and knowledge you need to do your job.

Assessment
A check of what's been learned

The assessments are simply a check to ensure that the Overview and the Training really worked—that you learned the right things.

Qualification at DDAO: OTA Detail

Answers That Matter.

New Employee:
This is someone new to a particular duty (it could also be someone new to Lilly). They will get an overview before they begin a duty.

Employee in Training
This is someone who is taking courses but is not ready to work independently.

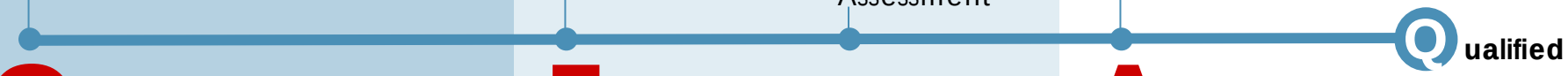
Qualified Employee:
This is an employee who is able to make an independent contribution to DDAO operations.

Take Overview Course

Take Required Courses

Finish Required Courses and Schedule Assessment

Take Assessment – a gate to working independently



Overview

An overview of a duty provides:

- The "big picture".
- Why the duty is important.
- What impact the duty (doing it right and doing it wrong) has on the patient.
- What knowledge and performance objectives you will need to meet.

Training

Training for a duty provides:

- All the courses necessary for successful performance of the duty.
- An opportunity to practice the duty.
- An opportunity to ask questions.

Assessment

Assessment for a duty provides:

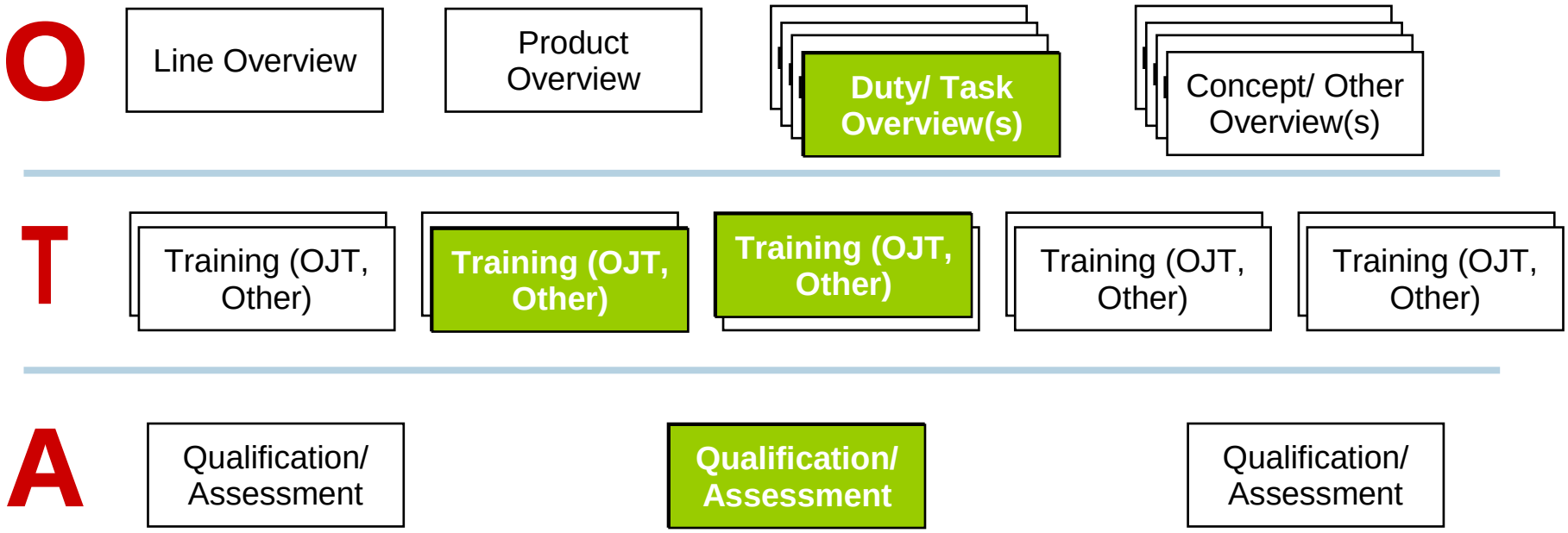
- An opportunity to show what you have learned.
- Assurance that you can perform the duty according to the correct procedures.

Planning and Organization

Architecture

Mapping out the “chunks” and how they are related at the front-end is critical to ensure the priority items are developed first and to avoid gaps or overlaps.

DOMAIN, e.g., Area, Product, Manufacturing Line, Role, etc.



Deliverables Tracking

The architecture allowed us to generate and track a master list of items through the development process.

PROJECT OBJECT STATUS

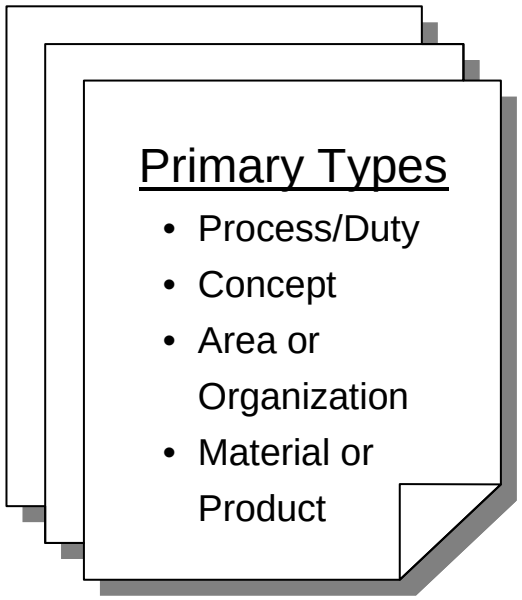
GROUP	#	Deliverable/Object	SME	Devel	DEVEL STAGE: Overall Status	Design	Content	Draft 1	Rev	Draft 2	Rev	Key IOUs	Pilot Version	Post-Pilot Revs
Eli 122a_DDAO Overviews and Performance Assessments														
		Critical Sensor Check												
1	1	(Common) Critical Sensor Check Overview	GP	PRH							TBD	Photos		N/A
	2	T4 Machine F/G-Critical Sensor Check PA	GP	PRH					wk 10/2					N/A
	3	T4 Machine C-Critical Sensor Check PA	GP	PRH					wk 10/2					N/A
	4	T4 Labeling Machine-Critical Sensor Check PA	GP	PRH					wk 10/2					N/A
	5	T4 Packaging-Critical Sensor Check PA	GP	PRH					wk 10/2					N/A
	6	E1 Module A-Critical Sensor Check PA	GP	PRH						TBD				N/A
	7	E1 Module B-Critical Sensor Check PA	GP	PRH						TBD				N/A
	8	E1 Labeling-Critical Sensor Check PA	GP	PRH					wk 10/2					N/A
	9	E1 Packaging-Critical Sensor Check PA	GP	PRH					wk 10/2					N/A
		QC Lab												
2	10	QC Lab OV	JR/ KB	PRH										N/A
	11	ABD PA	JR/ KB	PRH										N/A
	12	T4 Sub-Assembly Visual/ Functional Testing PA	JR/ LM	PRH										N/A
	13	T4 Performing DAGF Testing PA	JR/ TB	PRH										N/A
	14	E1 Sub-Assembly Visual/ Functional Testing PA	JR/ LM	PRH										N/A
	15	E1 Performing DAGF Testing PA	JR/ TB	PRH										N/A
	16	Daily Set-up (Backlab) PA	JR/ Deb	PRH			TBD							N/A

Components of an Effective Overview

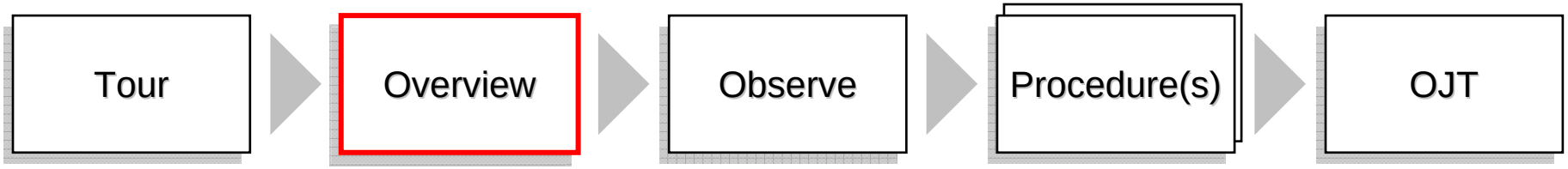
Purpose of the Overview

To establish context

- Boundaries and definitions
- How things work
- “Why’s”
- Watch-fors
  - Safety
  - Product quality
  - Equipment damage



Where it Fits



Materials

Overviews establish conceptual models, terms, labels

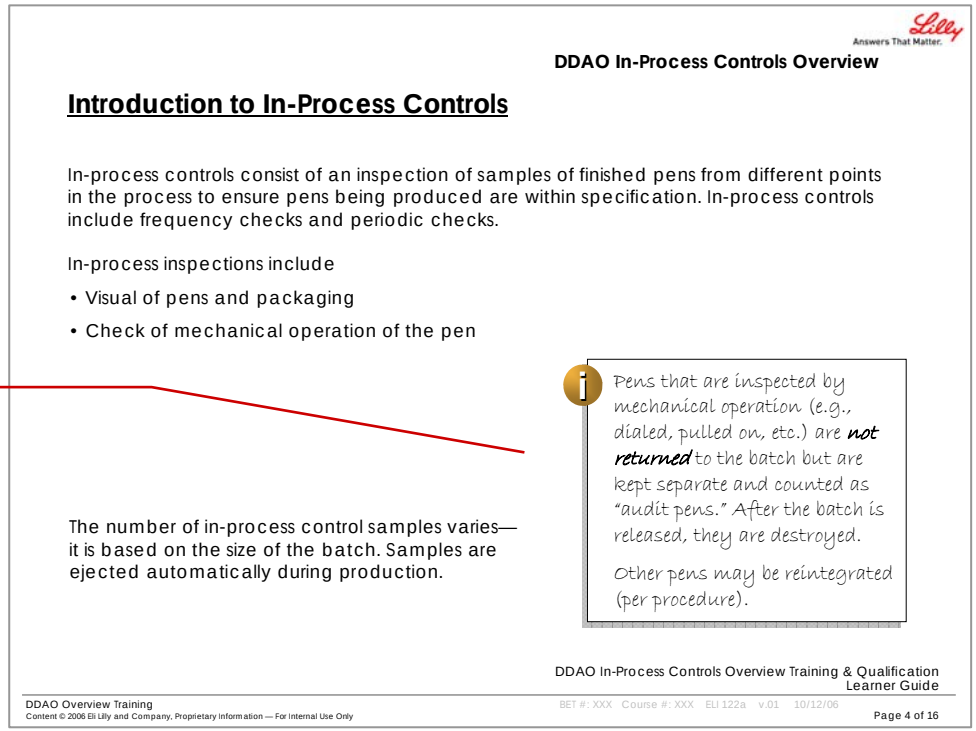
- Simplify/clarify
  - Use visuals appropriately (e.g., illustrations where possible)
  - Reinforce
  - Referable; “job aid-like”
- Design for consumability
  - Segment/focus
  - Template
- Connect to real environment

Example—Definitions and Background

The first step should be to establish the framework

- Boundaries
- Key terms and concepts
- Why this content is important

Sometimes, for interest, add a “fast fact” or point of interest



Lilly
Answers That Matter.

DDAO In-Process Controls Overview

Introduction to In-Process Controls

In-process controls consist of an inspection of samples of finished pens from different points in the process to ensure pens being produced are within specification. In-process controls include frequency checks and periodic checks.

In-process inspections include

- Visual of pens and packaging
- Check of mechanical operation of the pen

The number of in-process control samples varies—it is based on the size of the batch. Samples are ejected automatically during production.

Pens that are inspected by mechanical operation (e.g., dialed, pulled on, etc.) are ***not returned*** to the batch but are kept separate and counted as “audit pens.” After the batch is released, they are destroyed.

Other pens may be reintegrated (per procedure).

DDAO In-Process Controls Overview Training & Qualification
Learner Guide

DDAO Overview Training

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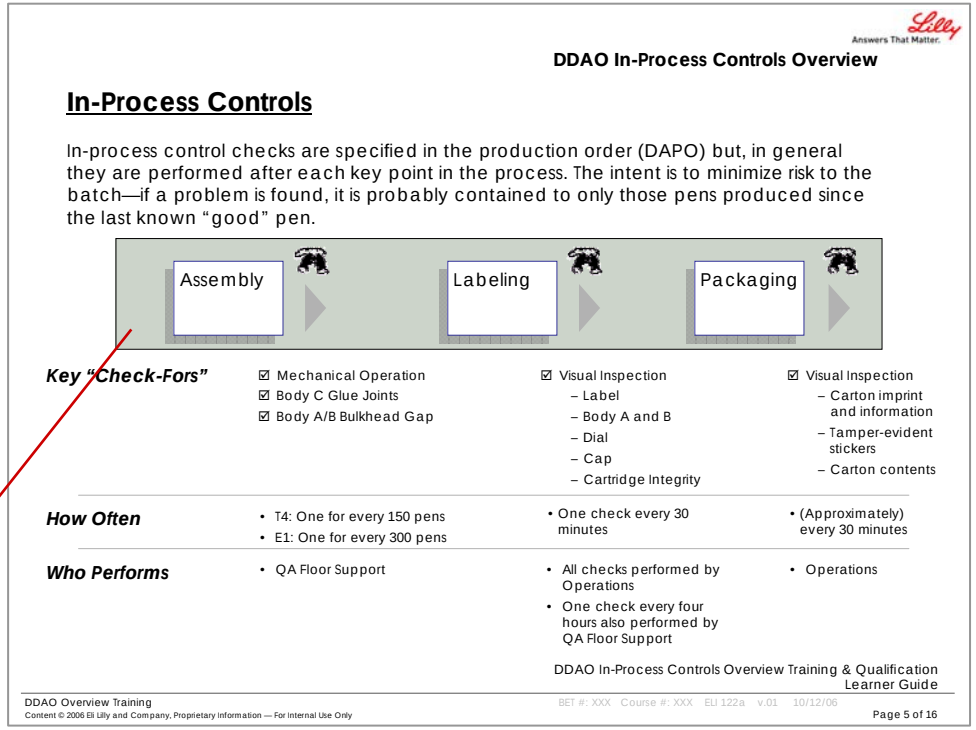
Example—Integration and Discrimination

Where possible, try to cover the entire scope of the content, rather than “drilling down”

- Emphasizes the concept
- Makes the specifics (discrimination) easier to learn
- Promotes share-ability of materials

Processes (and other organizing models) provide a clear framework for illustrating differences, supporting information, watch-fors, etc.



Lilly Answers That Matter.

DDAO In-Process Controls Overview

In-Process Controls

In-process control checks are specified in the production order (DAPO) but, in general they are performed after each key point in the process. The intent is to minimize risk to the batch—if a problem is found, it is probably contained to only those pens produced since the last known “good” pen.

Assembly → Labeling → Packaging

	Assembly	Labeling	Packaging
Key “Check-Fors”	☑ Mechanical Operation ☑ Body C Glue Joints ☑ Body A/B Bulkhead Gap	☑ Visual Inspection – Label – Body A and B – Dial – Cap – Cartridge Integrity	☑ Visual Inspection – Carton imprint and information – Tamper-evident stickers – Carton contents
How Often	• T4: One for every 150 pens • E1: One for every 300 pens	• One check every 30 minutes	• (Approximately) every 30 minutes
Who Performs	• QA Floor Support	• All checks performed by Operations • One check every four hours also performed by QA Floor Support	• Operations

DDAO In-Process Controls Overview Training & Qualification Learner Guide

DDAO Overview Training

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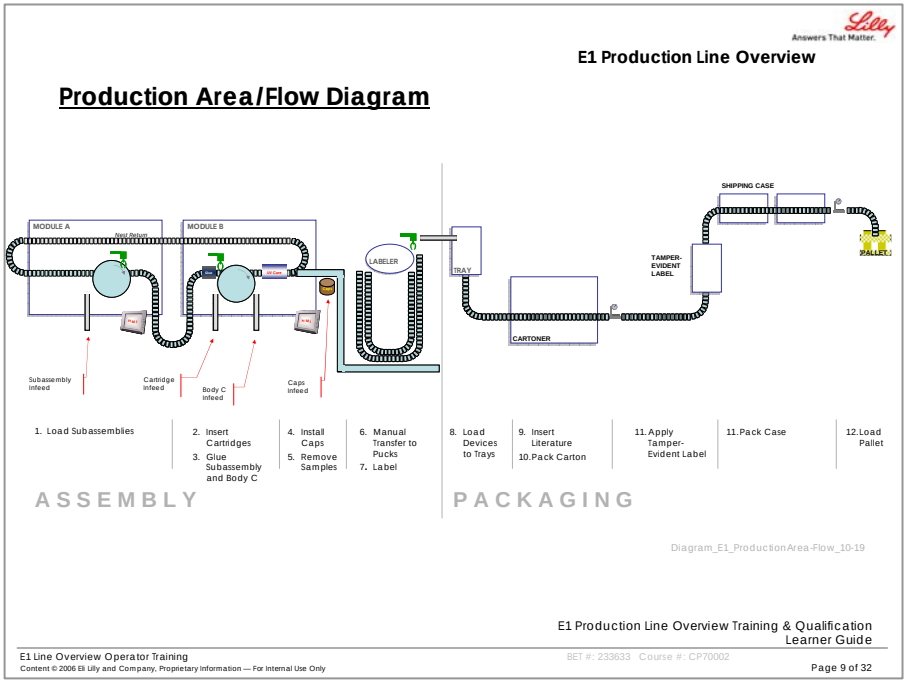
Example—Manufacturing Process

We recommend creating an overall model of the process as an advance organizer

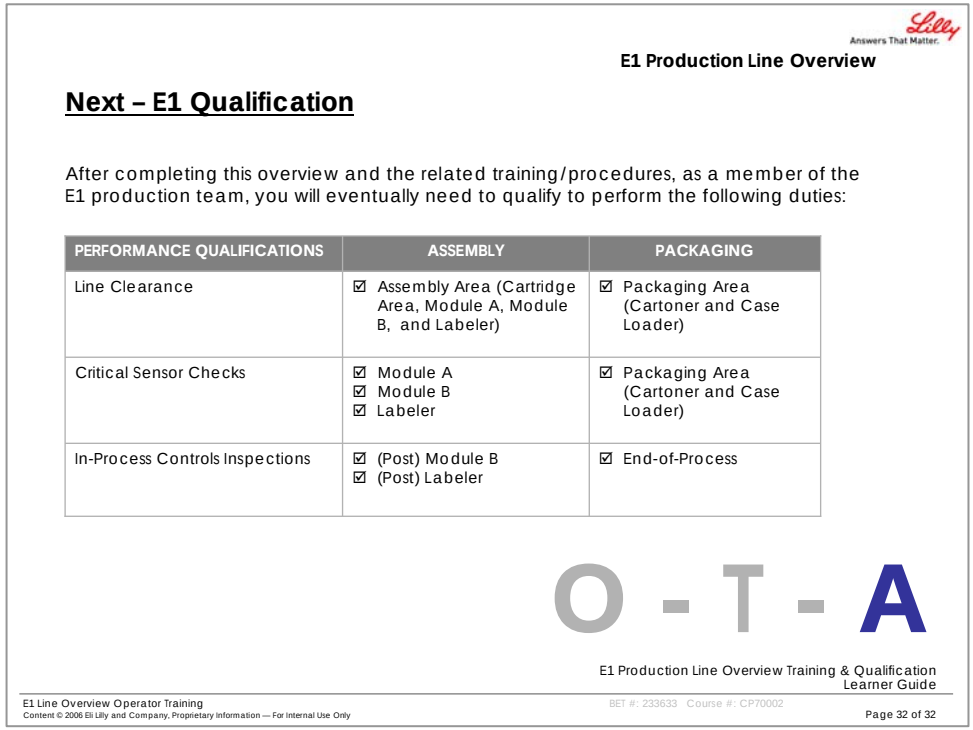
- Should be simplified—not including every detail
- Should link to the actual environment—too abstract will not resonate with learners
- If possible, use a “right to left”/ “top to bottom” organization



Example--Providing a “Heads-Up” About Qualification

Point to what is next—in this case, WIIFM is qualification

- Depends on the breadth of the scope—different audiences may have different next steps



Lilly Answers That Matter.

E1 Production Line Overview

Next – E1 Qualification

After completing this overview and the related training/procedures, as a member of the E1 production team, you will eventually need to qualify to perform the following duties:

PERFORMANCE QUALIFICATIONS	ASSEMBLY	PACKAGING
Line Clearance	☑ Assembly Area (Cartridge Area, Module A, Module B, and Labeler)	☑ Packaging Area (Cartoner and Case Loader)
Critical Sensor Checks	☑ Module A ☑ Module B ☑ Labeler	☑ Packaging Area (Cartoner and Case Loader)
In-Process Controls Inspections	☑ (Post) Module B ☑ (Post) Labeler	☑ End-of-Process

O - T - A

E1 Production Line Overview Training & Qualification
Learner Guide

E1 Line Overview Operator Training

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Components of Effective Training

Context

Culturally

- “Training” = Procedures
- OJT meant both the training materials and the somewhat unstructured “watch and learn” process
- Content focused on the steps vs. concepts and generalizable skills

(New) Purpose of the Training

- Bring the employee up the learning curve
  - Bridge between what they know and need to learn
  - Reinforce core concept models
  - Build skills/"hands-on" in a safe learning environment
- Focus on training as a ***process*** versus compliance event
  - Leverage procedures for content
  - Instructions for trainer
  - Situations, skill practice

Example—SOP

FROM

Inspection Station Set-up

The PT-3 or EMO will use the following steps to set the cotton detector sensors to the appropriate height for the set-up bottle.

Step	Action
1	Place the cottoner in the set-up level.
2	Go to the Calibrate Cotton Sensor Screen.
3	Place a properly cottoned bottle under the Cotton Presence Sensor 5PX.
4	Make sure that the sensor is centered on the bottle opening.
5	With an appropriate bottle in position under the sensor, view the Cotton Presence Sensor 5PX. **Note: It will be *red* when activated.**
6	If sensor is not red, adjust the height of the sensor until it turns red. Once it has turned red, press the 1 Button.
7	Place a bottle without cotton (Reject) under the Cotton Presence Sensor 5PX.
8	Make sure that the sensor is centered on the bottle opening.
9	With a reject bottle in position under the sensor, view the Cotton Presence Sensor 5PX indicator bar.
10	It will remain ***black***. Press the 2 Button. Remove the reject bottle.
11	Test the high cotton sensors by blocking the cotton and bottle sensor and verifying the reject gate activates. If the reject gate does not activate, contact Supervision, QC, and Engineering.
12	Test the missing cotton sensors by blocking the bottleneck sensor and verifying the reject gate activates. If the reject gate does not activate, contact Supervision, QC, and Engineering.
13	Test the set-up by sending through the bottle without rayon/cotton and verify that it is rejected. If the reject gate did not actuate, verify the set-up and repeat the test. If the reject gate does not activate, contact Supervision, QC, and Engineering.
14	Test the set-up by sending through a bottle with rayon/cotton above the rim and verify that it is rejected. (If the reject gate actuated, but did not completely reject the bottle adjust the timing in detector panel.) If the flipper did not actuate verify the set-up and repeat the test. If the reject gate does not activate, contact Supervision, QC and Engineering.
15	Verify the Fail-safe alarm by tripping the missing cotton/rayon sensor five (5) times in quick succession. Verify the alarm sounds, the strobe indicates, and the machine stops running. If the alarm does not activate, contact Supervision, QC, and Engineering.
16	Discard the two (2) defaced set-up bottles after set-up has been complete.
17	Upon Completion of set up, place the cottoner in the operator user level.

TO

Changeover Set-Up, continued

INSTALL SLATS (BATCH-SPECIFIC), continued

Step	Action	Detail
11.	When the slats have stopped moving, insert the slat indicated on the HMI at the top of the machine.	
12.	Press the [Advance Slats] button and place the indicated slat on the Lakso Filler.	
13.	After installing all the slats, the [Proceed to Microscan Set-up] button will appear.	

⚠ Slats must be sequenced correctly for the process to work.

Components of an Effective Assessment

Approach

- Assessment was used in a variety of ways
  - OJT “sign-off” – Okay to perform (subjective)
  - Knowledge test (CBT)

- Goal: Objective evidence of capability to perform
  - Use as “gate” to performing solo
  - Capable of “normal” performance (including non-standard events)
  - In real job environment with normal job tools (i.e., “open book”)

Changes in Approach

More focus on performance-based

- Real-work
- Simulated work
- “What-if” scenarios

*The trainer should **not** be the assessor.*

Method for Assessment

	Process	**Output**
	Must *observe* to assess	May evaluate an *output*
For Example	Sensor Checks	Batch Release Decision

Materials

Development of qualification instruments requires distilling procedure steps to “the right scale” and defining criteria—usually through observation and interviews.

Example – Performance Checklist

The key to ***consistent and objective*** assessment is the criteria.

The key to ***avoiding problems*** is alignment with the procedure.

Describe the steps the ***assessor*** should take

List criteria as objectively as possible

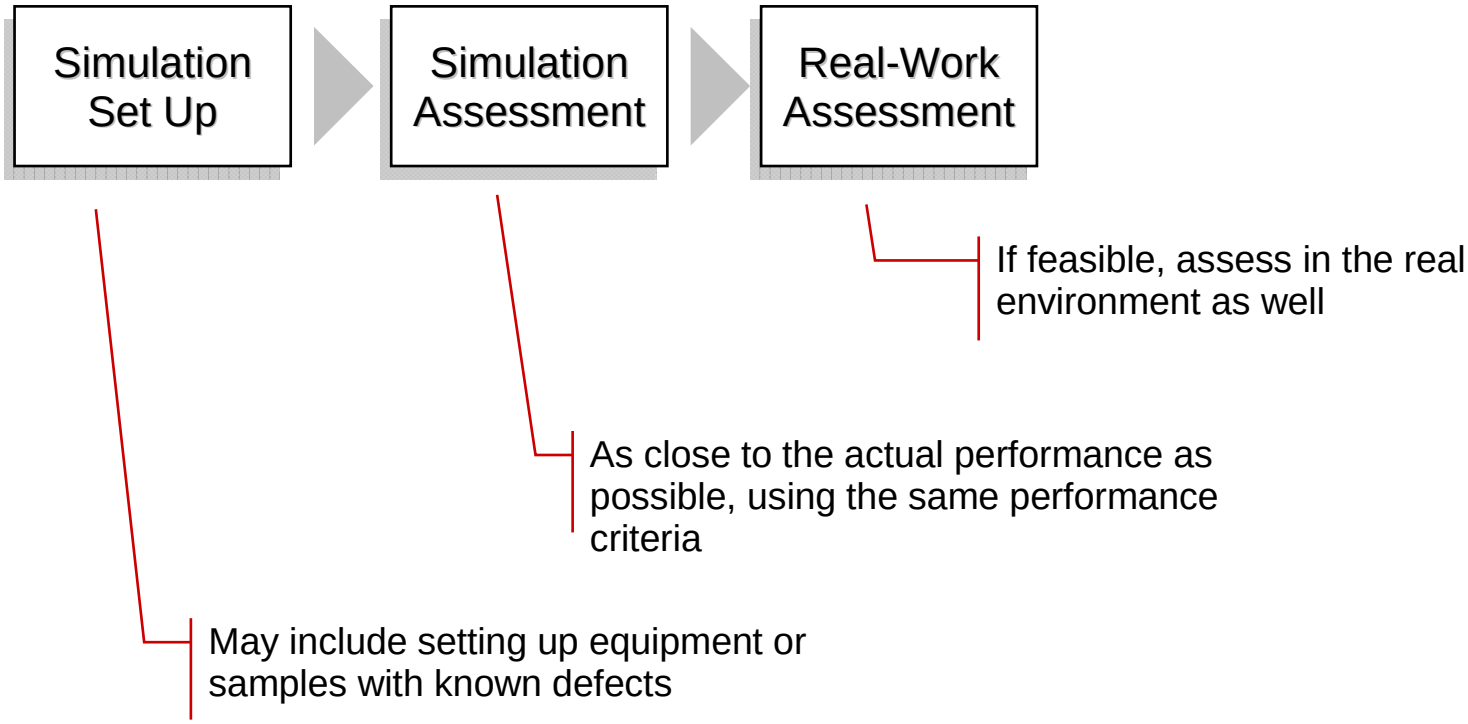
Action Item No.	Activity	Expected Response(s) and/or Comments	Met	Not Met	PA Facilitator Initials (If Action Item is Performed Correctly)
PERFORM: SIMULATED FREQUENCY CHECKS AFTER MACHINE D, continued					
1.	OBSERVE check of Body A and B	• Identified any defects that were present	❑	❑	
2.	OBSERVE check of the dial	• Identified any defects that were present	❑	❑	
3.	ASK "Please describe three examples of dial defects for which you are inspecting."	• Answer included the following: o Arrow not centered o Arrow not completely visible o Damage or deformities to dial	❑	❑	

Incorporate ***knowledge*** questions in context of performance

Include space for documentation

Example – Performance Checklist for a Simulation

This format is a similar as possible to a “real-work” checklist – the difference is additional simulation set-up instructions.



Simulation—In-Process Inspection

This performance required inspection of partially assembled products—in practice, performers would be unlikely to encounter a defect during an entire shift.

Action Item No.	Activity	Expected Response(s) and/or Comments	Met	Not Met	PA Facilitator Initials (If Action Item is Performed Correctly)
PERFORM: DEFECT IDENTIFICATION AND CLASSIFICATION					
16.	For first defect found, ASK participant to identify and classify the defect. (Note the defect and device number)	• Identified the defect correctly	❑	❑	
		• Classified the defect correctly	❑	❑	
		• Used additional tools (e.g., ruler) appropriately	❑	❑	
		• Set defective device aside	❑	❑	
17.	For first defect found, ASK participant to explain the rationale for the defect category selected	• Criteria matched specification/procedure	❑	❑	
18.	For second defect found, ASK participant to identify and classify the defect. (Note the defect and device number)	• Identified the defect correctly	❑	❑	
		• Classified the defect correctly	❑	❑	

Environmental Solutions and Implementation Tips

On the Training

- Don’t replicate SOP content for training. It creates a mess and is redundant work.
- Build user-centered SOPs – leveraging usability and information design. Everything rests on this foundation.
- Leverage the SOP content as the course for OJT.
- Administrate OJT activity in terms of frequency, duration and instructor accountability.
- Choose and rigorously train OJT instructors.

On Assessment

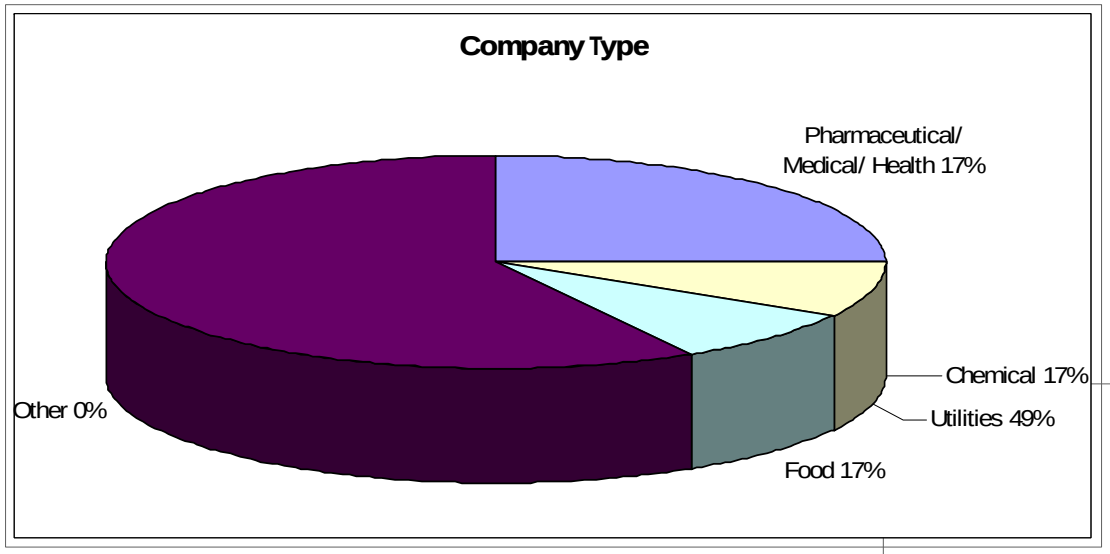
- Don’t assess everything. Have leadership (including line leadership) choose the most critical duties requiring assessment.
- State the objectives for the Assessment in your Overview – knowledge and skills.
- The Overview should be represented in the assessment.
- Ensure the Assessment covers knowledge and skills – the whole range of the duty.
- Be curious about combining knowledge and skills in one performance assessment. Pros and Cons.
- Decisions about grandfathering are critical; be careful and build consensus.

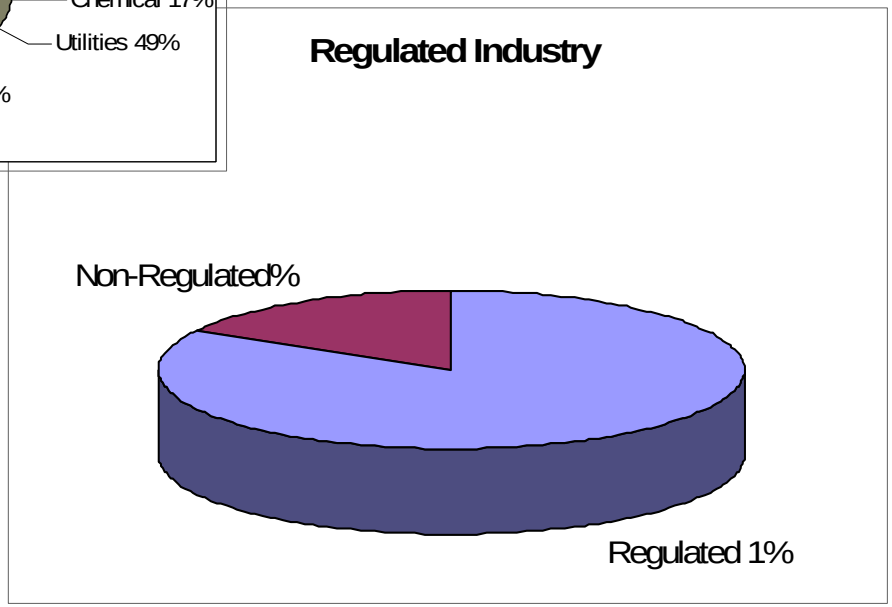
Get Engaged on the Line

- Work with line leadership to winnow the list of OJT instructors.
- Place OJT instruction on individuals' performance plans.
- Line leader conducts Assessment after OJT instructor and trainee have agreed the trainee is ready to be assessed.
- Observe assessments and OJTs.
- OJT instructor should be engaged in any necessary remediation.
- Regularly meet with line leaders and OJT instructors to get honest feedback.
- Communicate early and often to minimize concerns about testing.

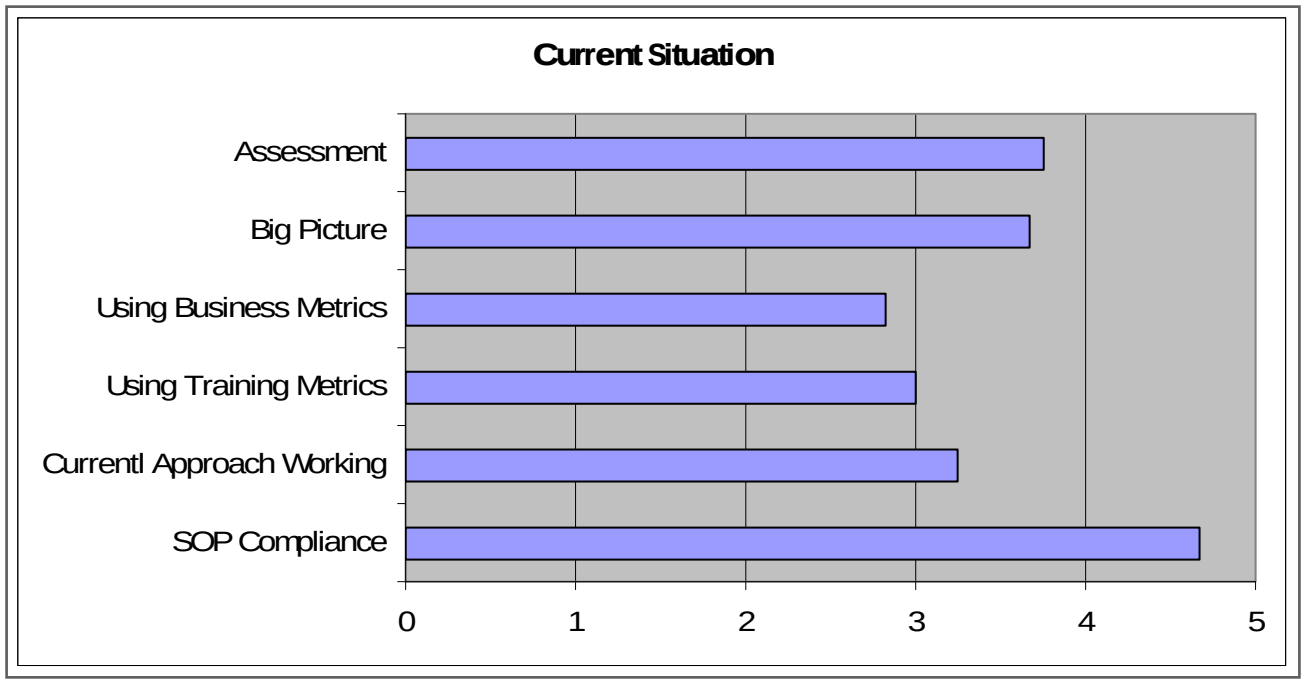
Survey Summary/ Read-Out

Demographics





Current Situation



Q&A

Thanks for your interest and participation!

Please remember to fill out an evaluation form.

Enjoy the rest of the conference!

For More Information . . .

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See Also

Articles

On the PRH Consulting website:

- Pdf version of this presentation
- "It Only Counts if You can do the Job!," by Peter R. Hybert and Kelly R. Smith, (originally authored in 1999)
- "Project Profile: Developing a Qualification Catalog for an Engineering Organization," by Peter R. Hybert (originally authored in 1999)
- "Why Employees Need to Know Why," (extended version of an article originally published in Building Capability, Volume 1, Issue 1, March 2005)

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