

The Moment a Customer Asks About the Production History of One Product · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Process Sequence	Interpret the Code List and Check Equipment Separately	Check the Registered Equipment Layout and Product Results Together
Production History of the Semi-Finished Product	Copy the Number and Search Separately	Follow the Input Relationships to Expand the Process on the Same Screen
Location of the Material Problem	Reinvestigate Where Used from the Full Material List	Check Input Locations, LOTs, and Quantities by Process and Equipment

Production Events and Traceability Evidence · Meaning and Judgment

Even when a product’s process codes and timestamps exist on multiple screens, customer responses remain manual if personnel must reconcile the relationships again. The starting point of this proposal is confirming the connections among finished products, semi-finished products, materials, inspections, and repairs as the flow of a single product.

The goal is not simply to display more data. It is to allow users to drill down to the necessary records without losing the product being queried and to explain the evidence on which a judgment was based.

Implementation Check Before implementation, record where the current inquiry stops and which person and screen are used to check it again, using one representative product.

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Actions After a Defect	Compile Repair Reports and Retest Results Separately	Link Defects · Repairs · Retests under the Relevant Equipment

Production Events and Traceability Evidence · Execution and Validation

The review items for “Process Sequence” are as follows. Business process · Record: Interpret the code list and check equipment separately; Judgment · Implementation Criteria: Check the registered equipment layout and product results together.

The review items for “Production History of the Semi-Finished Product” are as follows. Business process · Record: Copy the number and search separately; Judgment · Implementation Criteria: Follow the input relationships to expand the process on the same screen.

The review items for “Location of the Material Issue” are as follows. Work and records: Reinvestigate where materials are used across the full material list; decision and implementation criteria: Confirm input locations by process and equipment, as well as LOTs and quantities.

The moment a customer asks about the production history of a single product · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Actions After a Defect” are as follows. Work and records: Compile repair reports and reinspection results separately; decision and implementation criteria: Link defects, repairs, and reinspections under the relevant equipment.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing “The Moment a Customer Asks About the Production History of a Single Product” in this chapter, product, manufacturing number, process, time, operator, and material LOT must be interpreted using the same criteria. Those responsible for production, materials, quality, and customer response must verify not only the values they enter, but also the information received from the previous step and the status passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

CMC MES and Graphical Production History Traceability: Proposal Scope · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Verified in the provided materials	Code and instruction lookup, equipment-specific history, semi-finished product expansion	Description of the current functions in this proposal
Verified in the provided materials	Material LOTs and quantities by process, repair details, reinspection, output	Introduce in connection with the actual screens
Customer-specific implementation review	Equipment interfaces, collection items, identification relationships, exception handling	Finalize the applicable scope through on-site investigation and demonstrations

Production Events and Traceability Evidence · Meaning and Judgment

CMC MES links processes, equipment, operators, material input, inspections, repairs, and semi-finished products based on product identification and production performance data collection. Graphical production history traceability is a lookup method for verifying these links using the actual equipment layout and process sequence.

“Perfect traceability” is not an unconditional guarantee that no records will ever be missing. The implementation objective is to define the required scope of links, compare source records with the screens, and supplement any uncollected segments to create a state that can be explained from beginning to end.

Separate the implementation validation demonstration, interface list, and acceptance items, and agree on the contract scope and completion criteria.

Production Events and Traceability Evidence · Execution and Validation

The review items for “Verified in the Provided Materials” are as follows. Work and records: Code and instruction lookup, equipment-specific history, semi-finished product expansion; decision and implementation criteria: Description of the current functions in this proposal.

The review items for “Verified in the Provided Materials” are as follows. Work and records: Material LOTs and quantities by process, repair details, reinspection, output; decision and implementation criteria: Introduce in connection with the actual screens.

The review items for “Customer-Specific Implementation Review” are as follows. Work and records: Equipment interfaces, collection items, identification relationships, exception handling; decision and implementation criteria: Finalize the applicable scope through on-site investigation and demonstrations.

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Requires separate validation	Automatic shipment blocking, automatic retrieval and disposal, immediate connection of all equipment	Do not claim that implementation is complete based solely on the materials

CMC MES and Graphical Production History Traceability: Proposal Scope · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Requires Separate Validation” are as follows. Work and records: Automatic shipment blocking, automatic retrieval and disposal, immediate connection of all equipment; decision and implementation criteria: Do not claim that implementation is complete based solely on the materials.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

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Production Events and Traceability Evidence · Execution and Validation

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A Consistent Usage Flow for Lookup, Selection, Process, and Details · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
1. Lookup	Product code or production instruction	Finalize the criteria for finding the target
2. Selection	Model, current step, status, input and completion times	Distinguish other targets with the same name or related codes
3. Process Verification	Step summary and performance by equipment	Determine the location of the event to be verified
4. Detail Verification	Materials, repairs, downstream semi-finished products	Verify the basis for the judgment and the scope of the links

Production Events and Traceability Evidence · Meaning and Judgment

If all records are expanded from the beginning, the event you are looking for can get buried. Set the scope using the product or instruction, locate it within the overall process, and then expand the necessary details.

A customer response can start with a single product, while an on-site progress check can start with an entire production instruction. Even when the starting conditions differ, the same product identification relationships are maintained during detailed verification.

Implementation validation: When the same product is looked up from the two starting points, verify that identical process, material, and inspection histories are displayed.

Order of On-Site Implementation and Acceptance Testing

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Production Events and Traceability Evidence · Execution and Validation

The review items for “1. Lookup” are as follows. Work and records: Product code or production instruction; decision and implementation criteria: Finalize the criteria for finding the target.

The review items for “2. Selection” are as follows. Work and records: Model, current step, status, input and completion times; decision and implementation criteria: Distinguish other targets with the same name or related codes.

The review items for “3. Process Verification” are as follows. Work and records: Step summary and performance by equipment; decision and implementation criteria: Determine the location of the event to be verified.

A Consistent Usage Flow for Lookup, Selection, Process, and Details · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “4. Detail Verification” are as follows. Work and records: Materials, repairs, downstream semi-finished products; decision and implementation criteria: Verify the basis for the judgment and the scope of the links.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

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Production Events and Traceability Evidence · Execution and Validation

When reviewing “A Consistent Usage Flow for Lookup, Selection, Process, and Details” in this chapter, product, manufacturing number, process, time, operator, and material LOT must be interpreted using the same criteria. Those responsible for production, materials, quality, and customer response must verify not only the values they enter, but also the information received from the previous step and the status passed to the next step.

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Find Using Multiple Codes, but Maintain a Single Product Identity · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Product identification code	Serial, matching code, process code	Verify which actual product the related code refers to
Package identification	BOX code	Verify the scope of the link between the box and its component products
Instruction lookup	Period and production instruction	Verify the production targets and status for the instruction

Production Events and Traceability Evidence · Meaning and Judgment

The introductory materials explain lookup by cross-checking Serial, matching code, process code, and BOX in sequence, as well as looking up a product list by period and instruction number. This reduces the burden of first selecting the appropriate code type.

Do not state that all label formats and reissue rules are automatically supported without prior verification. Validate code interpretation and target selection using on-site samples, and agree on how relationships will be preserved when codes change.

Implementation validation: Organize the expected results for valid codes, related codes, unregistered codes, and scanned values containing additional information.

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Additional scan information	Actual barcode samples from the site	Verify recognizable formats and exception values through demonstrations

Production Events and Traceability Evidence · Execution and Validation

The review items for “Product Identification Code” are as follows. Work and records: Serial, matching code, process code; decision and implementation criteria: Verify which actual product the related code refers to.

The review items for “Package Identification” are as follows. Work and records: BOX code; decision and implementation criteria: Verify the scope of the link between the box and its component products.

The review items for “Instruction Lookup” are as follows. Work and records: Period and production instruction; decision and implementation criteria: Verify the production targets and status for the instruction.

Find Using Multiple Codes, but Maintain a Single Product Identity · 2

Provided Introduction, Chapter 4 · Find Using Multiple Codes, but Maintain a Single Product Identity



Previously Published Demonstration Materials · Implementation Screens and Scope to Be Finalized After Business Review

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Additional Scan Information” are as follows. Work and records: Actual barcode samples from the site; decision and implementation criteria: Verify recognizable formats and exception values through demonstrations.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

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Production Events and Traceability Evidence · Execution and Validation

When reviewing “Find Using Multiple Codes, but Maintain a Single Product Identity” in this chapter, product, manufacturing number, process, time, operator, and material LOT must be interpreted using the same criteria. Those responsible for production, materials, quality, and customer response must verify not only the values they enter, but also the information received from the previous step and the status passed to the next step.

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Read the Current Status Together with Past Events · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Current status	The product's current status	Used to determine whether it is in progress, complete, or defective
Past defect	Where and what type of defect occurred	Used to analyze the circumstances and identify improvements
Repair history	What action was taken	Verify the person responsible, details, and time
Reinspection result	How the inspection concluded after the action	Verify as the basis for the current status

Production Events and Traceability Evidence · Meaning and Judgment

Narrow the targets to in progress, complete, defective, or disposed, while distinguishing past defect events from the current product status. The materials explain that products passing reinspection are classified according to their current status and are not counted as defective.

Do not hide past events through reinspection approval, and do not mistake the number of past defect occurrences for the number of currently defective products. Confirm the aggregation unit and status determination criteria together with the actual operating rules.

Implementation validation: Prepare examples of normal completion, an unresolved defect, reinspection approval after repair, and disposal, and compare the lists with the details.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

The review items for “Current Status” are as follows. Work and records: The product's current status; decision and implementation criteria: Used to determine whether it is in progress, complete, or defective.

The review items for “Past Defect” are as follows. Work and records: Where and what type of defect occurred; decision and implementation criteria: Used to analyze the circumstances and identify improvements.

The review points for “Repair History” are as follows. Work and records: what action was taken; decision and implementation criteria: verify the person in charge, details, and time.

Read the current status and past events together · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review points for “Retest Results” are as follows. Work and records: how the inspection concluded after the action; decision and implementation criteria: verify it as the basis for the current status.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

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4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing “Read the current status and past events together” in this chapter, read the product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer response verify not only the values they enter, but also the information received from the preceding step and the status to be passed to the next step.

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Check production records at the locations of the actual equipment · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Step summary	Overall route and time by step	Decide which section to examine in detail
Equipment layout	Registered process sequence and equipment	Verify the correspondence between the shop floor and the screen
Production record location	Time, operator, and result under the relevant equipment	Verify the events that actually occurred for the product

Production Events and Traceability Evidence · Meaning and Judgment

Summarize the time required for each step and place the equipment and production records below it. Instead of memorizing process codes, understand the product’s progress through the shape and location of the equipment.

The meaning of the graphics becomes clear only when the process configuration and equipment registration match the actual shop floor. Equipment illustrations are not decoration; they provide location information for tracing events by product. The registration criteria must also be managed when equipment is replaced or lines are changed.

Implementation check: review the equipment names, layout sequence, and production record locations together with the shop-floor personnel. Do not replace unregistered equipment with arbitrary example illustrations.

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Expand details	Materials, repairs, and semi-finished products	Review while maintaining the context of a single product

Production Events and Traceability Evidence · Execution and Validation

The review points for “Step Summary” are as follows. Work and records: overall route and time by step; decision and implementation criteria: decide which section to examine in detail.

The review points for “Equipment Layout” are as follows. Work and records: registered process sequence and equipment; decision and implementation criteria: verify the correspondence between the shop floor and the screen.

The review points for “Production Record Location” are as follows. Work and records: time, operator, and result under the relevant equipment; decision and implementation criteria: verify the events that actually occurred for the product.

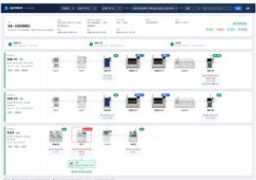
Check production records at the locations of the actual equipment · 2

Provided brochure, Chapter 5 · Check production records at the locations of the actual equipment

공정을 설비 그림으로 확인합니다

앞에서 해석하지 않고 보는 즉시 파악합니다

- 설비 없이도 확인합니다
설비 모형과 배치 순서가 실제와 같아, 공정흐름을 모르는 분
명확히 설비 배치 없이 확인할 수 있습니다. 고객 대응 목적으로 그
대로 사용합니다.
- 단계로 요약하고 상세로 내려갑니다
전단계 단계별 소요 시간을 파악하고, 그 하위에 각 단계의 상세
설비를 배치합니다. 단계를 먼저 보고 필요한 작업을 확인합니다.



Previously Published Demonstration Materials · Implementation Screens and Scope to Be Finalized After Business Review

Production Events and Traceability Evidence · Meaning and Judgment

The review points for “Expand Details” are as follows. Work and records: materials, repairs, and semi-finished products; decision and implementation criteria: review while maintaining the context of a single product.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

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Production Events and Traceability Evidence · Execution and Validation

When reviewing “Check production records at the locations of the actual equipment” in this chapter, read the product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer response verify not only the values they enter, but also the information received from the preceding step and the status to be passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Distinguish between connected lines and independent workstations · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
SMT	Continuous lines and production records by equipment	Distinguish line-wide responsibilities from equipment events
ICT · Routing	Independent workstation possible	Individually link each piece of equipment with its operator and work time
Insert · Coating	Applicability and sequence vary by product	Compare the registered route with the actual passage

Production Events and Traceability Evidence · Meaning and Judgment

SMT can be operated as a connected line, but ICT, routing, coating inspection, and assembly·EOL may be separate workstations or different lines. Lines on the screen represent the product's progression relationships and do not uniformly indicate physical conveyor connections.

This table provides criteria for distinguishing shop-floor designs; it is not a fixed sequence applied to all electronic products. First verify the actual route of a single product, then arrange the equipment.

Implementation check: verify the physical layout and the product's process sequence separately, and review whether the two concepts have been kept distinct.

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Assembly · EOL	Separate line and inspection configuration possible	Link semi-finished product input with final inspection

Production Events and Traceability Evidence · Execution and Validation

The review points for "SMT" are as follows. Work and records: continuous line and production records by equipment; decision and implementation criteria: distinguish line-wide responsibilities from equipment events.

The review points for "ICT·Routing" are as follows. Work and records: independent workstation possible; decision and implementation criteria: individually link each piece of equipment with its operator and work time.

The review points for "Insert·Coating" are as follows. Work and records: applicability and sequence vary by product; decision and implementation criteria: compare the registered route with the actual passage.

Distinguish between connected lines and independent workstations · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review points for “Assembly·EOL” are as follows. Work and records: separate line and inspection configuration possible; decision and implementation criteria: link semi-finished product input with final inspection.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

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Production Events and Traceability Evidence · Execution and Validation

When reviewing “Distinguish between connected lines and independent workstations” in this chapter, read the product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer response verify not only the values they enter, but also the information received from the preceding step and the status to be passed to the next step.

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Link operators and quantities according to the criteria applicable at the time · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Operator identification	Operator ID and, if necessary, name	Distinguish SMT line-wide assignment from independent workstation assignment
Assignment timing	Time of shift or assignment change	Verify the person responsible at the time the product passed through
Work time	Input, completion, inspection, and repair times	Clearly indicate what event the time refers to

Production Events and Traceability Evidence · Meaning and Judgment

The operator ID and production record for the time the queried product passed through are required. If the current equipment operator is applied to past history or records are overwritten after a shift change, it becomes difficult to explain what actually happened during the work.

Do not assume that productivity calculations by operator or automatic assignment of all equipment are standard features. Confirm the required history level and the items that can be collected during implementation.

Implementation check: compare products from before and after a shift and products recorded by different inspection or routing personnel to verify the identification links.

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Production quantity	Ordered quantity · passed quantity · quantity used	Distinguish the aggregation target and unit

Production Events and Traceability Evidence · Execution and Validation

The review points for “Operator Identification” are as follows. Work and records: operator ID and, if necessary, name; decision and implementation criteria: distinguish SMT line-wide assignment from independent workstation assignment.

The review points for “Assignment Timing” are as follows. Work and records: time of shift or assignment change; decision and implementation criteria: verify the person responsible at the time the product passed through.

The review points for “Work Time” are as follows. Work and records: input, completion, inspection, and repair times; decision and implementation criteria: clearly indicate what event the time refers to.

Link operators and quantities according to the criteria applicable at the time · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review points for “Production Quantity” are as follows. Work and records: ordered quantity, passed quantity, and quantity used; decision and implementation criteria: distinguish the aggregation target and unit.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

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Production Events and Traceability Evidence · Execution and Validation

When reviewing “Link operators and quantities according to the criteria applicable at the time” in this chapter, read the product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer response verify not only the values they enter, but also the information received from the preceding step and the status to be passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Which equipment used which material LOT? · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Material item	What was used?	Distinguish different LOTs of the same item
Input location	In which process or on which equipment was it used?	Link the product route with the usage location
Material LOT	Which production or management unit was it?	Investigate the scope of use of the same LOT
Quantity	How much was recorded, and according to what criteria?	Verify the meaning, such as mounted, used, or remaining quantity

Production Events and Traceability Evidence · Meaning and Judgment

Move beyond the overall materials list and link material LOTs and quantities to the input locations for each process and piece of equipment. This provides the basis for verifying the actual usage location when investigating material defects.

The planned materials registered in the BOM differ from the materials actually input. Do not confirm a material as part of the product's usage history merely because it was scheduled for use.

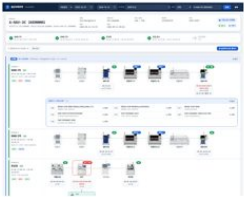
Implementation check: compare the actual material input records with the item, LOT, location, and quantity shown on the screen. For semi-finished items, also verify whether they are linked to their production history.

Provided brochure, Chapter 7 · Which equipment used which material LOT?

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Previously Published Demonstration Materials · Implementation Screens and Scope to Be Finalized After Business Review

Production Events and Traceability Evidence · Execution and Validation

The review points for “Material Item” are as follows. Work and records: what was used; decision and implementation criteria: distinguish different LOTs of the same item.

The review points for “Input Location” are as follows. Work and records: in which process or on which equipment was it used; decision and implementation criteria: link the product route with the usage location.

The review points for “Material LOT” are as follows. Work and records: which production or management unit was it; decision and implementation criteria: investigate the scope of use of the same LOT.

Which equipment used which material LOT · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review points for “Quantity” are as follows. Operations and records: What was recorded, and according to what criteria? Evaluation and implementation criteria: Confirm the meaning of such details as loaded quantity, used quantity, and remaining quantity.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

- 1. Confirm the Roles of Production · Materials · Quality · Customer Response
- 2. Compare Product Standards · Source Records
- 3. Confirm Exception Handling and Approval Evidence
- 4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Which equipment used which material LOT,” read the product, serial number, process, time, operator, and material LOT according to the same criteria. Personnel responsible for production, materials, quality, and customer response must verify not only the values they enter but also the information received from the preceding step and the status passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Validate the boundary between LOT changes and substitute materials · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Products before the LOT change	Previous LOT and input location	Compare source records with linkage results
Products after the LOT change	Changed LOT and time of application	Confirm that the previous LOT is no longer linked
Substitute materials	Approval criteria and actual input	Do not mistake planned materials for materials actually used

Production Events and Traceability Evidence · Meaning and Judgment

Even for the same item, the reel or LOT may change during production. If it is not possible to determine through which product the previous LOT was used, the scope of impact may become excessively broad.

This is a proposal for implementation validation. A live demonstration must confirm the level at which LOT boundaries can actually be distinguished, depending on equipment logs and the units used to collect production results.

Implementation validation Do not finish acceptance testing with just one normal production run; test before-and-after replacement cases and exceptions involving missing records.

The review points for “Products before the LOT change” are as follows. Operations and records: Previous LOT and input location; evaluation and implementation criteria: Compare source records with linkage results.

The review points for “Products after the LOT change” are as follows. Operations and records: Changed LOT and time of application; evaluation and implementation criteria: Confirm that the previous LOT is no longer linked.

The review points for “Substitute materials” are as follows. Operations and records: Approval criteria and actual input; evaluation and implementation criteria: Do not mistake planned materials for materials actually used.

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Part replacement during repair	Repair records and required material history	Confirm the collection scope separately for each customer

Production Events and Traceability Evidence · Execution and Validation

Validate the boundary between LOT changes and substitute materials · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review points for “Part replacement during repair” are as follows. Operations and records: Repair records and required material history; evaluation and implementation criteria: Confirm the collection scope separately for each customer.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

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Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Validate the boundary between LOT changes and substitute materials,” read the product, serial number, process, time, operator, and material LOT according to the same criteria. Personnel responsible for production, materials, quality, and customer response must verify not only the values they enter but also the information received from the preceding step and the status passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Link finished products to the actual intermediate products used · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Parent product	Finished product queried by the customer	Keep the query target
Input relationship	Identifier of the intermediate product actually used	Distinguish it from other intermediate products with the same item number
Downstream process	Production path of the intermediate product	Reduce the need to query again in another window
Downstream details	Material, inspection, and repair history	Verify even the evidence supporting the production history

Production Events and Traceability Evidence · Meaning and Judgment

When an intermediate product is selected from the input materials, its process is connected before the current product. The query context is maintained from the finished-product history through the board's inspection and material details.

Showing past history for the same item number is not the same as linking the intermediate product actually used. The collection procedure determines which identifier is matched and when during assembly.

Implementation validation Confirm with representative finished products that the actual assembly relationships at the site match the intermediate products displayed on screen.

Provided brochure, Chapter 6 · Link finished products to the actual intermediate products used

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Previously Published Demonstration Materials · Implementation Screens and Scope to Be Finalized After Business Review

Production Events and Traceability Evidence · Execution and Validation

The review points for “Parent product” are as follows. Operations and records: Finished product queried by the customer; evaluation and implementation criteria: Keep the query target.

The review points for “Input relationship” are as follows. Operations and records: Identifier of the intermediate product actually used; evaluation and implementation criteria: Distinguish it from other intermediate products with the same item number.

The review points for “Downstream process” are as follows. Operations and records: Production path of the intermediate product; evaluation and implementation criteria: Reduce the need to query again in another window.

Link finished products to the actual intermediate products used · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review points for “Downstream details” are as follows. Operations and records: Material, inspection, and repair history; evaluation and implementation criteria: Verify even the evidence supporting the production history.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Link finished products to the actual intermediate products used,” read the product, serial number, process, time, operator, and material LOT according to the same criteria. Personnel responsible for production, materials, quality, and customer response must verify not only the values they enter but also the information received from the preceding step and the status passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Review multi-level product relationships as one continuous flow · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Parent assembly	Process and status of the current product	Distinguish assembly completion from downstream status
Intermediate product	Process of the assembled product used	Maintain the linked production history
Downstream board	Board inspection, repair, and materials	Identify events not visible at the parent level
Changed relationship	Linkage handling during replacement and rework	Confirm the scope for implementing and recording additional exceptions

Production Events and Traceability Evidence · Meaning and Judgment

Follow multi-level relationships based on the input time, such as assemblies beneath a finished product and boards beneath an assembly. Expand only to the required depth and move between summaries and details.

The introductory material explains multi-level process linkage but does not define how every replacement and disassembly exception must be implemented. Determine which exceptions to apply according to site rules and validate them separately.

Implementation validation Prepare intermediate-product structures with at least two levels and rework cases to verify that incorrect parent-child links are not created.

Order of On-Site Implementation and Acceptance Testing

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Production Events and Traceability Evidence · Execution and Validation

The review points for “Parent assembly” are as follows. Operations and records: Process and status of the current product; evaluation and implementation criteria: Distinguish assembly completion from downstream status.

The review points for “Intermediate product” are as follows. Operations and records: Process of the assembled product used; evaluation and implementation criteria: Maintain the linked production history.

The review points for “Downstream board” are as follows. Operations and records: Board inspection, repair, and materials; evaluation and implementation criteria: Identify events not visible at the parent level.

Review multi-level product relationships as one continuous flow · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review points for “Changed relationship” are as follows. Operations and records: Linkage handling during replacement and rework; evaluation and implementation criteria: Confirm the scope for implementing and recording additional exceptions.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Review multi-level product relationships as one continuous flow,” read the product, serial number, process, time, operator, and material LOT according to the same criteria. Personnel responsible for production, materials, quality, and customer response must verify not only the values they enter but also the information received from the preceding step and the status passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Keep defect, repair, and retest events connected · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Defect	Time and details of occurrence	Identify the equipment where the event began
Cause and corrective action	Cause, cause code, and corrective action	Verify the registered repair evidence
Repair execution	Time, person responsible, and repair details	Distinguish planned actions from actions actually taken
Retest	Reinspection result	Do not infer acceptance from repair notes alone

Production Events and Traceability Evidence · Meaning and Judgment

Review the defect’s time and details, the repair personnel and actions taken, and the retest results in sequence under the relevant equipment. Explain the basis for the current status together with the past events.

Repair completion and inspection acceptance are not the same event. The verification performed after the action must be recorded in order to answer customer questions fully.

Implementation validation Compare the display order and current status across cases of an unresolved defect, an ongoing repair, and a passed retest.

Provided brochure, Chapter 8 · Keep defect, repair, and retest events connected

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Production Events and Traceability Evidence · Execution and Validation

The review points for “Defect” are as follows. Operations and records: Time and details of occurrence; evaluation and implementation criteria: Identify the equipment where the event began.

The review points for “Cause and corrective action” are as follows. Operations and records: Cause, cause code, and corrective action; evaluation and implementation criteria: Verify the registered repair evidence.

The review points for “Repair execution” are as follows. Operations and records: Time, person responsible, and repair details; evaluation and implementation criteria: Distinguish planned actions from actions actually taken.

Previously Published Demonstration Materials · Implementation Screens and Scope to Be Finalized After Business Review

Keep defect, repair, and retest events connected · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Reinspection” are as follows. Work and records: reinspection results; judgment and implementation criteria: do not infer a pass based solely on repair notes.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

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Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Do not break the chain of nonconformance, repair, and reinspection events,” read the product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer support must verify not only the values they enter but also the information received from the previous step and the status passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Do not fill in unregistered records as though they were facts · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Unregistered	Work records cannot be verified	Additional verification with the person in charge and source records
Not collected	Possibly outside the connection or collection scope	Verify the interface and collection procedure
Not applicable	A process not applied to the product route	Compare against the registration criteria

Production Events and Traceability Evidence · Meaning and Judgment

The materials explain that details are not provided when no repair record exists. Distinguish between the fact that no record exists and the conclusion that no actual work was performed.

The distinctions in the table are operational verification criteria. Do not claim that all status codes not included in the materials have already been implemented. Agree on the indicators and determination scope required on site.

Implementation verification: Confirm the indicators for products without repair details and processes not yet performed, and check whether users could misunderstand them as a pass or as a missing process.

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Not yet performed	The relevant process has not yet been reached	Compare with the current stage

Production Events and Traceability Evidence · Execution and Validation

The review items for “Unregistered” are as follows. Work and records: work records cannot be verified; judgment and implementation criteria: additional verification with the person in charge and source records.

The review items for “Not collected” are as follows. Work and records: possibly outside the connection or collection scope; judgment and implementation criteria: verify the interface and collection procedure.

The review items for “Not applicable” are as follows. Work and records: a process not applied to the product route; judgment and implementation criteria: compare against the registration criteria.

Do not fill in unregistered records as though they were facts · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Not yet performed” are as follows. Work and records: the relevant process has not yet been reached; judgment and implementation criteria: compare with the current stage.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

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Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Do not fill in unregistered records as though they were facts,” read the product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer support must verify not only the values they enter but also the information received from the previous step and the status passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Narrow the impact scope of a material issue based on evidence · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Verify the issue conditions	Item, LOT, and relevant conditions	Do not arbitrarily include all products of the same item
Verify the basis for use	Actual input location, quantity, and product	Distinguish from planned materials
Review the connection scope	Relationship between semi-finished and higher-level products	Check for connection omissions or collection limitations
Determine quality actions	Scope of inventory, inspection, and customer response	The person in charge reviews the evidence and takes action

Production Events and Traceability Evidence · Meaning and Judgment

Assume that a supplier has notified you of a possible issue with a specific LOT. Verify the processes, equipment, and products where the material was actually used, and also review connections through lower-level semi-finished products.

This scenario is not an actual customer incident. Do not explain that a recall or disposal is automatically confirmed based solely on traceability results. Focus on clarifying the basis for selecting the items subject to investigation.

Implementation verification: Prepare both products that used the same LOT and products that did not, and verify that the scope is distinguished.

Order of On-Site Implementation and Acceptance Testing

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4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

The review items for “Verify the issue conditions” are as follows. Work and records: item, LOT, and relevant conditions; judgment and implementation criteria: do not arbitrarily include all products of the same item.

The review items for “Verify the basis for use” are as follows. Work and records: actual input location, quantity, and product; judgment and implementation criteria: distinguish from planned materials.

The review items for “Review the connection scope” are as follows. Work and records: relationship between semi-finished and higher-level products; judgment and implementation criteria: check for connection omissions or collection limitations.

Narrow the impact scope of a material issue based on evidence · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Determine quality actions” are as follows. Work and records: scope of inventory, inspection, and customer response; judgment and implementation criteria: the person in charge reviews the evidence and takes action.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

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Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Narrow the impact scope of a material issue based on evidence,” read the product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer support must verify not only the values they enter but also the information received from the previous step and the status passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Consistency between customer responses and output materials · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Response recipient	Product identification and search criteria	Prevent inclusion of data from other products
Manufacturing history	Equipment, time, operator, and results	Enable the customer to understand the location and event together
Additional evidence	Materials, semi-finished products, and repairs	Expand only the required scope
Pre-submission verification	Display scope, text readability, and unverified items	Review exposure of personal and sensitive information

Production Events and Traceability Evidence · Meaning and Judgment

Use the product inquiry to output the expanded states for semi-finished products and materials, as well as nonconformance, repair, and reinspection, and include them in the response. Rather than reassembling multiple documents, conduct verification and explanation within the same flow.

The one-page output function does not automatically satisfy every customer requirement or audit criterion. Confirm the submission purpose and required items, and check that the text remains readable even in a long history.

Confirm that the product, event, and status on the implementation verification screen match those in the output, and obtain approval for the scope of external submission.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
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Production Events and Traceability Evidence · Execution and Validation

The review items for “Response recipient” are as follows. Work and records: product identification and search criteria; judgment and implementation criteria: prevent inclusion of data from other products.

The review items for “Manufacturing history” are as follows. Work and records: equipment, time, operator, and results; judgment and implementation criteria: enable the customer to understand the location and event together.

The review items for “Additional evidence” are as follows. Work and records: materials, semi-finished products, and repairs; judgment and implementation criteria: expand only the required scope.

Consistency between customer responses and output materials · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Pre-submission verification” are as follows. Work and records: display scope, text readability, and unverified items; judgment and implementation criteria: review exposure of personal and sensitive information.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

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4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Consistency between customer responses and output materials,” read the product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer support must verify not only the values they enter but also the information received from the previous step and the status passed to the next step.

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Improve collection gaps revealed in the diagram · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Verify the location	Equipment with no production record	Verify whether the process is required for the target product
Verify progress	Current stage and planned route	Distinguish whether it has not yet been performed
Verify collection	Equipment logs and input procedures	Check for possible non-collection, delays, or omissions
Verify improvements	Re-query after supplementing the connection	Compare source records with displayed results

Production Events and Traceability Evidence · Meaning and Judgment

The list may show only rows with records, but the overall process batch also reveals equipment locations with no production records. This provides an opportunity to identify and improve collection gaps.

Do not conclude that a process was omitted based solely on an empty interval. First verify the actual route and status, then determine whether there is a collection issue.

Implementation verification: Create interface-specific test items that distinguish normal, missing, duplicate, and delayed records.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

The review items for “Verify the location” are as follows. Work and records: equipment with no production record; judgment and implementation criteria: verify whether the process is required for the target product.

The review items for “Verify progress” are as follows. Work and records: current stage and planned route; judgment and implementation criteria: distinguish whether it has not yet been performed.

The review items for “Verify collection” are as follows. Work and records: equipment logs and input procedures; judgment and implementation criteria: check for possible non-collection, delays, or omissions.

Improve collection gaps revealed in the diagram · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Verify improvements” are as follows. Work and records: re-query after supplementing the connection; judgment and implementation criteria: compare source records with displayed results.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Improve collection gaps revealed in the diagram,” read the product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer support must verify not only the values they enter but also the information received from the previous step and the status passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Connecting production preparation with actual production records · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Production Preparation	Planning · material procurement · instruction criteria	Establishing execution criteria
Shop-floor execution	Actual inputs · pass-throughs · inspections	Collecting facts as they occur
Identifying discrepancies	Differences between the plan and actual usage and progress	Verifying the basis for changes and exceptions
History lookup	Linking events by product	Customer response and internal verification

Production Events and Traceability Evidence · Meaning and Judgment

A perspective is needed that prepares production and materials through MPS·MRP and connects confirmed instructions to MES production results. The direct scope of this introduction is production traceability, which is distinct from the detailed implementation of planning functions.

When production preparation is unstable, changes increase on the shop floor, and when change records are missing, traceability becomes difficult. We will consider building traceability screens as part of connecting production preparation with actual results.

As part of implementation verification, confirm whether instructed quantities and passed quantities, as well as planned materials and materials actually used, can each be distinguished.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

The review items for “Production Preparation” are as follows. Work·records: planning · material procurement · instruction criteria; decision·implementation criteria: establishing execution criteria.

The review items for “Shop-floor Execution” are as follows. Work·records: actual inputs · pass-throughs · inspections; decision·implementation criteria: collecting facts as they occur.

The review items for “Identifying Discrepancies” are as follows. Work·records: differences between the plan and actual usage and progress; decision·implementation criteria: verifying the basis for changes and exceptions.

Connecting production preparation with actual production records · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “History Lookup” are as follows. Work·records: linking events by product; decision·implementation criteria: customer response and internal verification.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Connecting production preparation with actual production records,” read product, manufacturing number, process, time, operator, and material LOT using the same criteria. Those responsible for production, materials, quality, and customer response must check not only the values they enter, but also the information received from the preceding step and the status to be passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Data criteria for linking events by product · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Identification relationships	Products and instructions, semi-finished products, and BOXes	Code changes and matching criteria
Event unit	Process input, completion, inspection, and repair	Collected items and identification keys
Time criteria	Equipment time and receipt time	Criteria for interpreting delays and sequence
Consistency	Duplicate, missing, and correction records	Compare source data with query results

Production Events and Traceability Evidence · Meaning and Judgment

Storing products, instructions, processes, equipment, operators, and material LOTs separately is not sufficient. The implementation design must establish criteria for linking each event to the relevant product at the time it occurs.

This table lists data design review items; it does not finalize interface specifications not included in the introductory material. The scope will be determined by investigating the actual equipment and existing systems.

Implementation check: Verify that records for different products are not linked together and that a current assignment does not overwrite a past operator.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

The review items for “Identification relationships” are as follows. Business and records: products and instructions, semi-finished products, and BOXes; decision and build criteria: code changes and matching criteria.

The review items for “Event unit” are as follows. Business and records: process input, completion, inspection, and repair; decision and build criteria: collected items and identification keys.

The review items for “Time criteria” are as follows. Business and records: equipment time and receipt time; decision and build criteria: criteria for interpreting delays and sequence.

Data criteria for linking events by product · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Consistency” are as follows. Business and records: duplicate, missing, and correction records; decision and build criteria: comparison of source data with query results.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing “Data criteria for linking events by product” in this chapter, products, manufacturing numbers, processes, times, operators, and material LOTs must be interpreted using the same standards. The people responsible for production, materials, quality, and customer response review not only the values they enter, but also the information received from the preceding step and the status to be passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Review criteria agreed through representative cases · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Normal production	Registration path and production results sequence	Equipment, time, and operator match
LOT changeover	Products before and after changeover	Match the actual LOT boundaries used
Semi-finished product assembly	Multi-level input relationships	Match the semi-finished products actually used
Defects, repairs, and reinspection	Event sequence and current status	Match the evidence for the cause, action, and inspection

Production Events and Traceability Evidence · Meaning and Judgment

Do not stop at confirming that the screen opens; compare the actual source records with the linked results. Select both normal and exceptional cases.

Record the review results by product group, process, equipment, and collected item. Expand the scope after the representative path has been completed, and supplement the criteria when new exceptions arise.

Implementation check: The customer representative and the CMC implementation representative review using the same product and the same source data.

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Missing records	No repair details · not collected	Display unverified status without causing misunderstanding

Production Events and Traceability Evidence · Execution and Validation

The review items for “Normal Production” are as follows. Work and records: registration path and performance sequence; assessment and implementation criteria: matching equipment, time, and operator.

The review items for “LOT Change” are as follows. Work and records: products before and after the change; assessment and implementation criteria: alignment with the actual LOT usage boundary.

The review items for “Semi-finished Product Assembly” are as follows. Work and records: multi-level input relationships; assessment and implementation criteria: alignment with the semi-finished products actually used.

Acceptance criteria agreed upon using representative cases · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Defect · Repair · Retest” are as follows. Work and records: event sequence and current status; assessment and implementation criteria: alignment of the cause, action taken, and inspection evidence.

The review items for “Missing Records” are as follows. Work and records: no repair details · not collected; assessment and implementation criteria: display unverified status without causing misunderstanding.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Acceptance Criteria Agreed Upon Using Representative Cases,” read product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer response must check not only the values they enter, but also the information received from the preceding stage and the status passed to the next stage.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Phased CMC MES Implementation Proposal · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
1. On-site Survey	List of representative products, routes, codes, and equipment	Organize current connections and gaps
2. Criteria Design	Operators · inputs · semi-finished products · inspections · repairs	Agree on record units and responsibility and completion criteria
3. Integration and Demonstration	Equipment · input procedures · graphical queries	Compare source data with displayed results
4. Acceptance Testing · Expansion	Representative exception testing and operational training	Expand from the verified scope

Production Events and Traceability Evidence · Meaning and Judgment

CMC MES establishes production record collection and graphical traceability together. Companies already operating an MES should review the scope of using existing records separately from the scope of new data collection.

The implementation period and cost are estimated according to equipment interfaces, the level of existing data, and the scope of application. We do not promise connection to all equipment without configuration or a uniform implementation period.

We prepare an implementation plan that distinguishes the scope of implementation verification functions, interfaces, data migration, training, and operational support.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

The review items for “1. On-site Survey” are as follows. Work and records: list of representative products, routes, codes, and equipment; assessment and implementation criteria: organize current connections and gaps.

The review items for “2. Criteria Design” are as follows. Work and records: operators, inputs, semi-finished products, inspections, and repairs; assessment and implementation criteria: agree on record units and responsibility and completion criteria.

The review items for “3. Integration and Demonstration” are as follows. Work and records: equipment, input procedures, and graphical queries; assessment and implementation criteria: compare source data with displayed results.

Phased CMC MES Implementation Proposal · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “4. Acceptance Testing · Expansion” are as follows. Work and records: representative exception testing and operational training; assessment and implementation criteria: expand from the verified scope.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Phased CMC MES Implementation Proposal,” read product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer response must check not only the values they enter, but also the information received from the preceding stage and the status passed to the next stage.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Confirm benefits through the quality of work and records · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Query operations	Time required to verify one product	Compare the same product type and verification scope
Customer response	Number of times materials are recreated and responsible personnel are consulted	Record the response scope and difficulty together
Investigation basis	Whether the LOT usage scope can be narrowed	Include uncollected sections and assessment limitations
Data quality	Identify omissions, incorrect links, and duplicates	Reconfirm alignment with source data after corrective action

Production Events and Traceability Evidence · Meaning and Judgment

The goal is to reduce the recreation of materials and back-and-forth confirmation required for customer responses, while helping users understand the evidence at the process location. We do not present unsupported reduction rates; instead, we measure before and after implementation under the same conditions.

Equipment diagrams reduce the effort required to understand information, but they do not replace training on recording criteria and access rights. We verify both faster queries and more accurate records.

We define the implementation verification target metrics and the personnel responsible for measurement, and do not present unverified effects as customer results.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

The review items for “Query Operations” are as follows. Work and records: time required to verify one product; assessment and implementation criteria: compare the same product type and verification scope.

The review items for “Customer Response” are as follows. Work and records: number of times materials are recreated and responsible personnel are consulted; assessment and implementation criteria: record the response scope and difficulty together.

The review items for “Investigation Basis” are as follows. Work and records: whether the LOT usage scope can be narrowed; assessment and implementation criteria: include uncollected sections and assessment limitations.

Confirm benefits through the quality of work and records · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Data Quality” are as follows. Work and records: identify omissions, incorrect links, and duplicates; assessment and implementation criteria: reconfirm alignment with source data after corrective action.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Confirm Benefits Through the Quality of Work and Records,” read product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer response must check not only the values they enter, but also the information received from the preceding stage and the status passed to the next stage.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Materials to Prepare Before Implementation and Disclosure Scope · 1

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
Products and codes	Anonymized identification examples and relationships	Confirm the required query methods
Processes and equipment	Actual sequence · independent workstations · representative equipment	Confirm the collection and display scope
Traceability samples	Examples of materials, defects, repairs, and semi-finished products	Establish acceptance criteria
Security criteria	Operator display · output · access rights	Agree on the viewing and submission scope

Production Events and Traceability Evidence · Meaning and Judgment

We can prepare a detailed demonstration based on one of your representative products and its actual route. There is no need to provide sensitive product, customer, or operator information externally without restriction.

The screens in this proposal are reduced views of the introductory PPT provided by the user. Zoom functionality and downloads of the original PPT are not provided. Detailed demonstrations will be conducted within the approved scope.

We prepare demonstration materials after defining the scope for providing and displaying customer information for implementation verification and internal company information.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

The review items for “Products and Codes” are as follows. Work and records: anonymized identification examples and relationships; assessment and implementation criteria: confirm the required query methods.

The review items for “Processes and Equipment” are as follows. Work and records: actual sequence, independent workstations, and representative equipment; assessment and implementation criteria: confirm the collection and display scope.

The review items for “Traceability Samples” are as follows. Work and records: examples of materials, defects, repairs, and semi-finished products; assessment and implementation criteria: establish acceptance criteria.

Materials to Prepare Before Implementation and Disclosure Scope · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review items for “Security Criteria” are as follows. Work and records: operator display, output, and access rights; assessment and implementation criteria: agree on the viewing and submission scope.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing this chapter’s “Materials to Prepare Before Implementation and Disclosure Scope,” read product, serial number, process, time, operator, and material LOT using the same criteria. Personnel responsible for production, materials, quality, and customer response must check not only the values they enter, but also the information received from the preceding stage and the status passed to the next stage.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

CMC MES Demonstrated Through Process Flow

Comparison with Business Standards

Items to Check	Business Process · Record	Judgment · Implementation Criteria
What to review first	Hannah's presentation · Production traceability at a glance	How to read the actual screens
Detailed review	David's webinar · Building Perfect Traceability	Functional and implementation validation criteria
Implementation Consultation	Representative products and points where queries break	Finalize the required recording, linkage, and acceptance scope

Production Events and Traceability Evidence · Meaning and Judgment

We explain the production history of one product using equipment diagrams and actual records. Together with CMC MES implementation, we establish traceability covering operators and times, material LOTs and quantities, the production routes of semi-finished products, and defects, repairs, and retests.

The goal of implementing CMC MES is to connect on-site records and verify them in an easy-to-understand format. We supplement missing records without concealing them and validate traceability suited to your products and processes.

All major topics from pages 1–10 of the implementation verification PPT provided have been reflected. Exception handling and integration conditions not shown on the screens are explicitly identified as customer-specific implementation review items.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

The review items for “What to Review First” are as follows. Work and records: Hannah’s presentation · Production traceability at a glance; assessment and implementation criteria: how to read the actual screens.

The review items for “Detailed Review” are as follows. Work and records: David’s webinar · Building Perfect Traceability; assessment and implementation criteria: functional and implementation validation criteria.

The review items for “Implementation Consultation” are as follows. Work and records: representative products and points where queries break; assessment and implementation criteria: finalize the required recording, linkage, and acceptance scope.

Let’s review one representative product together first

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

Review where traceability currently breaks down and what needs to be collected and connected.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing “Let’s review one representative product together first” in this chapter, read the product, manufacturing number, process, time, operator, and material LOT according to the same criteria. Personnel responsible for production, materials, quality, and customer support should check not only the values they enter, but also the information received from the preceding step and the status to be passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.

Traceability completeness is revealed in exception records · 1

Comparison with Business Standards

Exception	Relationships to verify
LOT changeover	Product boundaries before and after replacement
Repair-reinspection	Original defect and final determination
Semi-finished product assembly	Connections between parent and child products
Uncollected event	Missing indicator and supplementary evidence

Production Events and Traceability Evidence · Meaning and Judgment

LOTs and products are easy to connect during normal operations, but records can easily break during material replacement, line transfers, rework, and repairs. Query one product and one material LOT in both directions to verify whether the same event and quantity can be explained.

Cross-check the assembly relationship between the finished product and subordinate semi-finished products, the time when input materials were replaced, and inspection and reinspection results. Do not fill unregistered events with current inventory or the person in charge’s assumptions. Mark them as missing and link them to a supplementation procedure.

For one representative manufacturing number, trace the materials used and inspection results, and conversely compare the range of products affected by a specific material LOT.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
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4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

The scope of impact shown by the system is limited to the scope of the evidence collected. Actual actions such as recalls and shipment holds should be decided by the quality manager after verifying the completeness of the materials and the customer’s requirements.

The review item for “LOT replacement” is as follows. Relationship to verify: product boundaries before and after replacement.

The review item for “Repair·reinspection” is as follows. Relationship to verify: original defect and final determination.

Traceability completeness is revealed in exception records · 2

Criteria for Connecting Production Events and Traceability Evidence

Connection Criteria	Items to Check
Product	Check Entries and Change History on the Same Basis
Manufacturing Number	Check Entries and Change History on the Same Basis
Processes	Check Entries and Change History on the Same Basis
Timestamp	Check Entries and Change History on the Same Basis

Production Events and Traceability Evidence · Meaning and Judgment

The review item for “Semi-finished product assembly” is as follows. Relationship to verify: connections between parent and child products.

The review item for “Uncollected event” is as follows. Relationship to verify: missing indicator and supplementary evidence.

The production history cannot be reconstructed from the current status alone. Input, replacement, inspection, hold, repair, and reinspection must be recorded as separate events, with the relationships between upstream and downstream semi-finished products and the original product linked together.

Order of On-Site Implementation and Acceptance Testing

1. Confirm the Roles of Production · Materials · Quality · Customer Response
2. Compare Product Standards · Source Records
3. Confirm Exception Handling and Approval Evidence
4. Validate Results Using a Representative Case

Production Events and Traceability Evidence · Execution and Validation

When reviewing “Traceability completeness is revealed in exception records” in this chapter, read the product, manufacturing number, process, time, operator, and material LOT according to the same criteria. Personnel responsible for production, materials, quality, and customer support should check not only the values they enter, but also the information received from the preceding step and the status to be passed to the next step.

Confirm cases involving changes, cancellations, or omissions alongside normal processing results. Record where judgments differ between production, materials, quality, and customer response, and agree on who will approve them and on what basis. Any scope of automation that cannot be verified from existing materials should remain a review item before implementation.