Flowcharting Your Quality System

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Quality systems

- Manage the flow of work and information through a company, from order entry to shipping.
- Use *process control* to *prevent* quality problems.
- Provide consistency and improvement in your operations.
- If required, your Quality System can be audited and certified by a third party registrar to a Quality Management System (QMS) standard, e.g. ISO 9001.
- ISO 9001 makes an excellent checklist for any Quality System, even if you are not seeking a certified QMS.

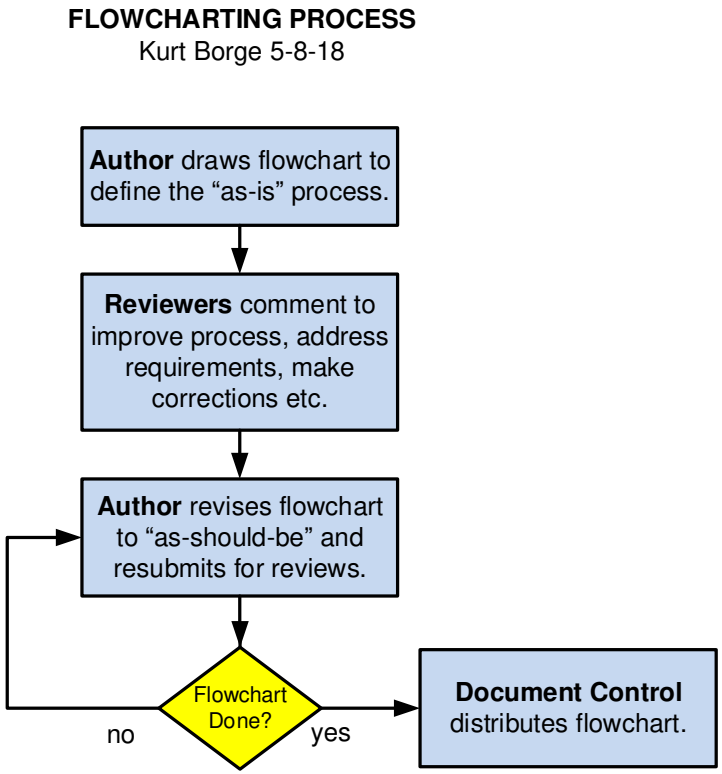
Overview

- Flowcharting can make developing and implementing your Quality System easier.
- Flowcharting helps define process, responsibilities and relationships in a company.
- Flowcharting provides a bases for Risk Management and Continual Improvement.
- Each company has unique processes. This presentation shows examples of process flowcharting, which are not intended to be implemented as your own processes.

Start at the bottom

- Develop your Quality System from *existing process*, rather then develop processes to address QMS requirements (the Top-Down approach).
- Flowchart your existing process first (the “as-is condition”), then review and revise to improve the process and to address QMS requirements (the “as-should-be condition”).

Flowcharting process



IMPORTANT POINTS

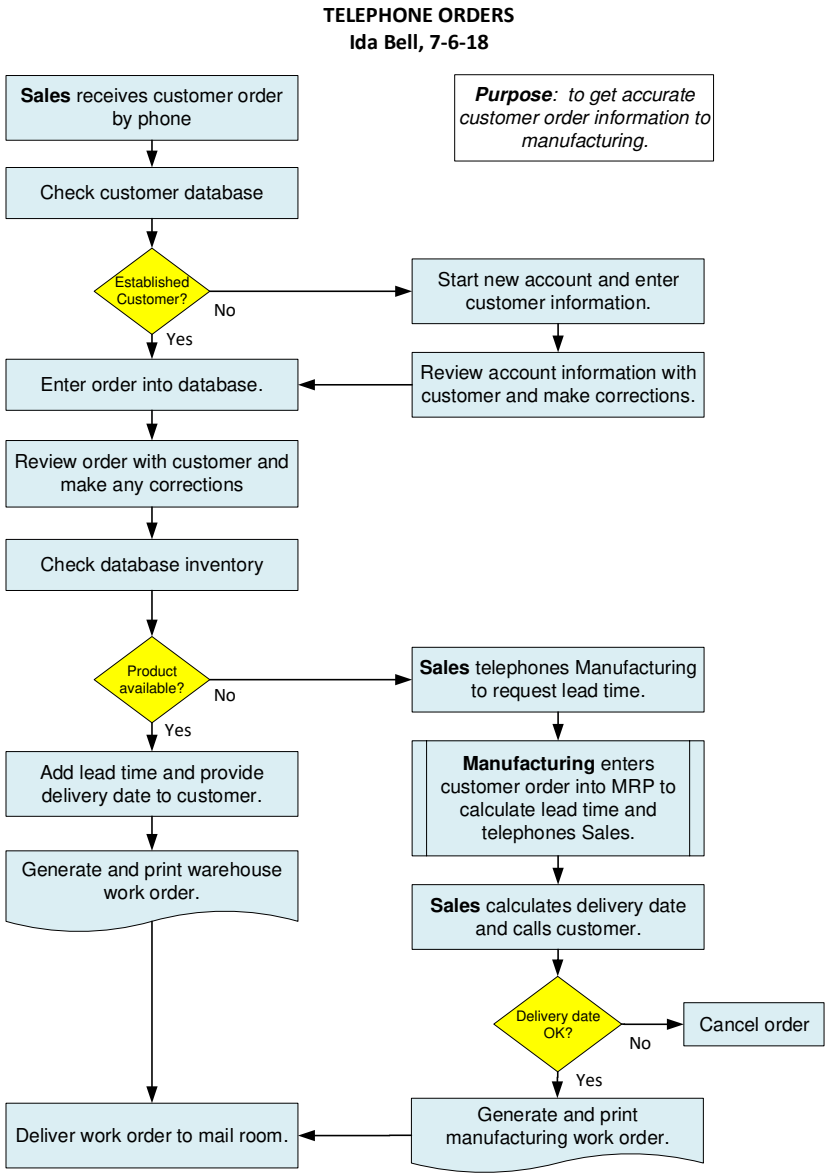
Begin with the “as-is” process, then revise to “as-should-be.”

Flowchart as group using a white board, flip chart with sticky notes, etc.

Typical quality system processes

- Planning Activities
- Order Entry
- Design & Development
- Purchasing
- Manufacturing & Inventory Control
- Testing and Inspection
- Monitoring, Measuring & Analysis
- Training
- Document & Records Control
- Calibration

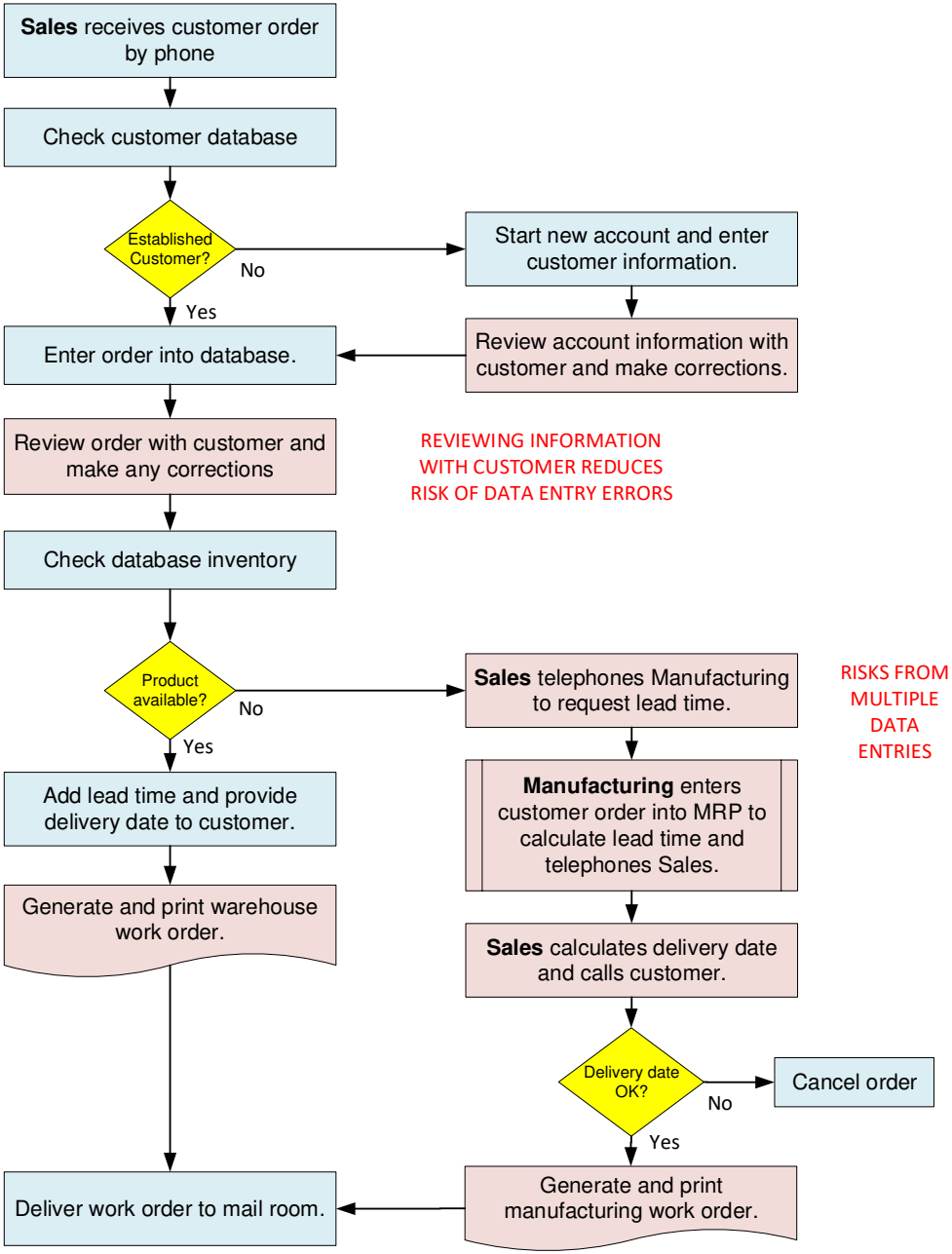
Typical process flow chart



Adding risk management

- Risk management is the new focus for developing Quality Systems.
- Flowcharts can be used to identify potential risks:
  - data entry errors
  - manufacturing errors
  - wrong formulation
- After the risks have been identified, manage them by reducing the chances of risks occurring and their impact if they do occur.
- If you make significant changes, use risk management again.
- The following flowchart for the Telephone Orders process has areas of higher risk highlighted in rose, showing where measures are needed to minimize the possibility of data entry errors:

CRITICAL AREAS / RISK MANAGEMENT



Risk management example (cont.)

- The first two highlighted blocks show how to minimize entering wrong customer information by reviewing the information with the customer.
- The next set of highlighted blocks, starting when Sales has to telephone Manufacturing for a lead time, show potential data entry problems due to the number of times data must be entered or transferred. A possible solution might be an integrated database.

Process improvement example

- Flowcharts can be used to identify areas for improvement.
- Improvement is an ongoing process.
- The first “Receiving Inspection” flowchart shows the “as-is condition” for receiving inspections.
- The second flowchart shows the process after improvements were added in green, the “as-should-be condition.”
- Quality metrics have been added to gather data for “Continual Improvement.”

RECEIVING INSPECTION in the AS-IS CONDITION

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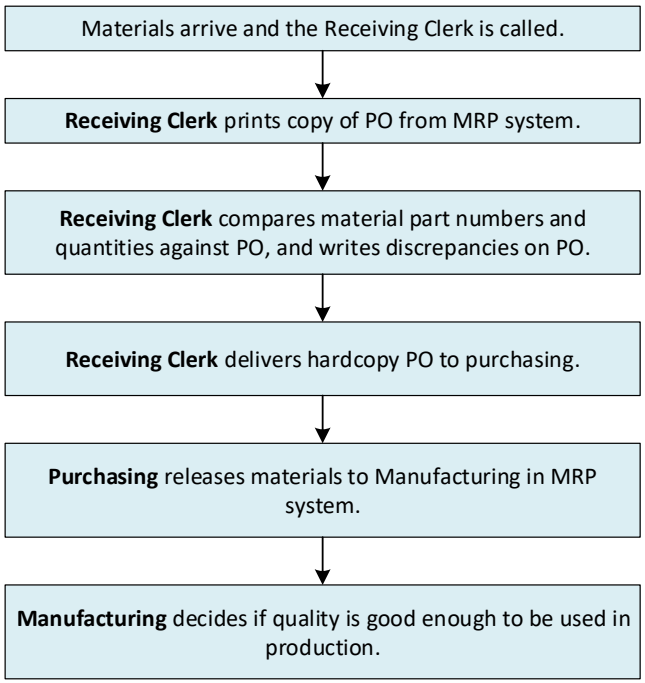

***Purpose**: to enter materials received into MRP system and release them to manufacturing.*

RISK OF BAD QUALITY MATERIALS USED IN PRODUCTION.

RECEIVING INSPECTION with IMPROVEMENTS and METRICS

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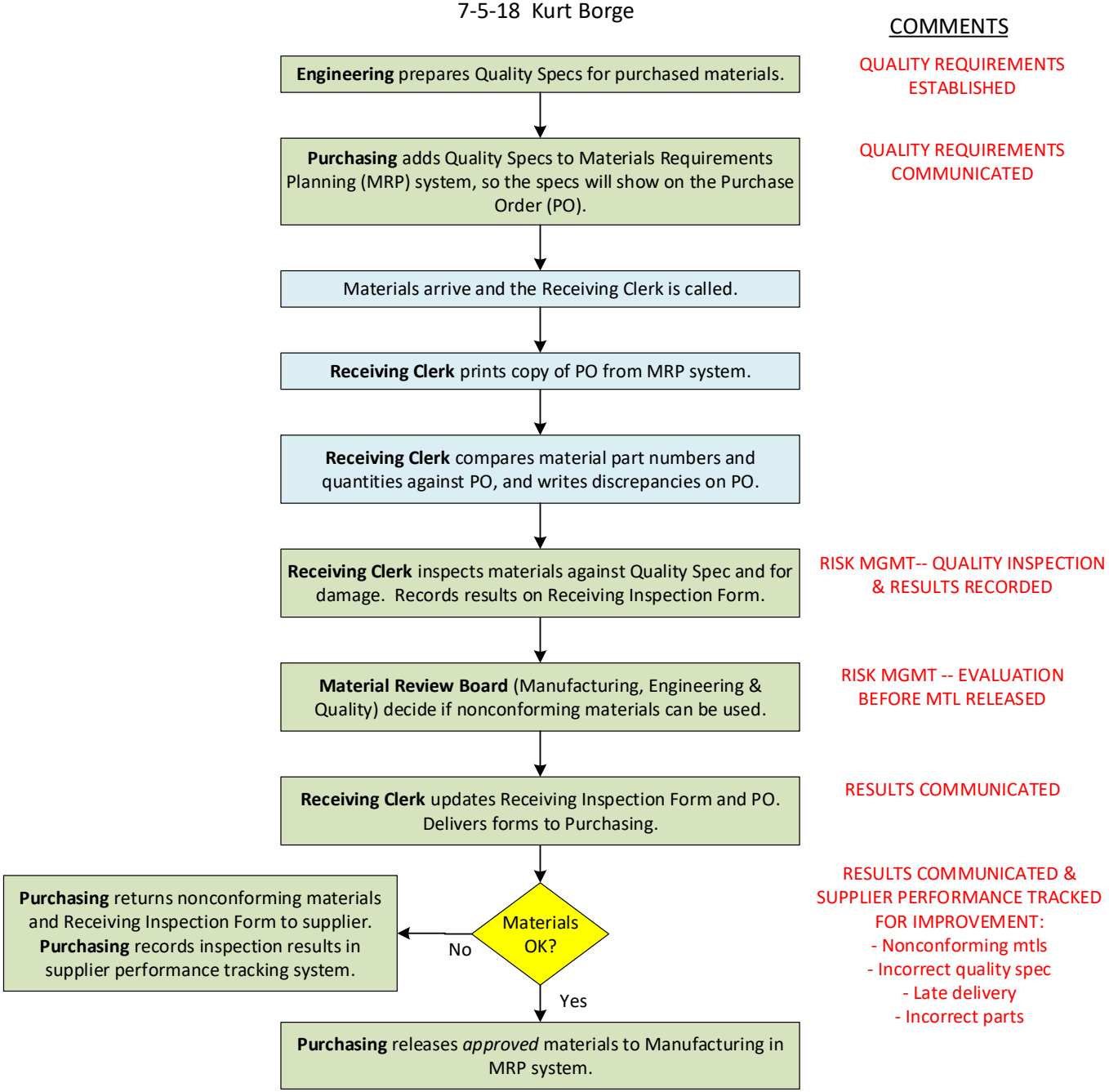

Improved receiving inspection

- Now, only good materials reach production.
- Quality specifications have been established and communicated to the supplier and the receiving inspector.
- Quality issues are communicated to the supplier for their corrective action.
- Supplier performance is tracked for trends and improvements.

Conclusions

- Quality Systems help your company manage all the processes affecting quality from order entry to shipping.
- Flowcharts simplify the creation of Quality Systems by beginning with your existing processes, which are then reviewed for improvements.
- When needed, review the flowcharts for compliance with QMS requirements (e.g. ISO 9001).
- Flowcharts help identify and manage risks.
- Flowcharts help identify areas for ongoing improvements and quality metrics.

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Helping companies develop effective Quality Systems

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