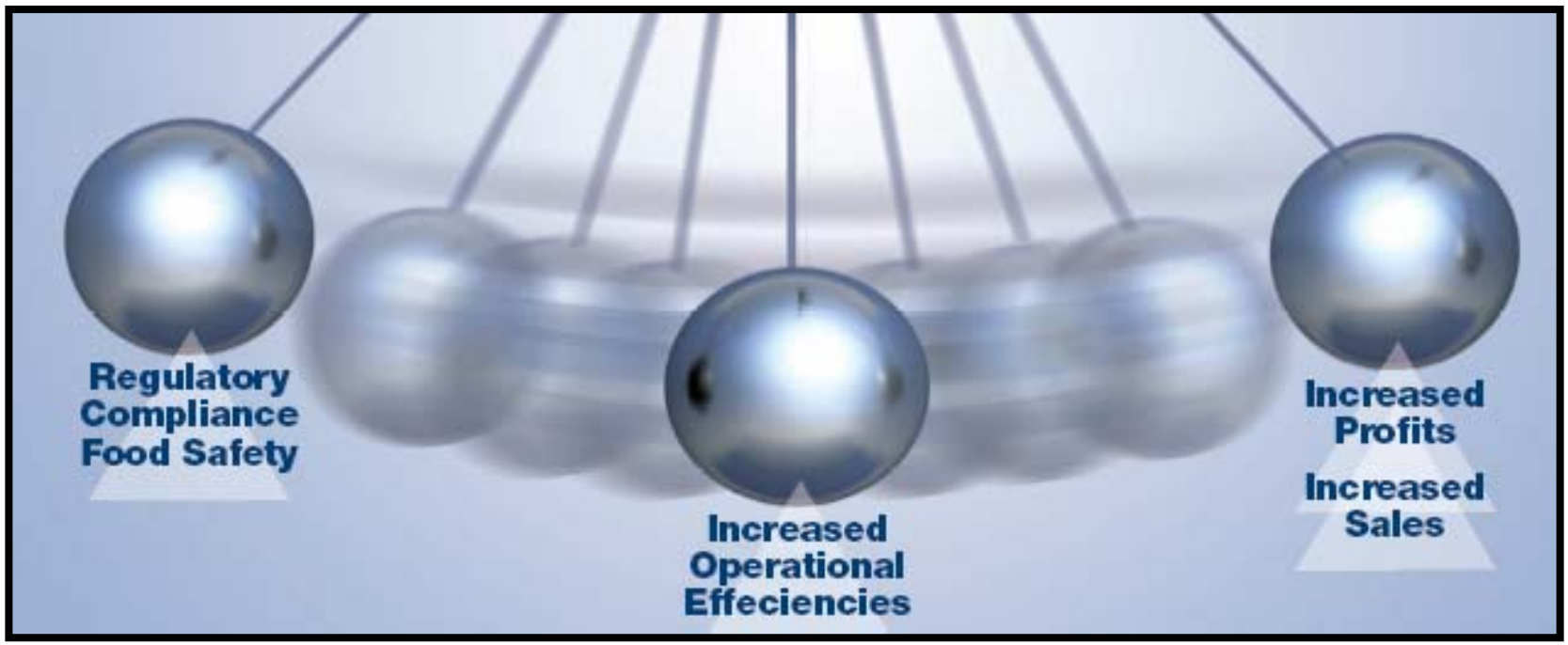
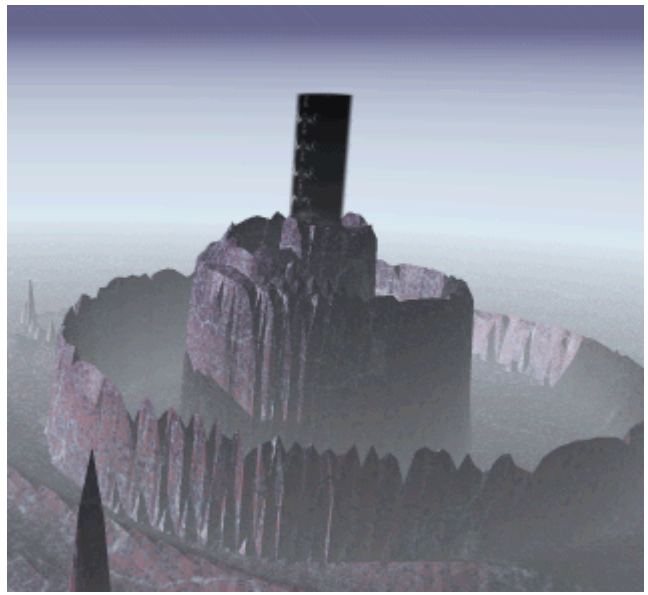
REGULATORY COMPLIANCE: CATALYST FOR MANUFACTURING COST REDUCTION AND INCREASED SALES



WORDS ARE IMPORTANT

- **Communication requires alignment**
- **The speaker must be clear and concise**
- **The listener must be attentive**
- **The listener must ask questions to clarify**
- **Or this might happen..**

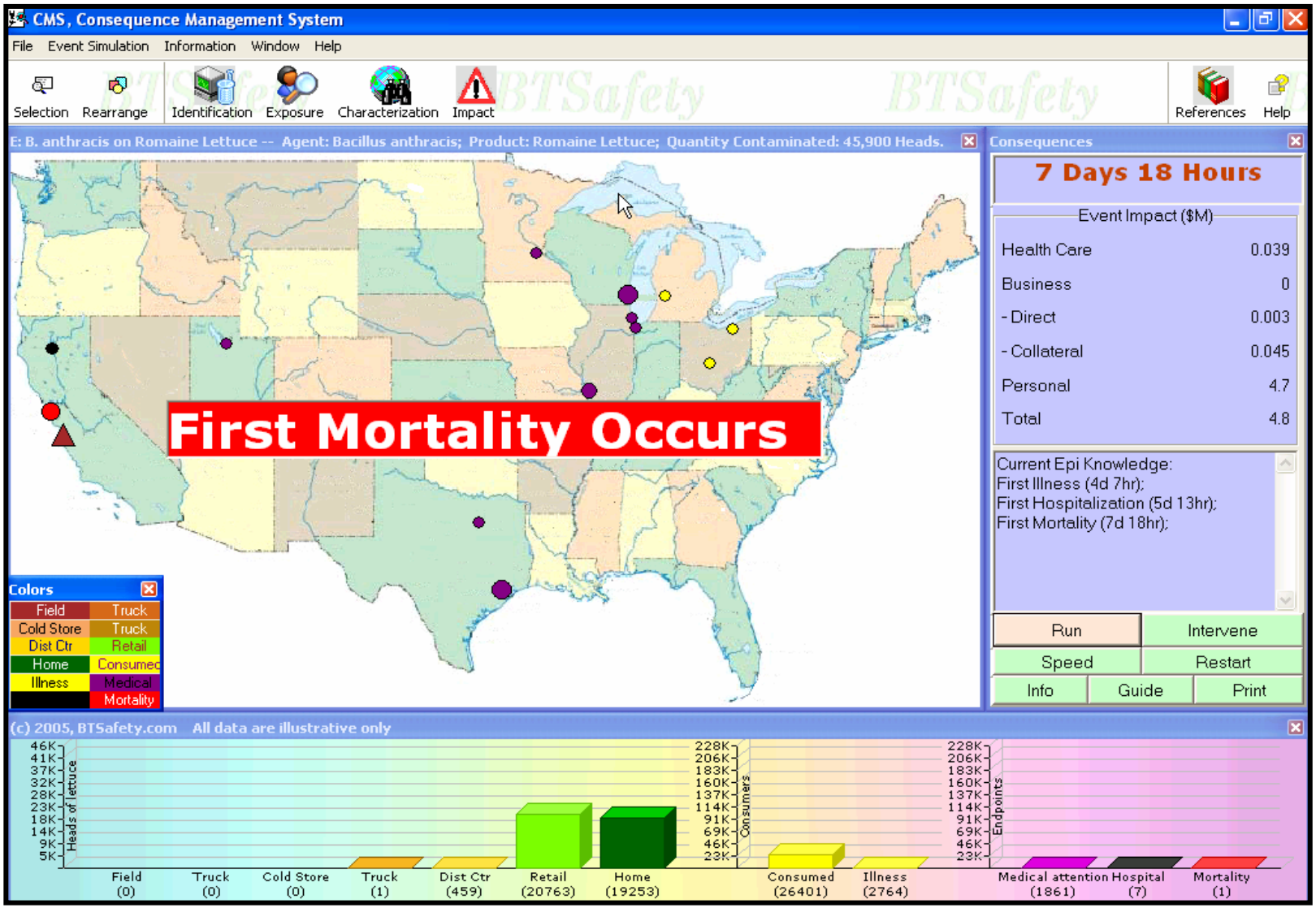


REGULATORY COMPLIANCE: CATALYST FOR MANUFACTURING COST REDUCTION AND INCREASED SALES

DISCUSSION OUTLINE:

- **Bio-toxin attack simulation**
- **Top ten - (10) critical issues: Food Engineering**
- **Buzz word bingo**
- **Bioterrorism Act, record keeping**
- **HACCP**
- **ISO 9001 – 2000/ISO2200**

BIOTERRORISM BIO-TOXIN ATTACK SIMULATION



COURTESY BT SAFETY

THE MOST CRITICAL ISSUES THE FOOD & BEVERAGE MANUFACTURING EXECUTIVE MUST DEAL WITH

FOOD ENGINEERING'S TOP TEN ISSUES:

1. **Food Safety**
2. **Automation**
3. **Skilled Labor**
4. **Product Traceability**
5. **Systems integration**

THE MOST CRITICAL ISSUES THE FOOD & BEVERAGE MANUFACTURING EXECUTIVE MUST DEAL WITH

FOOD ENGINEERING'S TOP TEN ISSUES:

6. Maintenance improvements

7. Supply-chain integration

8. Increased capacity

9. Employee Training

10.Improved changeover

REGULATORY COMPLIANCE: CATALYST FOR MANUFACTURING COST REDUCTION AND INCREASED SALES

BUZZWORD BINGO

- **Enterprise Resource Planning (ERP)**
- **Material Requirements Planning (MRP)**
- **Lean Manufacturing**
- **Value Stream Mapping**
- **5S**
- **AVI**

BUZZWORD BINGO: ENTERPRISE RESOURCE PLANNING (ERP)

Framework

Organizing business processes

Integrated

Single unified database

Effectively plan & control

Seek external advantage

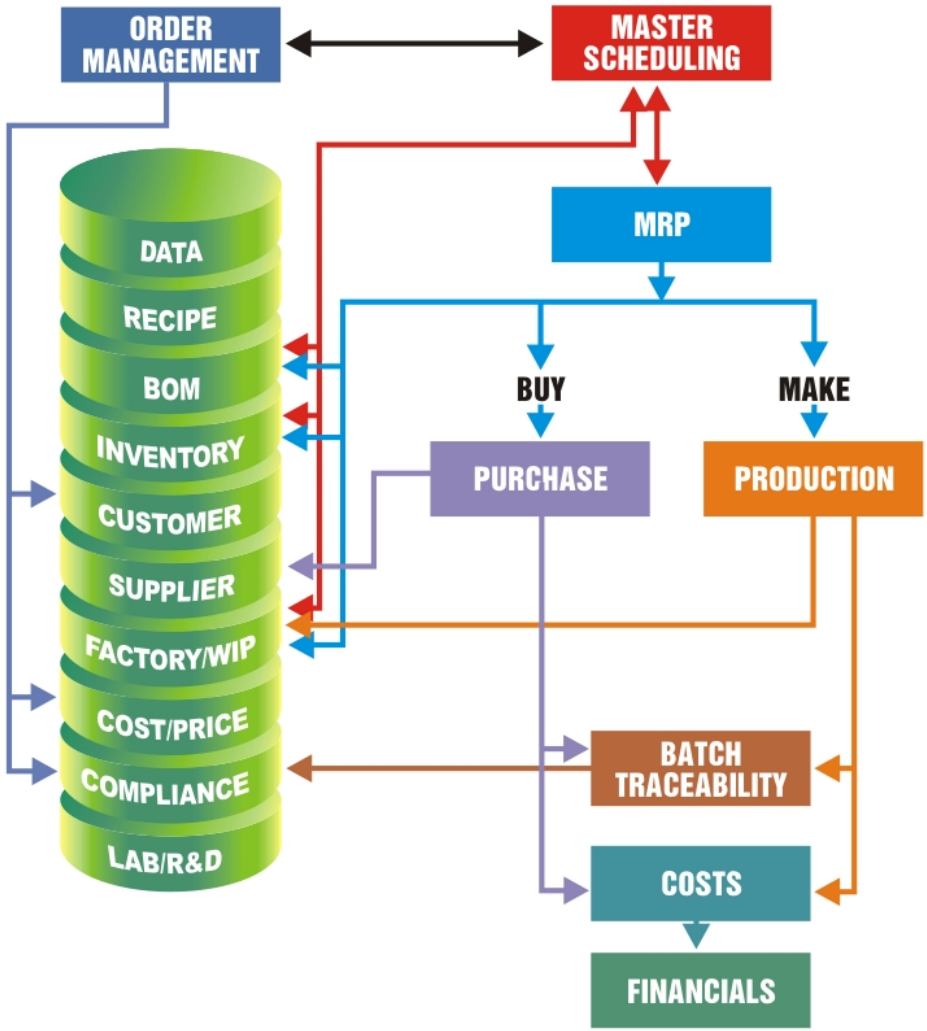
Enterprise Resource Planning (ERP) – Framework for organizing, defining, and standardizing the business processes necessary to effectively plan and control an organization so the organization can use its internal knowledge to seek external advantage.

Source: APICS Dictionary, Eleventh Edition

Enterprise Resource Planning systems (ERPs) integrate all data and processes of an organization into a single unified system. A typical ERP system will use multiple components of computer software and hardware to achieve the integration. A key ingredient of most ERP systems is the use of a single, unified database to store data for the various system modules.

Source: Wikipedia, the free encyclopedia

CONCEPTUAL GENERIC ERP REPRESENTATION



Buzz Word Bingo:
Material Requirements Planning (MRP)

A set of techniques

Recipe & BOM, inventory, demand

Time phased

Recommendations

What, when & why

Proven

Material Requirements Planning (MRP) – A set of techniques that uses bill of material data, inventory data, and the master production schedule to calculate requirements for materials. It makes recommendations to release replenishment orders for material. Further, because it is time-phased, it makes recommendations to reschedule open orders when due dates and need dates are not in phase. Time-phased MRP begins with the items listed on the MPS and determines:

(1) the quality of all components and materials required to fabricate those items and (2) the date that the components and materials are required.

Time-phased MRP is accomplished by exploding the bill of material, adjusting for inventory quantities on hand or on order, and offsetting the net requirements by the appropriate lead times.

Source: APICS Dictionary, Eleventh Edition

BUZZ WORD BINGO: LEAN MANUFACTURING/PRODUCTION

- Minimization of resources used
- Eliminating non value-added
- A set of principles and practices
- Reduce cost
- Relentless removal of waste
- Simplification

Lean production – A philosophy of production that emphasizes the minimization of the amount of all the resources (including time) used in the various activities of the enterprise. It involves identifying and eliminating non-value-adding activities in design, production, supply-chain management, and dealing with customers. Lean producers employ teams of multiskilled workers at all levels of the organization and use highly flexible, increasingly automated machines to produce volumes of products in potentially enormous variety. It contains a set of principles and practices to reduce cost through the relentless removal of waste and through the simplification of all manufacturing and support processes.

Source: APICS Dictionary, Eleventh Edition

BUZZ WORD BINGO: VALUE-STREAM MAPPING

Simple .. No equipment needed

See and understand

Flow

Activity + information

Eliminate waste

Value Stream Mapping - Value stream mapping is a paper and pencil tool that helps you to see and understand the flow of material and information as a product or service makes its way through the value stream.

Value stream map (AKA end-to-end system map) takes into account not only the activity of the product, but the management and information systems that support the basic process. This is especially helpful when working to reduce cycle time, because you gain insight into the decision making flow in addition to the process flow. It is actually a Lean tool.

Source: iSixSigma

BUZZ WORD BINGO:5S

Sort

Straighten

Shine

Standardize

Sustain

5S is the Japanese concept for House Keeping:

1. Seiri - Put things in order
(remove what is not needed and keep what is needed)
2. Seiton - Proper Arrangement
(Place things in such a way that they can be easily reached whenever they are needed)
3. Seiso - Clean
(Keep things clean and polished; no trash or dirt in the workplace)
4. Seiketsu - Purity
(Maintain cleanliness after cleaning - perpetual cleaning)
5. Shitsuke - Commitment

Source: iSixSigma

REGULATORY BUZZWORD BINGO: HACCP

HAZARD ANALYSIS AND CRITICAL CONTROL POINT

ANALYZE

IDENTIFY

PREVENTIVE MEASURES

PROCEDURES TO MONITOR

CORRECTIVE ACTIONS

VERIFY

DOCUMENT

U.S. Food and Drug Administration

The Food and Drug Administration has adopted a food safety program developed nearly 30 years ago for astronauts and is applying it to seafood and juice. The agency intends to eventually use it for much of the U.S. food supply.

One of the most important challenges is the increasing number of new food pathogens.

Advantages:

- Focuses on identifying and preventing hazards
- Is based on sound science
- Permits more efficient and effective government oversight
- Places responsibility on the producer
- Helps food companies compete more effectively in the world market
- Reduces barriers to international trade.

REGULATORY COMPLIANCE: CATALYST FOR MANUFACTURING COST REDUCTION AND INCREASED SALES

DISCUSSION OUTLINE:

√ Bio-toxin attack simulation

√ Top ten critical issues – Food Engineering

√ Buzz word bingo

► Bioterrorism Act, record keeping

- HACCP
- ISO 9001 – 2000/ISO2200

THE BIOTERRORISM ACT – RECORD KEEPING

- **The Act**
- **Implied requirements**
- **“How to” satisfy the implied requirements**
- **Leveraging the results into significant inventory reduction and improved on-time delivery**

PUTTING THE PIECES TOGETHER FOR COMPETITIVE ADVANTAGE

REGULATORY COMPLIANCE BUZZ WORD BINGO

U.S. Food and Drug Administration

SECURITY STRATEGY (301)

FOOD ADULTERATION (302)

DETENTION (303)

REGISTRATION (305)

RECORDS MAINTENANCE (306)

PRIOR NOTICE (307)

MARKING (308)

THE BIOTERRORISM ACT 2002

- The events of Sept. 11, 2001, reinforced the need to enhance the security of the United States. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which President Bush signed into law June 12, 2002.
- Complete Text: HTML; PDF
- The Bioterrorism Act is divided into five titles:
- Introduction
- Title I -- National Preparedness for Bioterrorism and Other Public Health Emergencies
- Title II -- Enhancing Controls on Dangerous Biological Agents and Toxins
- Title III -- Protecting Safety and Security of Food and Drug Supply
- Title IV -- Drinking Water Security and Safety
- Title V -- Additional Provisions
- FDA is responsible for carrying out certain provisions of the Bioterrorism Act, particularly **Title III**, **Subtitle A** **(Protection of Food Supply)** and Subtitle B (Protection of Drug Supply).

BIOTERRORISM ACT – RECORD KEEPING

FINAL DIRECTIVE & IMPLIED REQUIREMENTS

- **Examine the FDA final directive**
- **Implied requirements**
- **Why an approximation often is not adequate**
- **The 90% data accuracy dilemma**
- **The role of data flow integration & real-time validation**

IT DOESN'T HAVE TO BE THIS WAY

BIOTERRORISM ACT – RECORD KEEPING: THE FINAL FDA DIRECTIVE

The records that must be established and maintained by non-transporters of food

1. Identify the immediate non- transporter previous *sources*…of all foods received. *Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.*

2. Identify the immediate non-transporter subsequent *recipients* of all foods released. *Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.* The records must include information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

What are the record availability requirements?

Not to exceed 24 hours from time of receipt of the official request. The records requested may be related to the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such an article of food

http://www.cfsan.fda.gov/~dms/fsbtac23.htm

When is compliance with the recordkeeping regulation required?

All businesses… must comply…

- 500 - XXX number of employees - 12/09/05
- 11 - 499 number of employees - 06/09/06
- 1 - 010 number of employees - 12/09/06

IMPLIED REQUIREMENTS

IMPLIED REQUIREMENTS

- **Accurate recipes and Bill of Materials**
- **Defined procedures and processes**
  - **cGMP**
  - **HACCP**
- **Organized receiving and warehouse storage areas**
- **Receiving data is accurate & recorded**
- **Defined quarantine or hold areas**

ATOMIC CLOCK

IMPLIED REQUIREMENTS

- **Data integrity and inventory record accuracy**
- **Accurate recording of materials used in production or scrapped**
- **Accurate recording of finished production**
- **Tracking of finished products to customer shipping locations**
- **Rapid access to critical regulatory data**

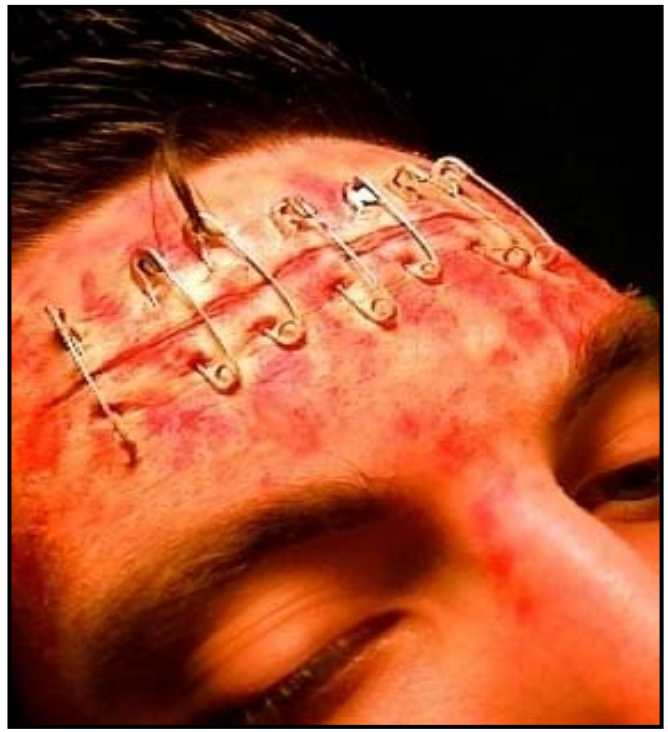
WHY AN APPROXIMATION IS NOT ADEQUATE

- **Port of departure -**
- **Cross the Atlantic Ocean**
- **Destination port -**
- **Two degree error during the journey**
- **Two degree's = this much**
- **Actual arrive point error =**

WHY AN APPROXIMATION IS OFTEN NOT ADEQUATE

“He was scheduled for a root canal. I was only off by eight inches, I’ll get right the next time, mistakes happen”

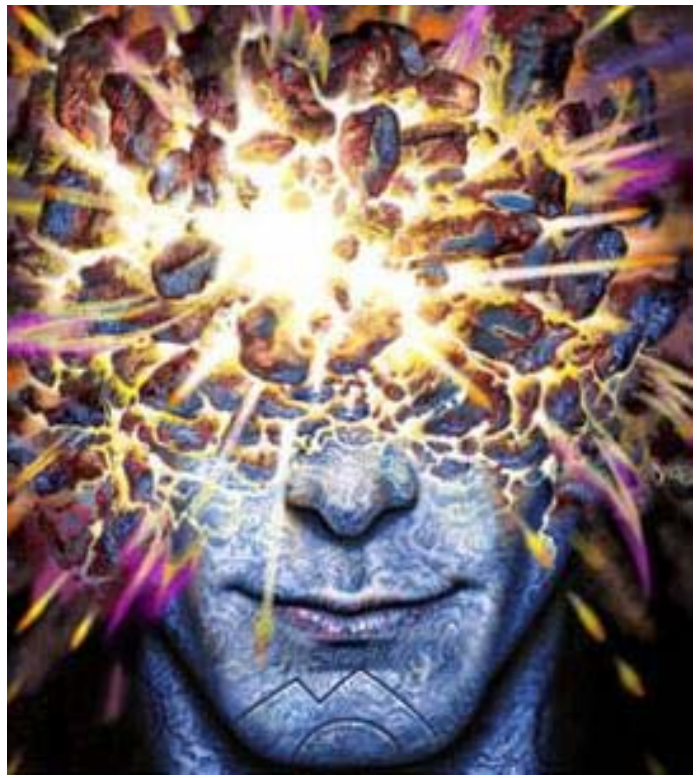
The surgeon



THE 90% DATA ACCURACY DILEMMA

90% SOUNDS GOOD UNTIL YOU CONSIDER The "AMPLIFICATION EFFECT"

- **90% Recipe accuracy X**
- **90% Bill-of-Material accuracy X**
- **90% Work instruction accuracy X**
- **90% Inventory record accuracy X**
- **90% Inventory issuing accuracy X**
- **90% Factory reporting accuracy X**



= THE CONFUSION FACTOR

HOW ACCURATE DO WE NEED TO BE?

- **Recipes/Bills of Materials = 98%**
- **Inventory Record Accuracy = 98%**
- **Order Shipping Accuracy = 99% +**

PRECISION SCALE

LIMITATIONS OF MANUAL TRACKING SYSTEMS – INCLUDING SPREADSHEETS!

- **Problems**
  - **Limited access**
  - **No central control system**
  - **Cumbersome to access in the event of a recall**
  - **No real time editing**

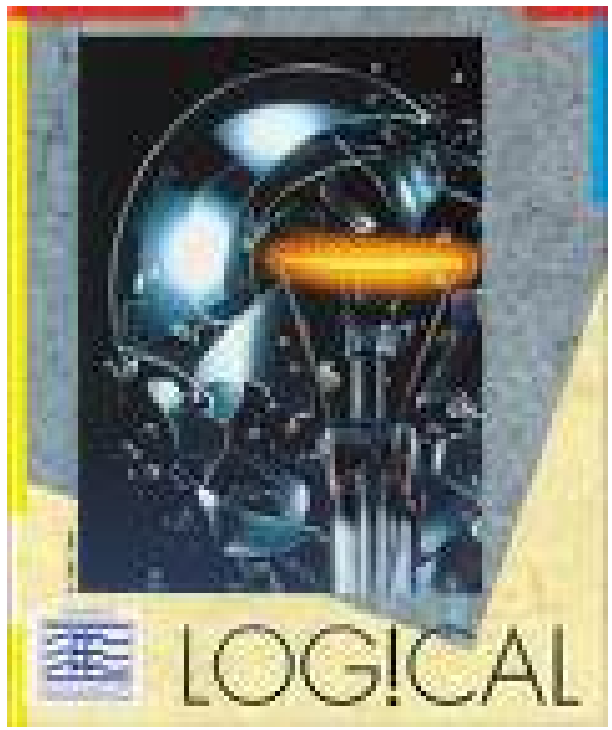
THE ROLE OF INTEGRATED DATA FLOW & REAL TIME INTEGRATION

DELUXE COLLECTION OF (INFORMATION) SILOS

THE ROLE OF INTEGRATED DATA FLOW & REAL TIME INTEGRATION

BENEFITS

- **One source for data**
- **Real time data validation**
- **User accessibility**
- **Allows for query and reporting**
- **Provides basis for performance measurements**



BIOTERRORISM ACT – RECORD KEEPING

- √ **Examine the FDA final directive**
- √ **Implied requirements**
- √ **Why an approximation often is not adequate**
- √ **The 90% data accuracy dilemma**
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√ The Act

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► **"How to" satisfy the implied requirements**

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BIOTERRORISM ACT – RECORD KEEPING

SATISFYING THE IMPLIED REQUIREMENTS

- **Computer supported lot trace**
- **Recipe management**
- **Receiving**
- **The warehouse**
- **Manufacturing (discussed later)**
- **Finished goods lot trace**

BEST PRACTICES

SATISFYING THE IMPLIED REQUIREMENTS

COMPUTER SUPPORTED LOT TRACEABILITY

- **Data security**
- **Lot trace ID scheme**
- **Company wide visibility**
- **Lot recall support**

DATA SECURITY AND AUDIT SUPPORT

EFFECTIVE SYSTEMS CONTAIN:

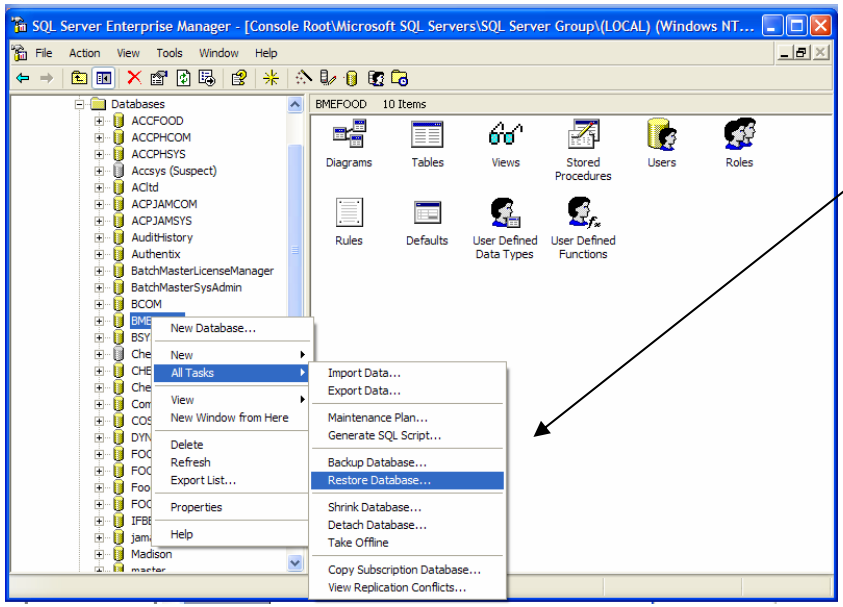
- **Flexible maintenance (CFR21 Part 11)**
  - **Secure data access**
- **Full Audit Support**
  - **User ID & Password by screen**
  - **Electronic signature**
  - **Transaction time, date & user stamp**
  - **Password protection / approvals**
  - **EASY LOT RECALL**

DATA SECURITY AND AUDIT SUPPORT

CFR 21 Part 11

- **Security & Authentication**
- **Traceability of Users Actions in the System**
- **Maintain Record Integrity**
- **Enforce Electronic Signature Capturing Date & Time**

FLEXIBLE MAINTENANCE

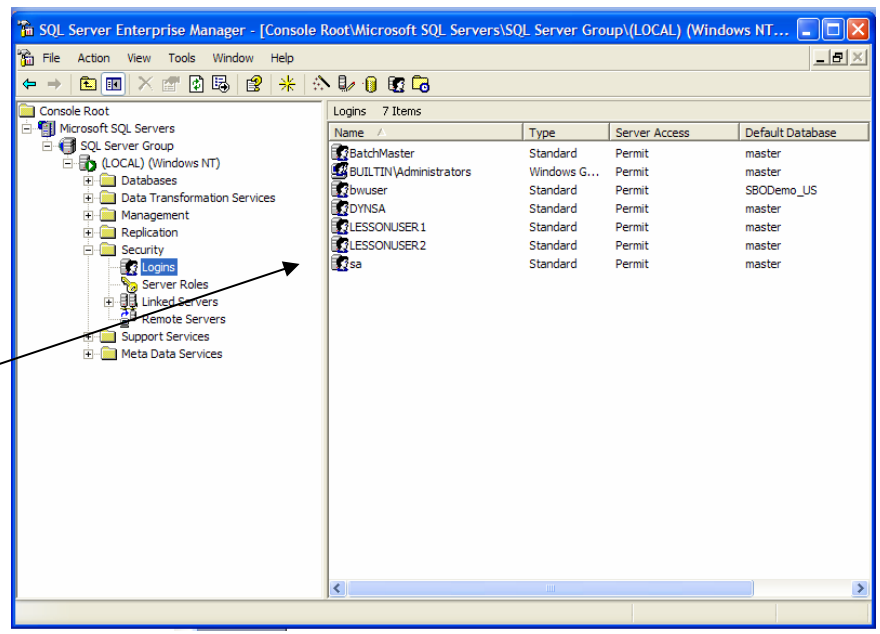


Industry Standard Architecture

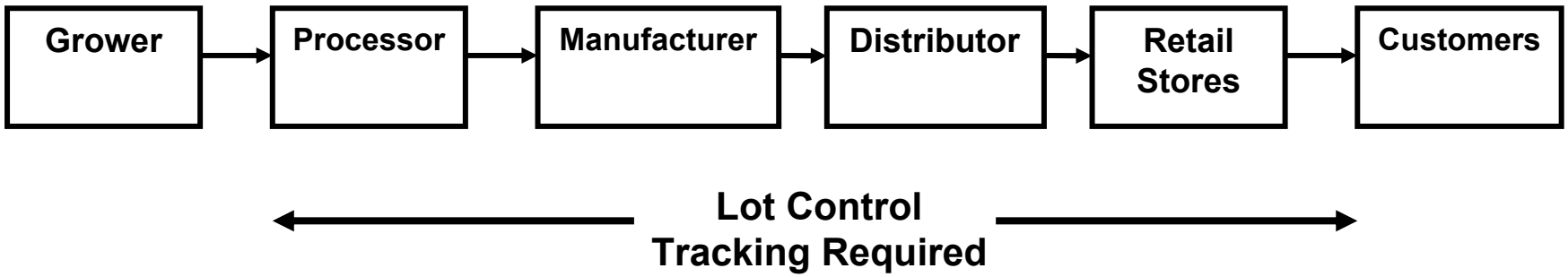
Simple Backup & Restore Features for Approved Users

Controls Who Accesses What Data

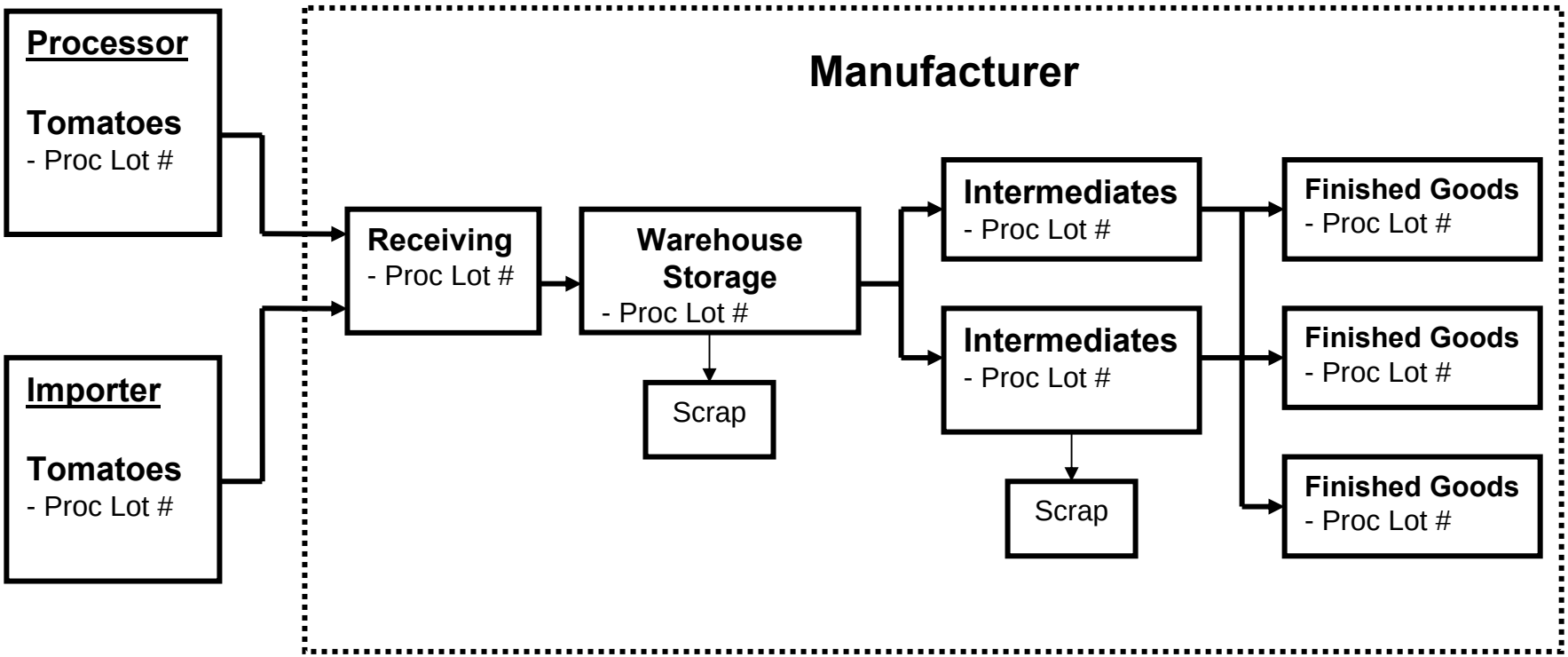
Manages Inheritance of Permissions



WHERE LOT CONTROL IS REQUIRED



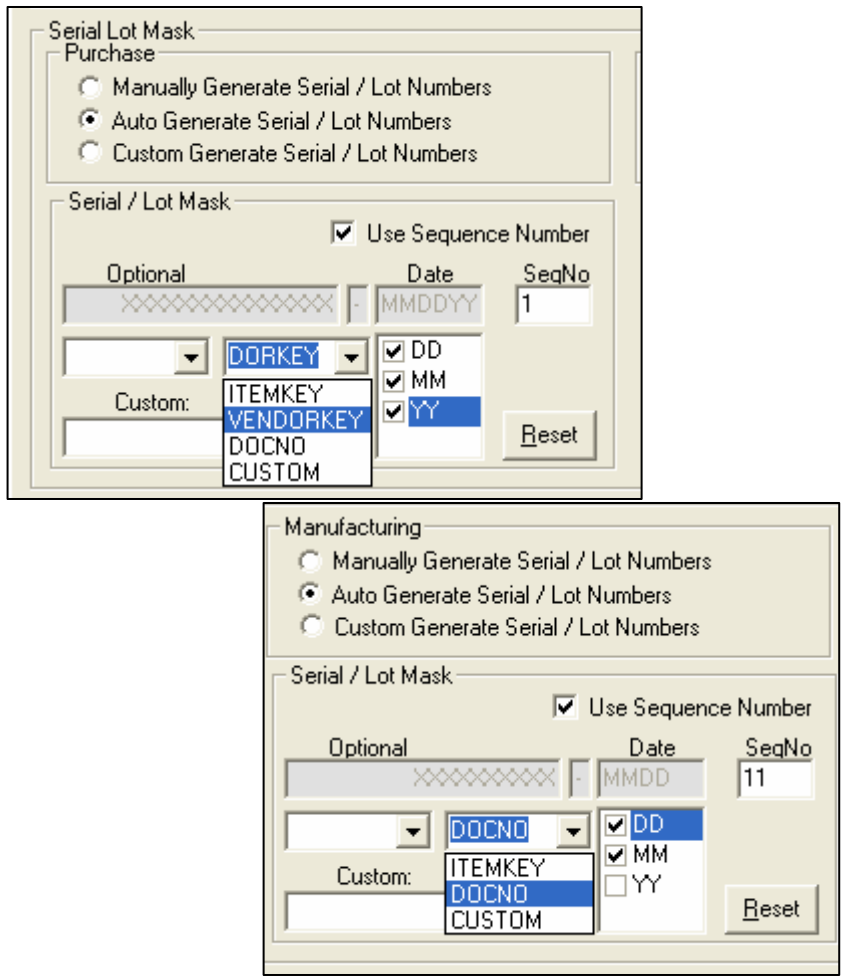
PROCESSOR LOT TRACKING



BUILDING THE FOUNDATION

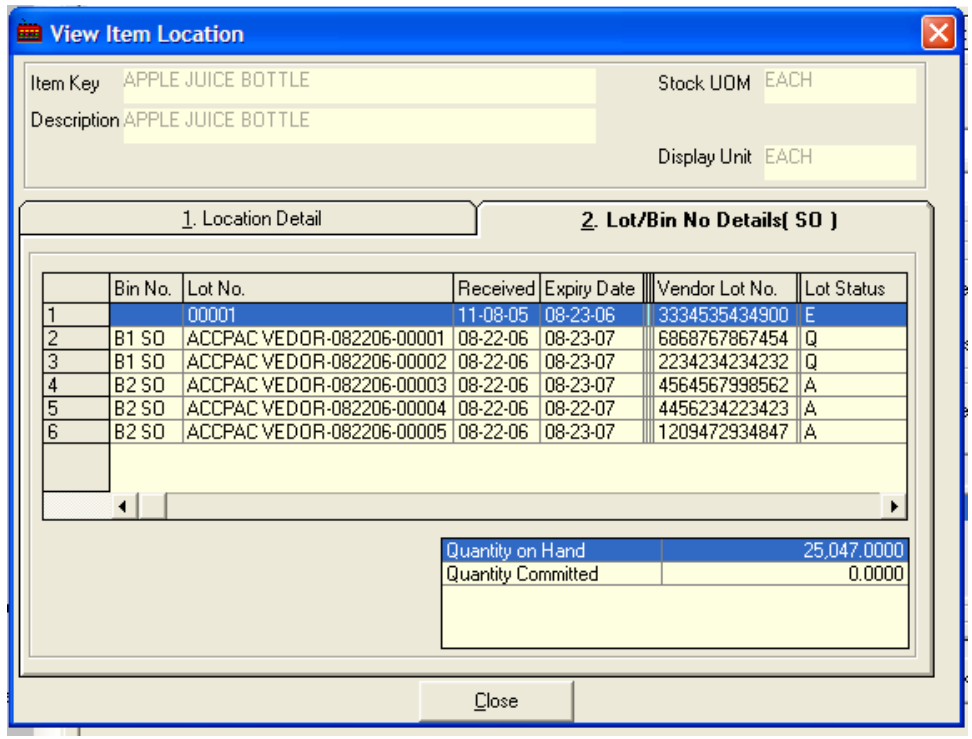
DESIGNING A SYSTEM TO SUPPORT LOT TRACEABILITY

- **Support intelligent & non-intelligent lot numbers**
- **Create masks- easy lot identification**
- **Track expirations**
- **Create unique naming conventions for item types**
- **Ensure consistency throughout**



COMPANY WIDE VISIBILITY

- **What is the location of a lot?**
- **Is the lot available or committed?**
- **Has the lot expired or what is the expiration date?**
- **Is the lot in use?**



INSTANT LOT RECALL

Lot Explosion

ItemKey	STF-ONION	Vendor	Raw Material Issue
Location	DO	Vendor Lot #	
Lot #	MR BAKER-042806-00001		

Level	Lot No / Item Key	Location	Date	Quantity	Document Details
	MR BAKER-042806-00001 STF-ONION Onion	DO	12:00:00AM	506.0241	BatchNo.0000000000009AA Raw Material Issue
	MR BAKER-042806-00001 STF-TURKFAT Turkey Fat	DO	12:00:00AM	25.3012	BatchNo.0000000000009AA Raw Material Issue
	REAL INC.-042806-00001 STF-1LBPAK Clear Plastic Celophane Sealed Container	DO	12:00:00AM	100.0000	BatchNo.0000000000009AA Raw Material Issue
	REAL INC.-042806-00001 STF-1LBPAK Clear Plastic Celophane Sealed Container	DO	12:00:00AM	100.0000	BatchNo.0000000000009AA Raw Material Issue
	REAL INC.-042806-00001 STF-1LBPAK Clear Plastic Celophane Sealed Container	DO	12:00:00AM	100.0000	BatchNo.0000000000009AA Raw Material Issue

Which Raw Materials Were Used

Lot Explosion

ItemKey	STF-CORNBREAD	Vendor	Finished Good Posting
Location	DO	Vendor Lot #	
Lot #	0000000000015AB-050106-00002		

Level	Lot No / Item Key	Location	Date	Quantity	Document Details
	0000000000015AB-050106-00002 STF-CORNBREAD Cornbread Intermediate	DO	12:00:00AM	36.1446	BatchNo.0000000000015AB Finished Good Posting
	0000000000015AC-050106-00002 STF-SPICEBLEND Herb Spice Blend	DO	12:00:00AM	36.1446	BatchNo.0000000000015AC Finished Good Posting
	0000000000027AB-050106-00004 STF-CORNBREAD Cornbread Intermediate	DO	12:00:00AM	36.1446	BatchNo.0000000000027AB Finished Good Posting
	0000000000027AC-050106-00004 STF-SPICEBLEND Herb Spice Blend	DO	12:00:00AM	36.1446	BatchNo.0000000000027AC Finished Good Posting
	0000000000009AA-042806-00001 STF-FG-CRNBRD1LBPI One Pound Package of Prepared Stuffing	DO	12:00:00AM	100.0000	BatchNo.0000000000009AA Finished Good Posting

What Intermediate & End Items Were Produced

Which Customers Received the Lots

BIOTERRORISM ACT – RECORD KEEPING

SATISFYING THE IMPLIED REQUIREMENTS

√**Computer supported lot trace**

►**Recipe management**

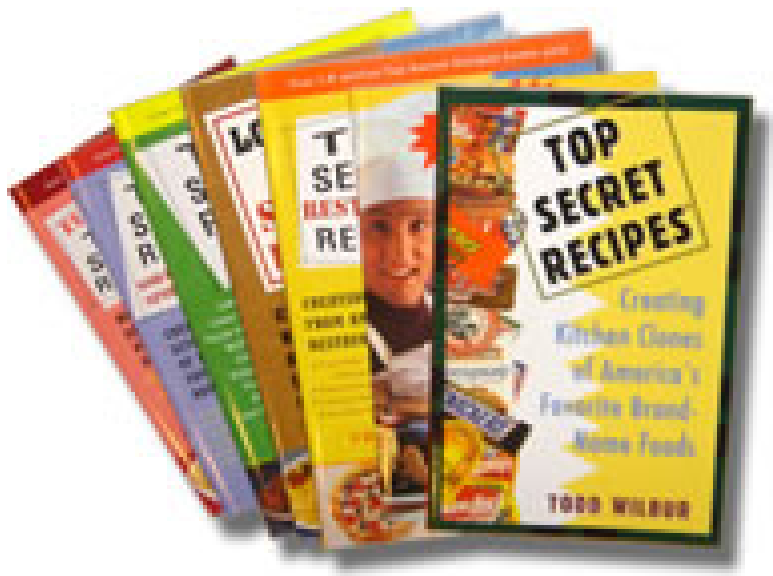
- **Receiving**
- **The warehouse**
- **Manufacturing (discussed later)**
- **Finished goods lot trace**

BEST PRACTICES

SATISFYING THE IMPLIED REQUIREMENTS

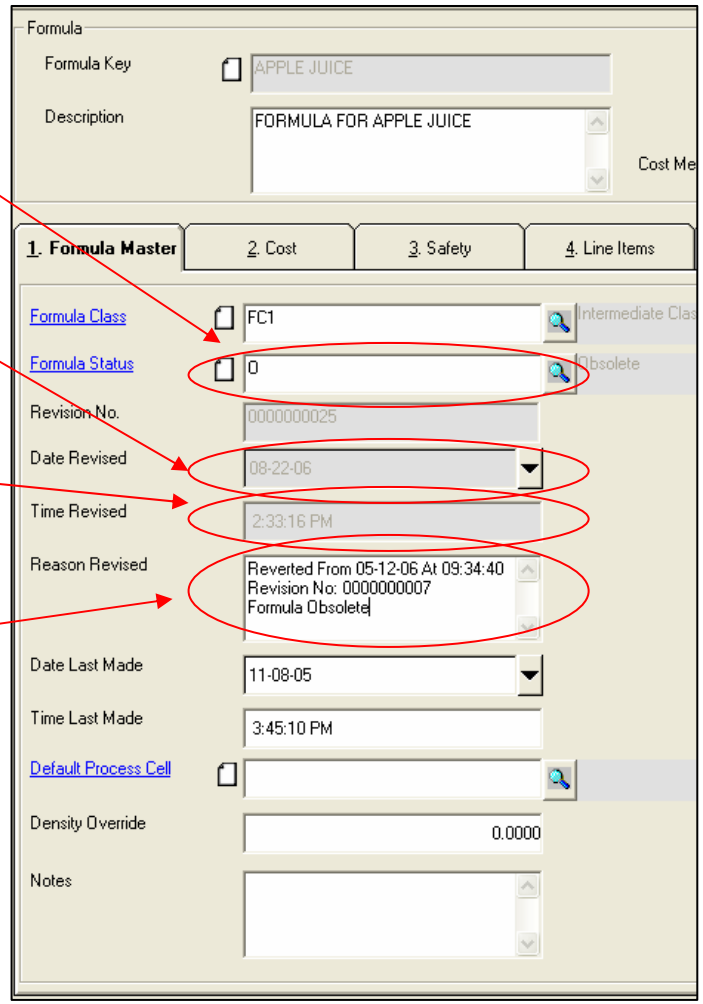
RECIPE MANAGEMENT

- **Secure & controlled access**
- **Versioning**
- **Ingredient, nutritional & cost integration**



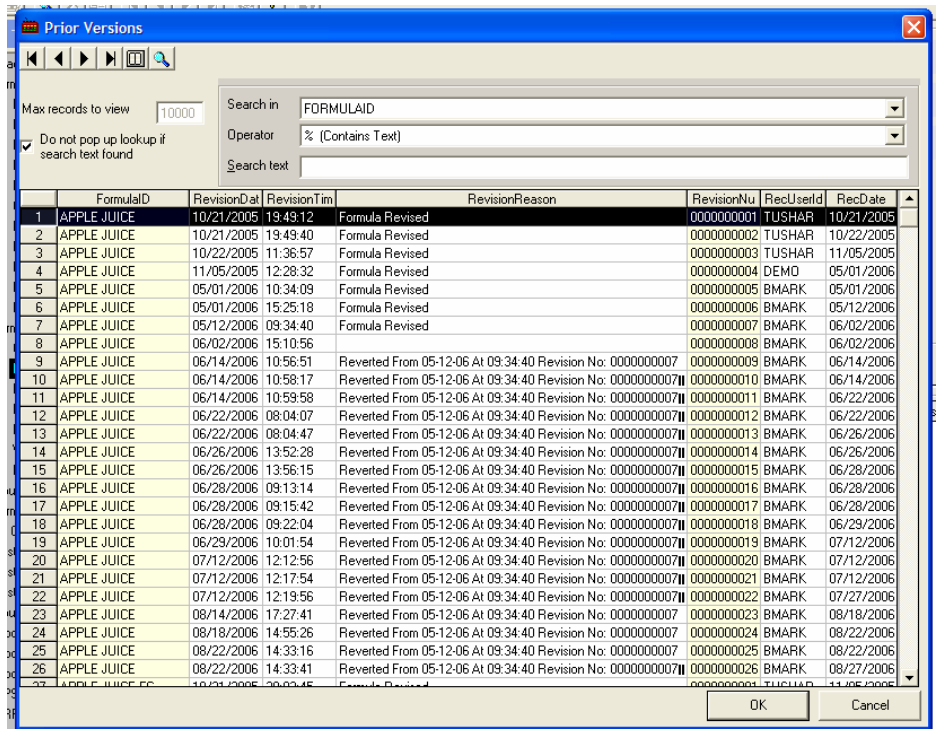
SECURING DATA ACCESS
PROTECTING INTELLECTUAL PROPERTY

- **Control the status of recipe / formulas**
- **Know when changes occur**
- **View who made changes**
- **Capture reasons for revision**



VERSIONING

- **Systems track what changes occurred and when**
- **Electronic signatures assigned to changes**
- **Reasons for changes are documented**



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2	APPLE JUICE	10/21/2005	19:49:40	Formula Revised	0000000002	TUSHAR	10/22/2005
3	APPLE JUICE	10/22/2005	11:36:57	Formula Revised	0000000003	TUSHAR	11/05/2005
4	APPLE JUICE	11/05/2005	12:28:32	Formula Revised	0000000004	DEMO	05/01/2006
5	APPLE JUICE	05/01/2006	10:34:09	Formula Revised	0000000005	BMARK	05/01/2006
6	APPLE JUICE	05/01/2006	15:25:18	Formula Revised	0000000006	BMARK	05/12/2006
7	APPLE JUICE	05/12/2006	09:34:40	Formula Revised	0000000007	BMARK	06/02/2006
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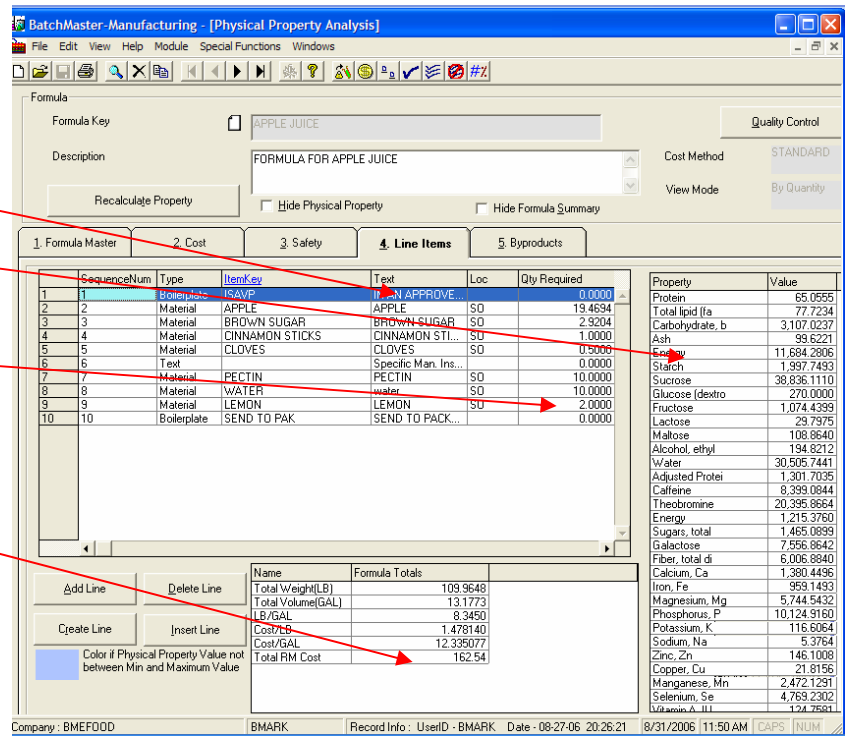
19	APPLE JUICE	06/29/2006	10:01:54	Reverted From 05-12-06 At 09:34:40 Revision No: 0000000007	0000000019	BMARK	07/12/2006
20	APPLE JUICE	07/12/2006	12:12:56	Reverted From 05-12-06 At 09:34:40 Revision No: 0000000007	0000000020	BMARK	07/12/2006
21	APPLE JUICE	07/12/2006	12:17:54	Reverted From 05-12-06 At 09:34:40 Revision No: 0000000007	0000000021	BMARK	07/12/2006
22	APPLE JUICE	07/12/2006	12:19:56	Reverted From 05-12-06 At 09:34:40 Revision No: 0000000007	0000000022	BMARK	07/27/2006
23	APPLE JUICE	08/14/2006	17:27:41	Reverted From 05-12-06 At 09:34:40 Revision No: 0000000007	0000000023	BMARK	08/18/2006
24	APPLE JUICE	08/18/2006	14:55:26	Reverted From 05-12-06 At 09:34:40 Revision No: 0000000007	0000000024	BMARK	08/22/2006
25	APPLE JUICE	08/22/2006	14:33:16	Reverted From 05-12-06 At 09:34:40 Revision No: 0000000007	0000000025	BMARK	08/22/2006
26	APPLE JUICE	08/22/2006	14:33:41	Reverted From 05-12-06 At 09:34:40 Revision No: 0000000007	0000000026	BMARK	08/27/2006

ONE VERSION OF THE TRUTH

- **Ingredients, costs, recipe classification & nutritional values in one screen**
- **Ownership of formulation**
- **Full traceability**

INTEGRATED WORK ENVIRONMENT
ONE VERSION OF THE TRUTH

- **Ingredient Management**
- **Nutritional Properties**
- **Line Item Costs**
- **Formula Costs**



BIOTERRORISM ACT – RECORD KEEPING

SATISFYING THE IMPLIED REQUIREMENTS

√Computer supported lot trace

√Recipe management

►**Receiving**

- **The warehouse**
- **Manufacturing (discussed later)**
- **Finished goods lot trace**

BEST PRACTICES

SATISFYING THE IMPLIED REQUIREMENTS

THE RECEIVING AREA

- **5S**
- **Incoming shipments scheduling & visibility**
- **On-line access to purchase specifications**
- **Reducing data input errors – wireless barcode**

SATISFYING THE IMPLIED REQUIREMENTS

THE RECEIVING AREA

- **Multi-lingual**
- **Lot trace ID scheme**
- **Quarantine support**
- **Standard Operating Procedure (SOP) access**

WORKPLACE ORGANIZATION

- **A safe, clean, neat, arrangement of the workplace which provides a specific location for everything, and eliminates anything not required.**

BUZZ WORD BINGO:5S

Sort

Straighten

Shine

Standardize

Sustain

5S is the Japanese concept for House Keeping:

1. Seiri - Put things in order
(remove what is not needed and keep what is needed)
2. Seiton - Proper Arrangement
(Place things in such a way that they can be easily reached whenever they are needed)
3. Seiso - Clean
(Keep things clean and polished; no trash or dirt in the workplace)
4. Seiketsu - Purity
(Maintain cleanliness after cleaning - perpetual cleaning)
5. Shitsuke - Commitment

Source: iSixSigma

STORAGE AREA BEFORE 5S

STORAGE AREA AFTER 5S

STORAGE AREA BEFORE 5S

STORAGE AREA AFTER 5S

SATISFYING THE IMPLIED REQUIREMENTS

THE RECEIVING AREA

√ **5S**

► **Incoming shipments scheduling & visibility**

► **On-line access to purchase specifications**

- **Reducing data input errors – wireless barcode**

SHIPMENT VISIBILITY

Expected Delivery Report
INFOFOOD Ltd.
05-Oct-2006

Itemkey: BROWN SUGAR BROWN SUGAR
Location: DO

PO No.	Line	Vendor	Ord date	Req Date	Qty Rcv	Qty Remaining	Unit	Price	Unit	Extended Amt.
RE000002	2	SUSAN	11-08-05	11-08-05	10.0000	0.0000	LB	1.0000	LB	10.0000

Itemkey: BROWN SUGAR BROWN SUGAR
Location: SO

PO No.	Line	Vendor	Ord date	Req Date	Qty Rcv	Qty Remaining	Unit	Price	Unit	Extended Amt.
RO000001	1	PILLSBURY	06-16-06	06-16-06	0.0000	45,000.0000	LB	0.7500	LB	33,750.0000

Itemkey: CAP CAP
Location: SO

PO No.	Line	Vendor	Ord date	Req Date	Qty Rcv	Qty Remaining	Unit	Price	Unit	Extended Amt.
PR000017	1	MR.BAKER	07-12-06	07-12-06	0.0000	45,000.0000	LB	1.0000	LB	45,000.0000

Itemkey: CARTON Carton
Location: DO

PO No.	Line	Vendor	Ord date	Req Date	Qty Rcv	Qty Remaining	Unit	Price	Unit	Extended Amt.
PR000027	1	MR.BAKER	10-04-06	10-04-06	0.0000	2010.0000	EACH	.50	EACH	1005.0000

Itemkey: CINNAMON STICKS CINNAMON STICKS
Location: SO

PO No.	Line	Vendor	Ord date	Req Date	Qty Rcv	Qty Remaining	Unit	Price	Unit	Extended Amt.
RE000002	1	SUSAN	11-08-05	11-08-05	10.0000	0.0000	LB	3.0000	LB	30.0000

Itemkey: CITRIC ACID CITRIC ACID
Location: DO

PO No.	Line	Vendor	Ord date	Req Date	Qty Rcv	Qty Remaining	Unit	Price	Unit	Extended Amt.
NO000001	1	WILLIAM	11-08-05	11-08-05	1.2500	0.0000	GAL	2.0000	GAL	2.5000

- **Point of Origin**
- **Destination**
- **Quantity Expected**
- **Valuation**

PURCHASE ORDER INFORMATION

- **Detail**
- **Status**
- **Quantity**
- **Value**
- **Expectations**

PO by Status 05-Oct-2006

With status Receipt, Rejected, Inspection, CreateLot, Not Processed, Processed, Pending Voucher, Voucher Generated

INFOFOOD Ltd.

Ord.Date From 10-05-06 To 10-05-06

Req.Date From 10-05-06 To 10-05-06

Receipt: 41
PO No: PR000024
Vendor: ABC VEDOR ACCPAC VEDOR

SLNo.	POLine	ItemKey	Loc.	Unit	Qty Ord	Qty Rcv	BasePrice (USD)	Amount (USD)	Status
1	1	XM905 Cros.Carmelose Sodium	SO	KG	2,400.0000	2,400.0000	0 (KG)	24,000.00	Pending Voucher
1	2	XD355 Diamond Hydronate	SO	KG	47,250.0000	47,250.0000	0 (KG)	10,050.00.	Inspection
1	3	RL050 lactose	SO	KG	66,900.0000	66,900.0000	0 (KG)	66,,900.00	receipt
1	4	RM050 mcc102	SO	KG	33,300.0000	33,300.0000	0 (KG)	66,600.00	CreateLot

SATISFYING THE IMPLIED REQUIREMENTS

THE RECEIVING AREA

√ 5S

√ Incoming shipments scheduling & visibility

√ On-line access to purchase specifications

► **Reducing data input errors – wireless barcode**

INTEGRATED MOBILITY AND TRACEABILITY

- **Warehouse management integrated with wireless, handheld hardware**
- **Real time inventory and improved data access**
- **Immediate visibility for inventory, lot data, shelf life**
- **Real-time capture of lot numbers and consumption at each step**

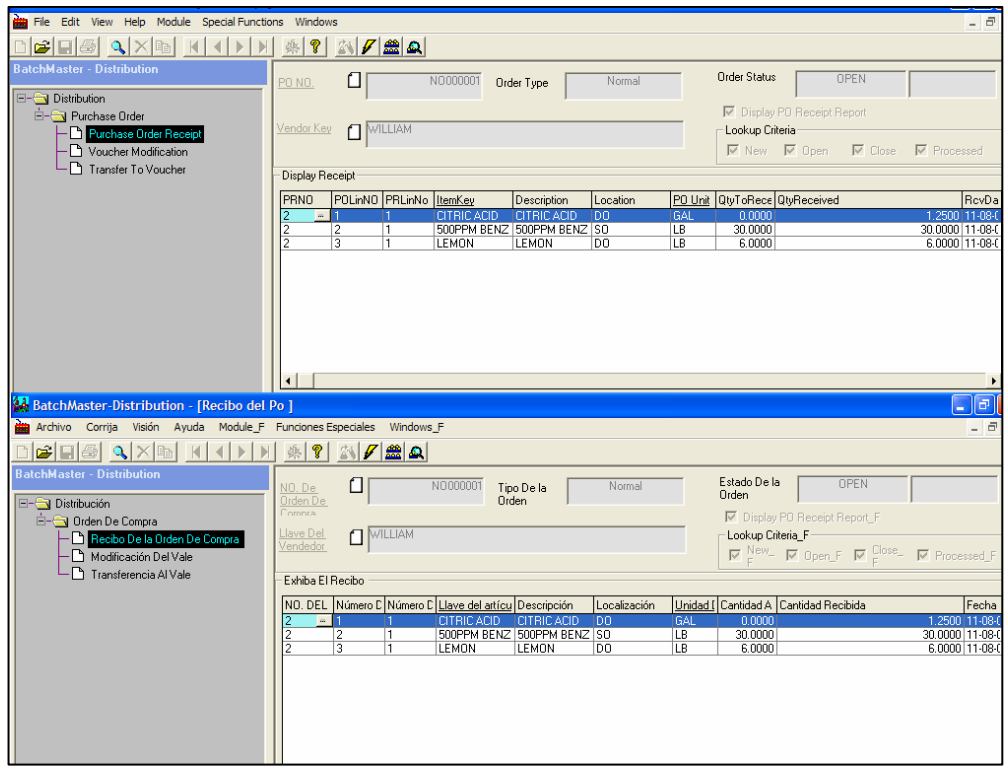
SATISFYING THE IMPLIED REQUIREMENTS

THE RECEIVING AREA

- **Multi-lingual**
- **Lot trace ID scheme**
- **Quarantine support**
- **Standard Operating Procedure (SOP) access**

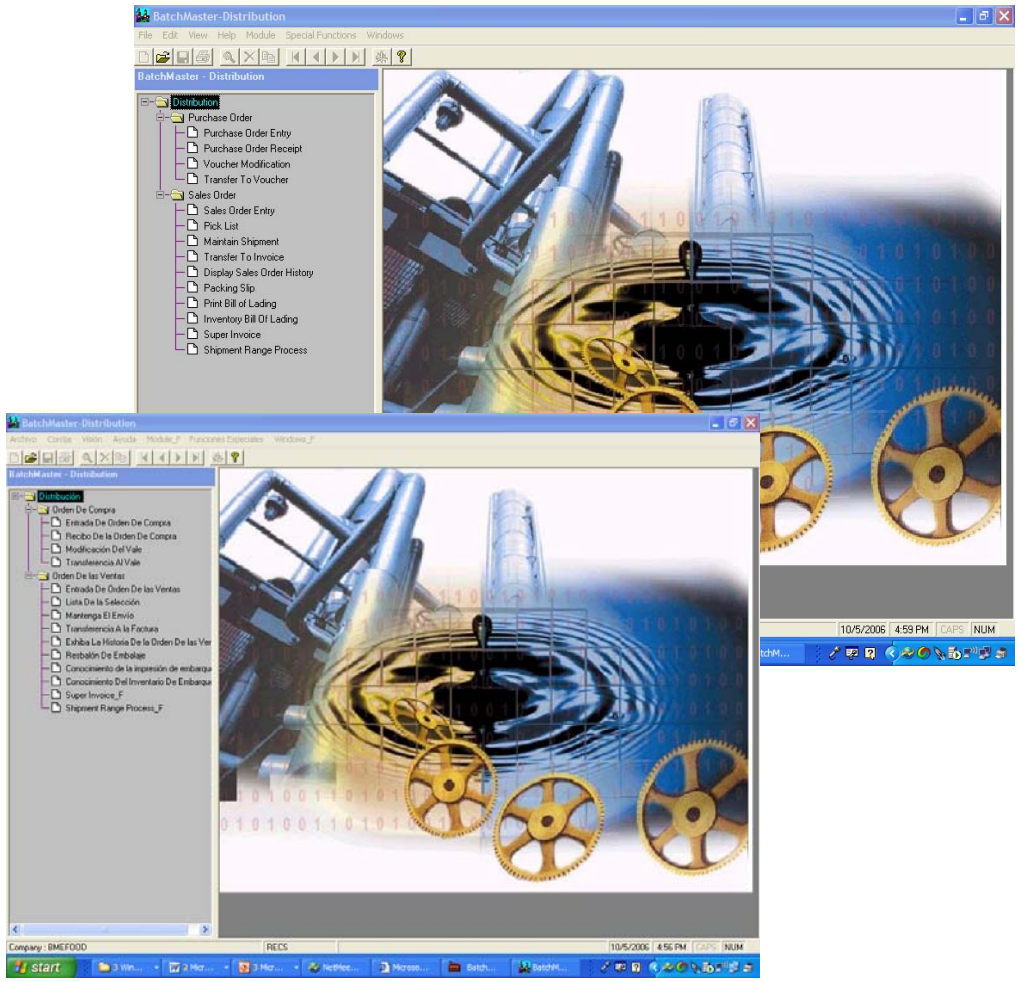
MULTI-LINGUAL SUPPORT

- **Define a Users Role**
- **Select the Users Language of Choice**
- **Supports:**
  - English
  - **French**
  - Spanish
  - **Common Chinese**
  - **Italian**
  - **German**



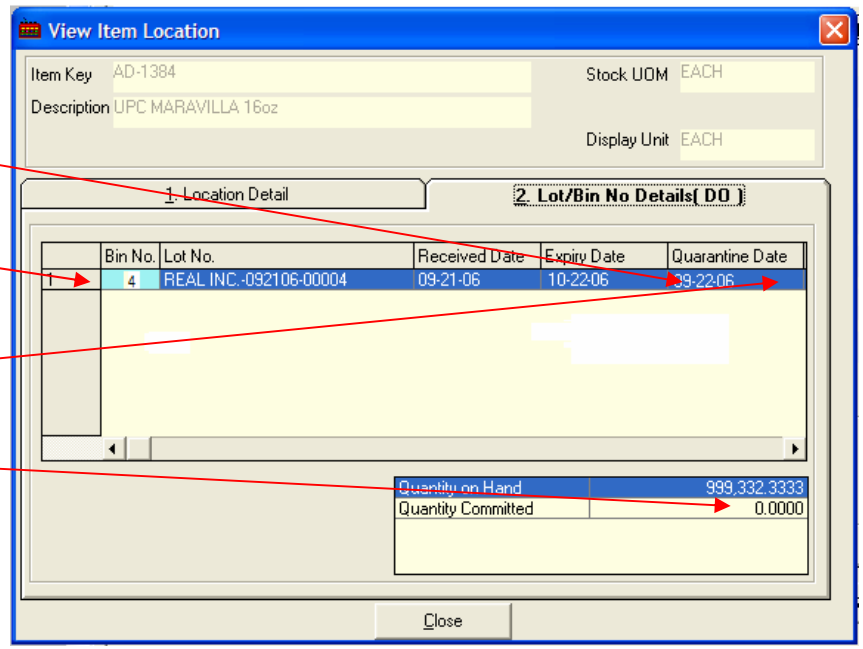
MULTI-LINGUAL SUPPORT

- **Seamless Multi-Lingual Interface**
- **Communicate in the Language of Manufacturing**
- **Maximize Efficiency**
- **Migrate to Common Environment while Training is Language Specific**



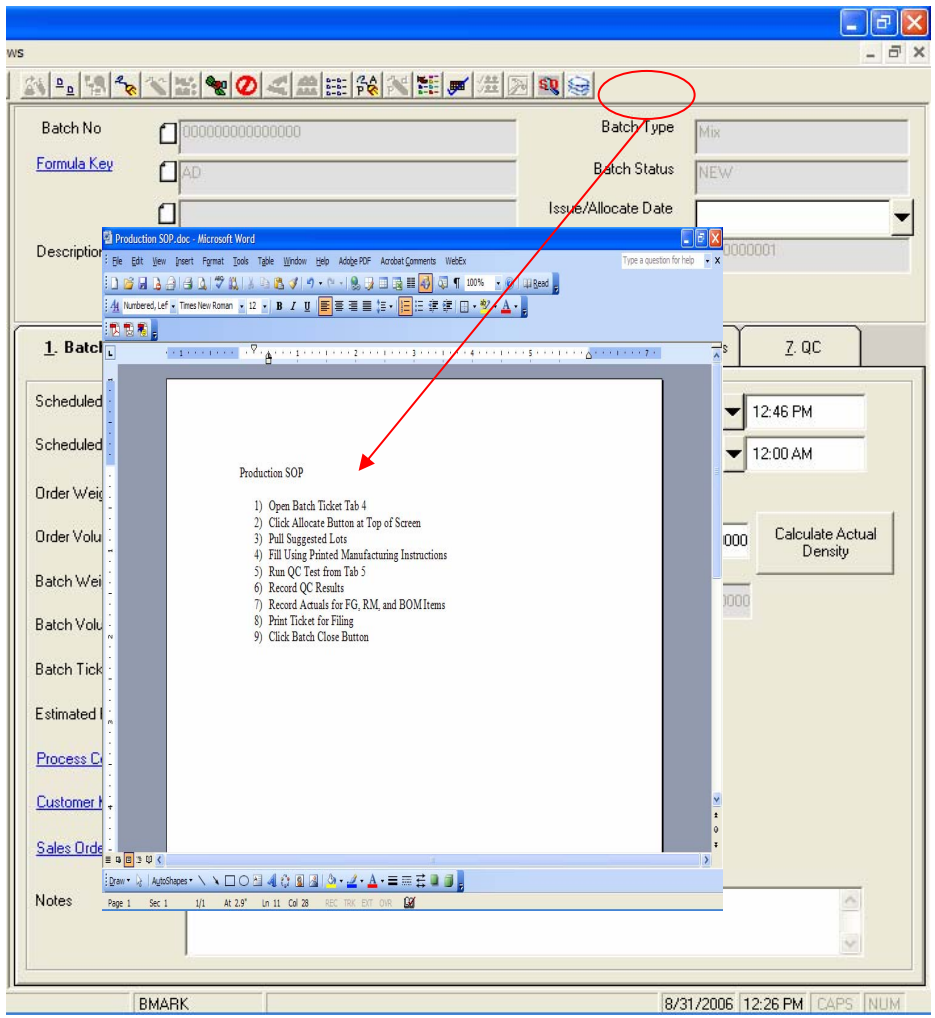
TIGHT LOT CONTROL - QUARANTINE

- **Calculate quarantine controls into lead times**
- **Understand physical location of lots**
- **Track expiration dates**
- **View availability**



SOP SUPPORT

- **Screen Embedded Access**
- **Support for unlimited MS Compatible File Types**
- **One Touch Compliance**



SATISFYING THE IMPLIED REQUIREMENTS

THE RECEIVING AREA

√ **Multi-lingual**

√ **Lot trace ID scheme**

√ **Quarantine support**

√ **Standard Operating Procedure (SOP) access**

BIOTERRORISM ACT – RECORD KEEPING

SATISFYING THE IMPLIED <u>REQUIREMENTS</u>

√Computer supported lot trace

√Recipe management

√Receiving

►**The warehouse**

- Manufacturing (discussed later)
- Finished goods lot trace

BEST PRACTICES

SATISFYING THE IMPLIED REQUIREMENTS

THE WAREHOUSE

- **Warehouse layout guidelines**
- **Minimizing data input errors**
- **Identifying and eliminating sources of errors**
- **Real-time access to information**
- **Personnel training**

THE WAREHOUSE

EFFECTIVE LAYOUT

- **5S**
- **Controlled access**
- **Support dry, refrigerated and frozen**
- **Simple numbering scheme**

THE WAREHOUSE

EFFECTIVE LAYOUT

- **Room for equipment movement**
- **Overflow**
- **Minimize travel distance**
- **Wireless support**

THE WAREHOUSE

MINIMIZING DATA INPUT ERRORS

- **SOP (why, how)**
- **Employee training (do)**
- **Wireless barcode (tools)**
- **Cycle counting**
  - **Prevention**

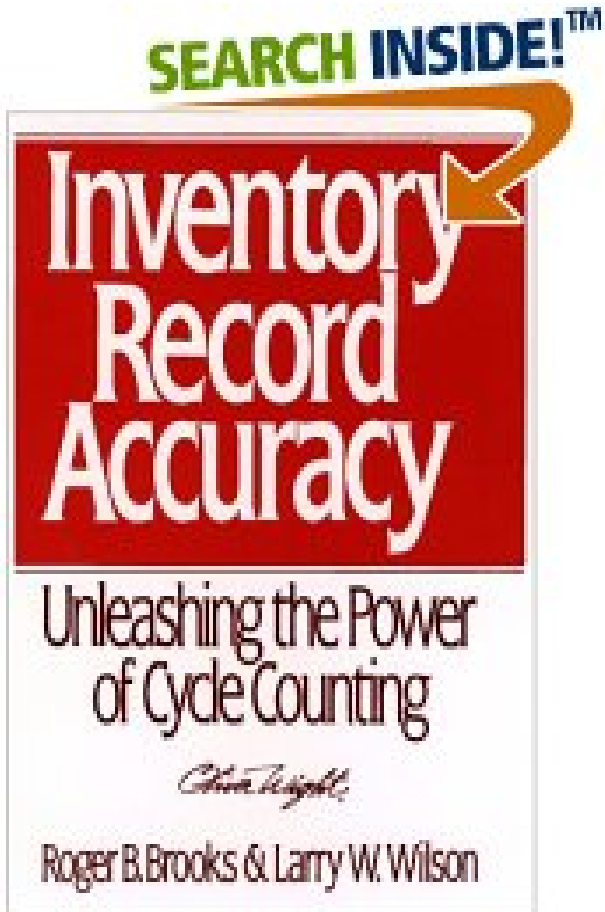
SATISFYING THE IMPLIED REQUIREMENTS

THE WAREHOUSE

- √ Warehouse layout guidelines
- √ Minimizing data input errors
- ► **Identifying and eliminating sources of errors**
- Real-time access to information
- Personnel training

THE WAREHOUSE

IDENTIFYING AND ELIMINATING SOURCES OF ERRORS



CYCLE COUNTING

INVENTORY ACCURACY AUDIT TECHNIQUE

INVENTORY COUNTED ON A CYCLIC SCHEDULE

PURPOSE – IDENTIFY ERROR, RESEARCH CAUSE AND ELIMINATE

An inventory accuracy audit technique where inventory is counted on a cyclic schedule rather than once a year.

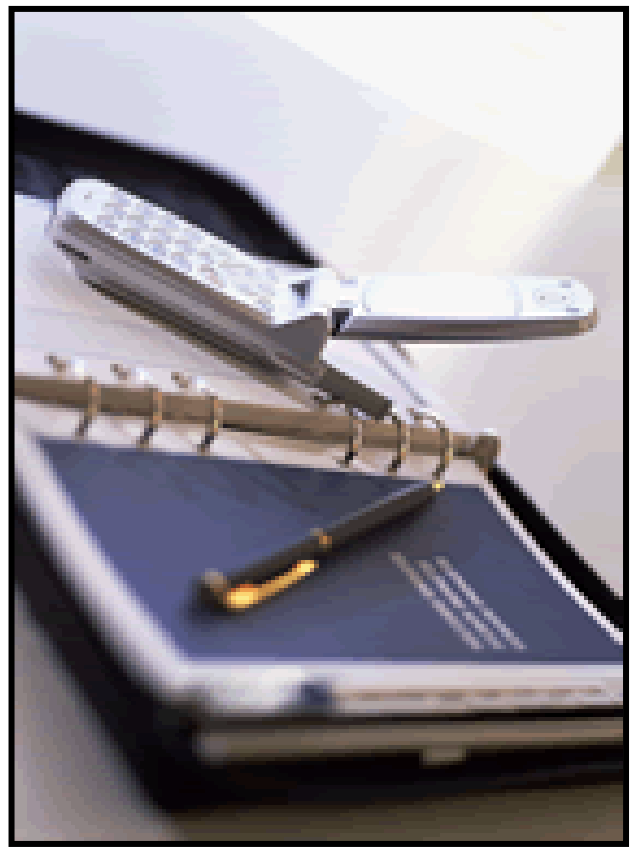
Most effective cycle counting systems require the counting of a certain number of items every workday with each item counted at a prescribed frequency. The key purpose of cycle counting is to identify items in error, thus triggering research, identification, and elimination of the cause of the errors.

Source: APICS Dictionary

CYCLE COUNTING

GOALS AND BENEFITS

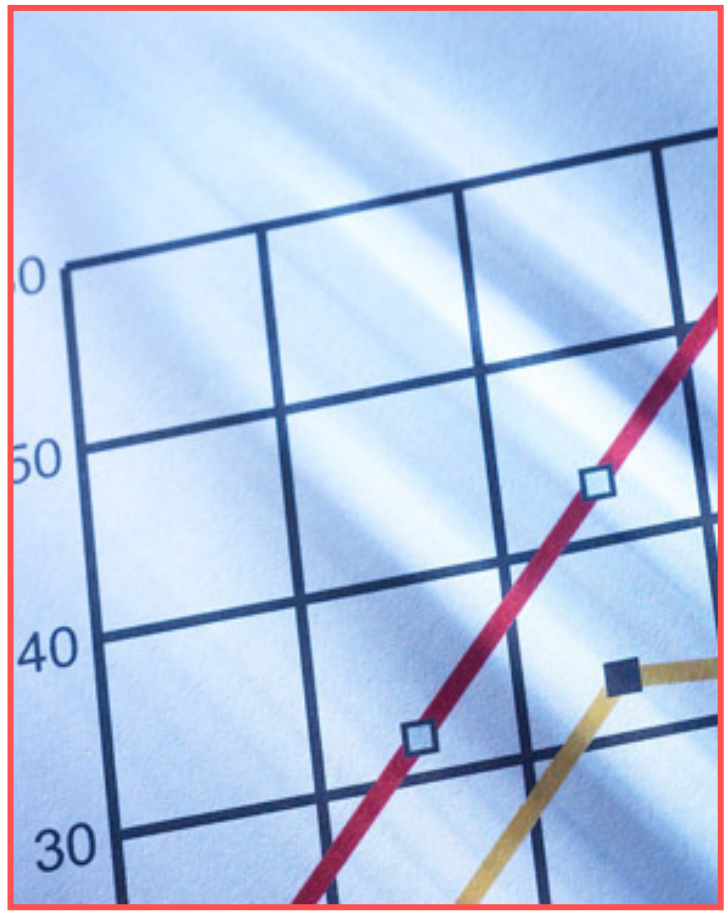
- **Lot Control records reflect actual balances and tracking of material**
- **Inventory records reflect actual physical counts, data integrity**
- **Inventory control procedures and processes are validated**



CYCLE COUNTING

GOALS AND BENEFITS

- **Accurate inventory balances support effective inventory planning, purchasing and factory scheduling**
- **Company assets are accurately stated**



CYCLE COUNTING METHODS

- **By item** – all locations showing inventory on the system.
- **Block method** – count all materials in a sequential list of locations.

Item #: 1000 - All items in system locations

By Item

100	101	102	103	104	105	106
	X		X			
200	201	202	203	204	205	206
		X		X		

Storage Locations

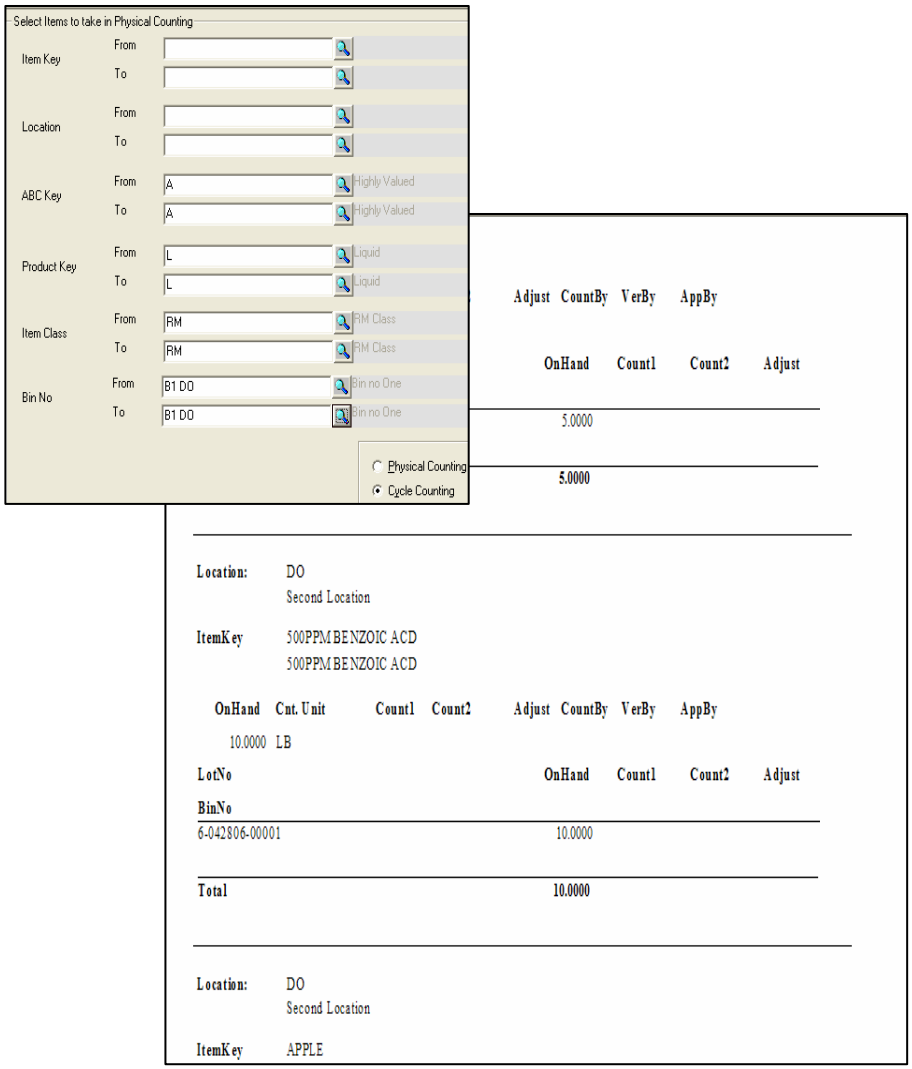
Block Method

100	101	102	103	104	105	106
200	201	202	203	204	205	206

Storage Locations

← All items in locations #200 - #203 →

COMPUTER SUPPORTED CYCLE COUNTING



- Determine which products, families and inventory valuation to count
- Utilize systems to interrogate inventory
- Generate count sheets

PROBLEM RESOLUTION / TROUBLE SHOOTING

Select Transaction Type

- [ ] A-Adjustment
- [ ] B-Std.Cost Modification
- [ ] C-Credit Memo
- [ ] D-Debit Memo
- [ ] E-Cost Adjustment
- [ ] G-Damaged
- [x] I-Inventory Commitment
- [ ] M-Move Out
- [ ] N-Notification of Receipt
- [ ] O-On Order
- [x] P-Purchase/Production Receipt
- [ ] R-Receipt of Transfer
- [ ] S-Sale
- [ ] T-Transfer Going Out
- [ ] U-Transfer Coming In
- [ ] V-Internal Move
- [ ] X-Commitment To Production
- [ ] Z-Batch Reversal

Select All | Unselect All

Transaction Sub Type

Transaction Sub Type From
Transaction Sub Type To

Select Item

Item From: APPLE — APPLE
Item To: APPLE — APPLE
Location From:
Location To:

Transaction History Report

INFOFOOD Ltd.

ItemKey :	APPLE	APPLE					Opening Balance	0.0000 LB
Location :	DO	Second Location					Closing Balance	2,000.0000 LB
Transaction Type :	P							Offset Account
Sub Type	To Location	Doc No.	Doc Date	Apply Date	Tran. Description	Tran. Qty LB	Unit Tran. Amt	Extended Amt	Control Account
PO		12	04-28-06	04-28-06	ROBERT-Rcpt12	1,000.0000	0.000000	0.00	0153 0151
PO		46	10-06-06	10-06-06	PILLSBURY-Rcpt46	1,000.0000	0.000000	0.00	0153 1000

ItemKey :	APPLE	APPLE					Opening Balance	0.0000 LB
Location :	SO	First Location					Closing Balance	1,000.0000 LB
Transaction Type :	P							Offset Account
Sub Type	To Location	Doc No.	Doc Date	Apply Date	Tran. Description	Tran. Qty LB	Unit Tran. Amt	Extended Amt	Control Account
			11-08-05	11-08-05	APPLE -Trn. OI-3	1,000.0000	0.500000	500.00	0900 0003

TOOLS FOR THE SHERLOCK IN YOUR ORGANIZATION

SATISFYING THE IMPLIED REQUIREMENTS

THE WAREHOUSE

- √ **Warehouse layout guidelines**
- √ **Minimizing data input errors**
- √ **Identifying and eliminating sources of errors**
- ► **Real-time access to information**
- ► **Personnel training**

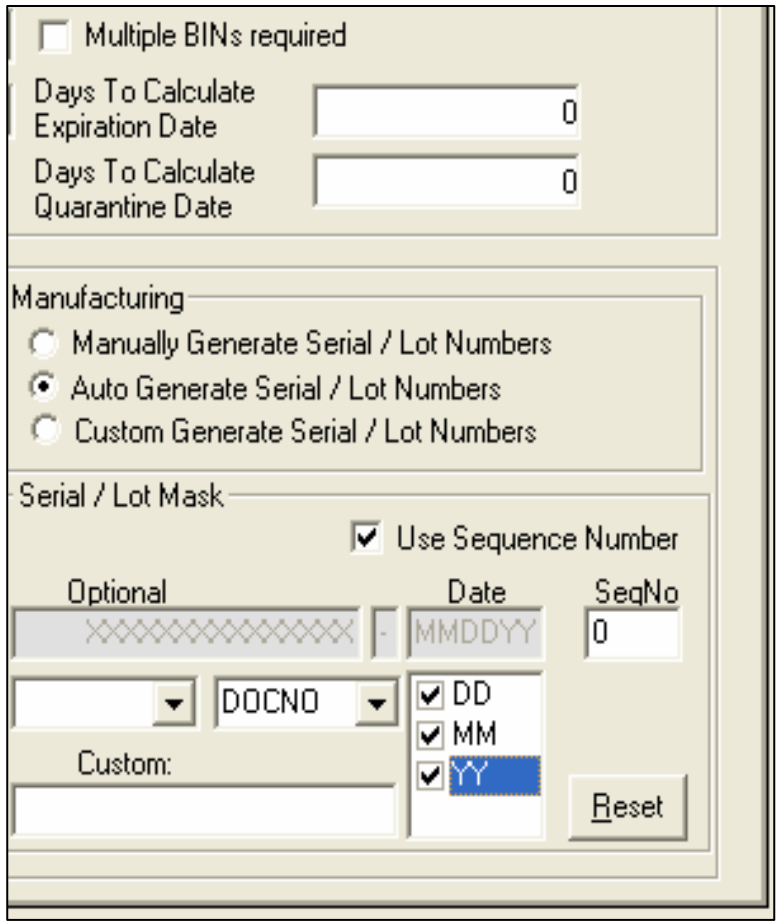
SATISFYING THE IMPLIED REQUIREMENTS

FINISH GOODS LOT TRACING

- **Raw materials to finished end-items (upstream)**
- **Finished goods to raw materials (downstream)**

FINISHED GOODS LOT TRACING

- **Define Finished Goods Handling**
- **Manage Intermediates**
- **Manage Quarantine Times / Locations**
- **Create Custom Fields**



BIOTERRORISM ACT – RECORD KEEPING

SATISFYING THE IMPLIED REQUIREMENTS

- √ **Computer supported lot trace**
- √ **Recipe management**
- √ **Receiving**
- √ **The warehouse**
- √ **Manufacturing (discussed later)**
- √ **Finished goods lot tracing**

BEST PRACTICES

THE BIOTERRORISM ACT – RECORD KEEPING

- √ The Act
- √ Implied requirements
- √ "How to" satisfy the implied requirements
- ► **Leveraging the results into significant inventory reduction and improved on-time delivery**

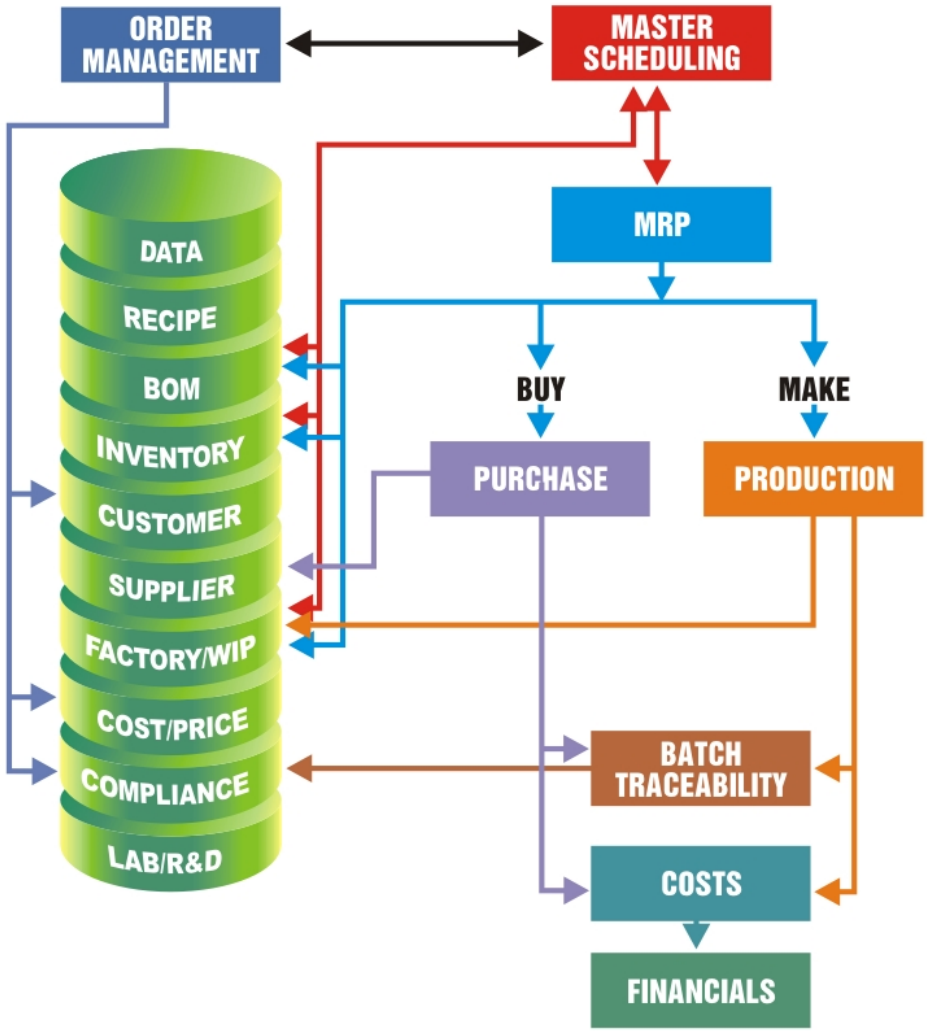
PUTTING THE PIECES TOGETHER FOR COMPETITIVE ADVANTAGE

LEVERAGING THE RECORD KEEPING REQUIREMENT

ADVANCED INVENTORY PLANNING

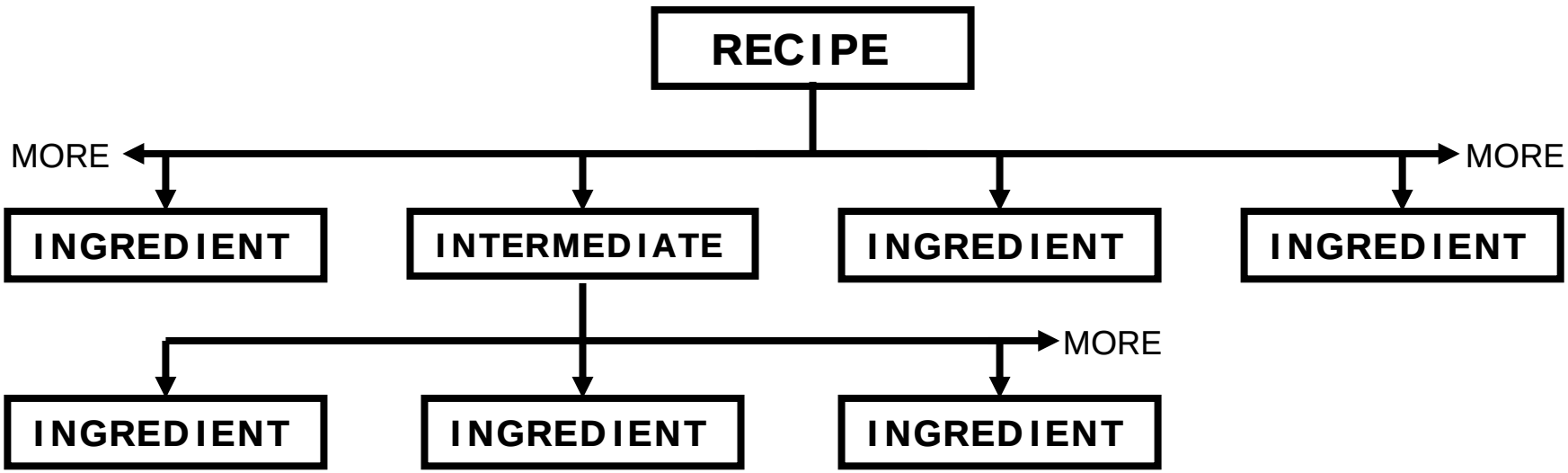
- **Material Requirements Planning (MRP) – old faithful**
- **Requires high levels of data accuracy - just like FDA record keeping**
- **Proven**
- **Existing implementation & usage know-how**
- **Excellent ROI**

CONCEPTUAL GENERIC ERP REPRESENTATION



MATERIAL REQUIREMENTS PLANNING (MRP)

SIMPLIFIED EXAMPLE



IMAGINE MANY BACKLOGGED ORDERS

MATERIAL REQUIREMENTS PLANNING (MRP)

WHAT DO WE NEED

HOW MANY

WHEN DO WE NEED THEM

WHEN DO WE NEED TO START

MATERIAL REQUIREMENTS PLANNING (MRP)

THE BENEFITS OF MATERIAL REQUIREMENTS PLANNING (MRP)

THIS.....

VS. THIS

THE BENEFITS OF ERP

SIGNIFICANT LEAD-TIME REDUCTION

SIGNIFICANT INVENTORY REDUCTION

IMPROVED ON-TIME DELIVERY

BUSINESS PROCESS RELIABILITY

THE BENEFITS OF ERP

METRIC	PRE-ERP	CURRENT ESTIMATE	FUTURE ESTIMATE
INVENTORY TURNOVER	4.5	7.9	11.2
LEAD-TIME (DAYS)	55.6	41.7	31.8
ON –TIME DELIVERY %	73.9	88.6	94.6
ORDER SPLITS %	29	13.5	2.1
NUMBER OF EXPEDITORS	10.8	5.1	2.1

SOURCE: APICS JOURNAL (CLEMSON)

THE BENEFITS OF ERP

INVENTORY TURNOVER

The number of times that an inventory cycles, or “turns over,” during the year. A frequently used method to compute inventory turnover is to divide the average inventory level into the annual cost of sales. For example, an average inventory of $3 million divided into an annual cost of sales of $21 million means that inventory turned over seven times. Syn: inventory turns, inventory velocity/turnover measures, turnover.

COST OF SALES

The total cost attached (allocated) to units of finished product delivered to customers during this period.

COST OF GOODS SOLD

An accounting classification useful for determining the amount of direct materials, direct labor, and allocated overhead associated with the products sold during a given time period.

Source: APICS Dictionary

THE BENEFITS OF ERP

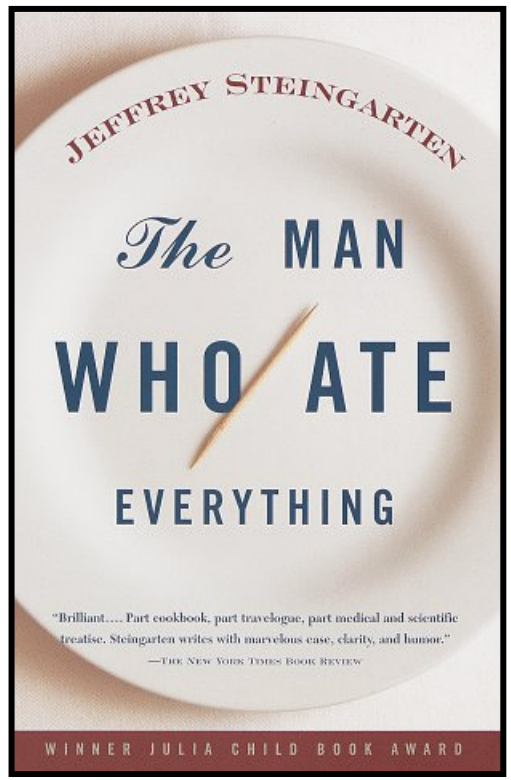
ON-TIME SCHEDULE PERFORMANCE

A measure (percentage) of meeting the customer's originally negotiated delivery request date. Performance can be expressed as a percentage based on the numbers of orders, line items, or dollar value shipped on time.

Source: APICS Dictionary

REGULATORY COMPLIANCE: CATALYST FOR MANUFACTURING COST REDUCTION AND INCREASED SALES

TIME FOR A SHORT BREAK, BUT FIRST A SHORT VIDEO FOR THOSE WITH A SENSE OF HUMOR



REGULATORY COMPLIANCE: CATALYST FOR MANUFACTURING COST REDUCTION AND INCREASED SALES

DISCUSSION OUTLINE:

√ Bio-toxin attack simulation

√ Top ten - (10) critical issues: Food Engineering

√ Buzz word bingo

√ Bioterrorism Act, record keeping

- HACCP
- ISO 9001 – 2000/ISO2200

REGULATORY BUZZWORD BINGO: HACCP

HAZARD ANALYSIS AND CRITICAL CONTROL POINT

ANALYZE

IDENTIFY

PREVENTIVE MEASURES

PROCEDURES TO MONITOR

CORRECTIVE ACTIONS

VERIFY

DOCUMENT

U.S. Food and Drug Administration

The Food and Drug Administration has adopted a food safety program developed nearly 30 years ago for astronauts and is applying it to seafood and juice. The agency intends to eventually use it for much of the U.S. food supply.

One of the most important challenges is the increasing number of new food pathogens.

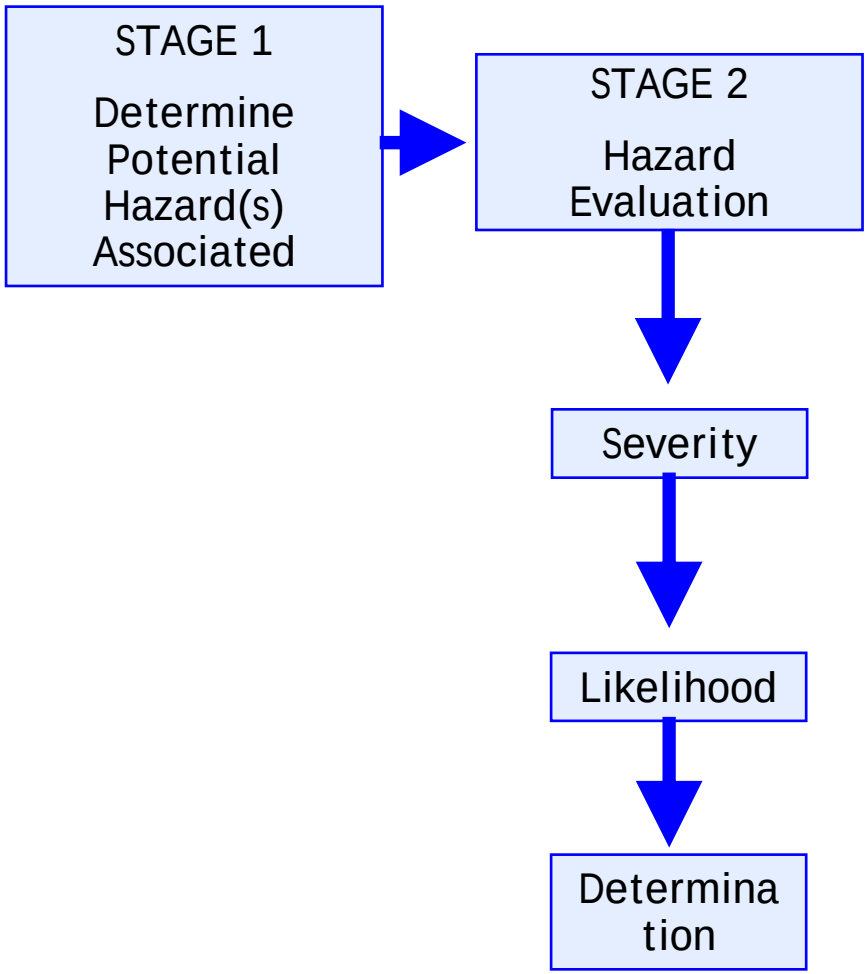
Advantages:

- Focuses on identifying and preventing hazards
- Is based on sound science
- Permits more efficient and effective government oversight
- Places responsibility on the producer
- Helps food companies compete more effectively in the world market
- Reduces barriers to international trade.

HACCP BENEFITS

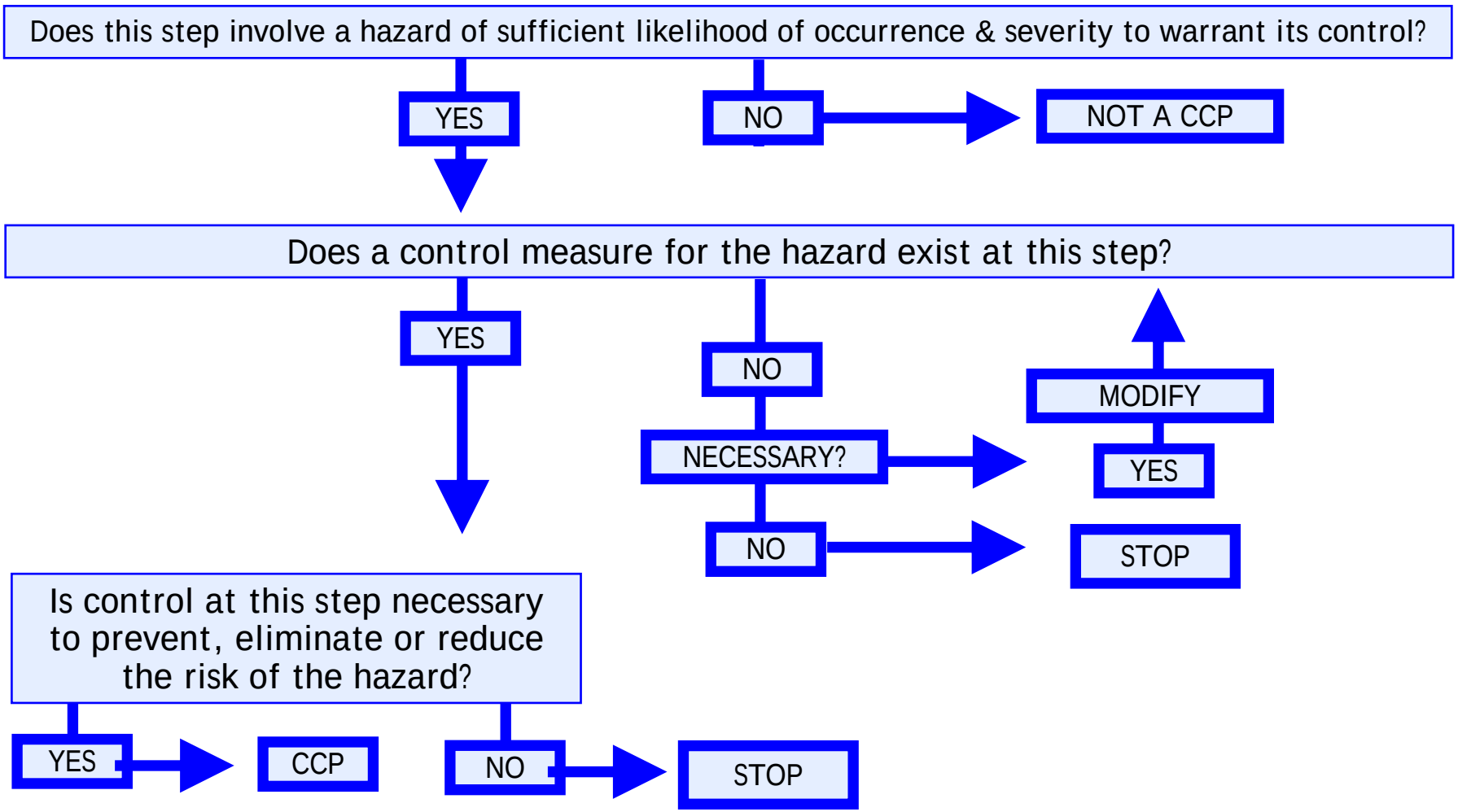
- **Protects your brand and consumers**
- **Brings production into Federal compliance**
- **Compete more effectively in world marketplace**
- **Eliminate the probability of product recalls**
- **Realized renewed operational efficiency**

USDA APPENDIX D: ASSESSING HAZARD STAGES



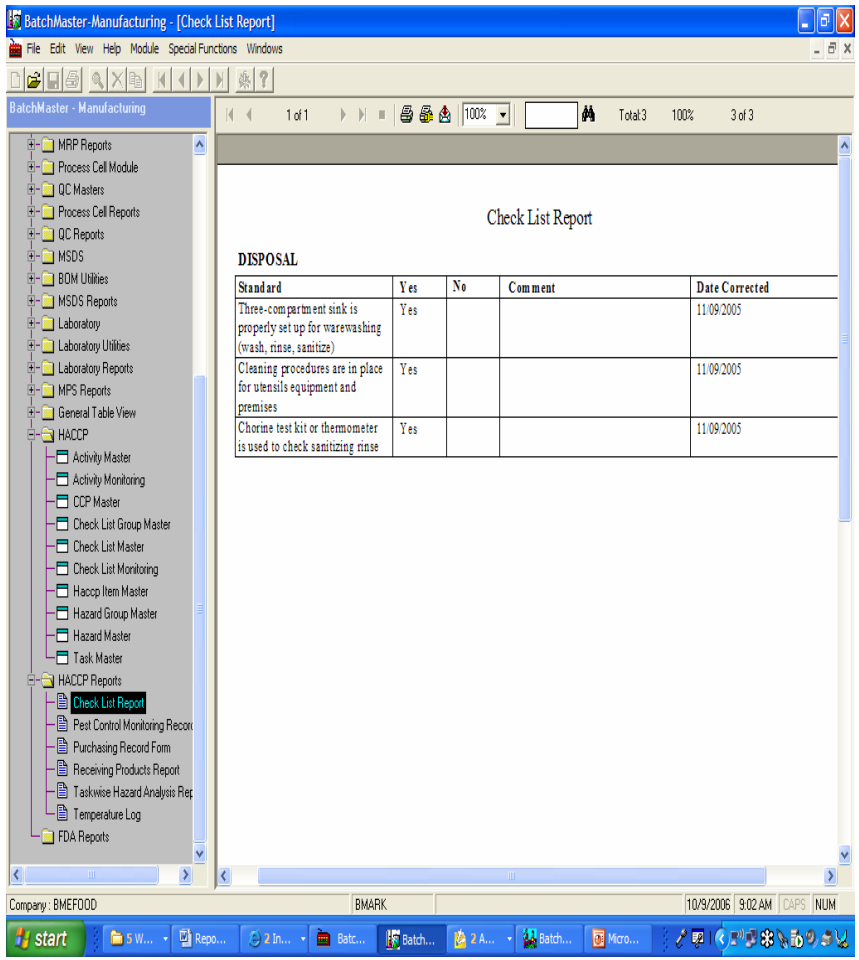
- **Ingredients**
- **Intrinsic factors**
- **Processing procedures**
- **Food content / composition**
- **Facilities / equipment**
- **Packaging**
- **Sanitation / employee hygiene**
- **Storage**
- **Intended consumer / use**

ASSESSING THE RISK



WHAT CAN COMPUTER BASED SYSTEMS DO TO SUPPORT HACCP?

- **Map & monitor critical control points**
- **Create hazard groups**
- **Electronically sign transactions**
- **Manage pest control**
- **Generate mandated reports**



LEVERAGING HACCP INTO OPERATIONAL IMPROVEMENTS

HACCP - CONCEPTUALLY SIMILAR BUT WITH A DIFFERENT PURPOSE TO:

- **SOX (financial)**
- **ABC (priority)**
- **TOC (bottlenecks)**
- Value Stream Mapping
  - Waste

MIRROR IMAGE

BUZZ WORD BINGO: VALUE-STREAM MAPPING

Simple .. No equipment needed

See and understand

Flow

Activity + information

Eliminate waste

Value Stream Mapping - Value stream mapping is a paper and pencil tool that helps you to see and understand the flow of material and information as a product or service makes its way through the value stream.

Value stream map (AKA end-to-end system map) takes into account not only the activity of the product, but the management and information systems that support the basic process. This is especially helpful when working to reduce cycle time, because you gain insight into the decision making flow in addition to the process flow. It is actually a Lean tool.

Source: iSixSigma

ELIMINATE WASTE
DEFINITION OF NON - VALUE ADDED

Non-Value Added

Any activity that does not add market form or function or is not necessary. These activities should be eliminated, simplified, reduced or integrated.

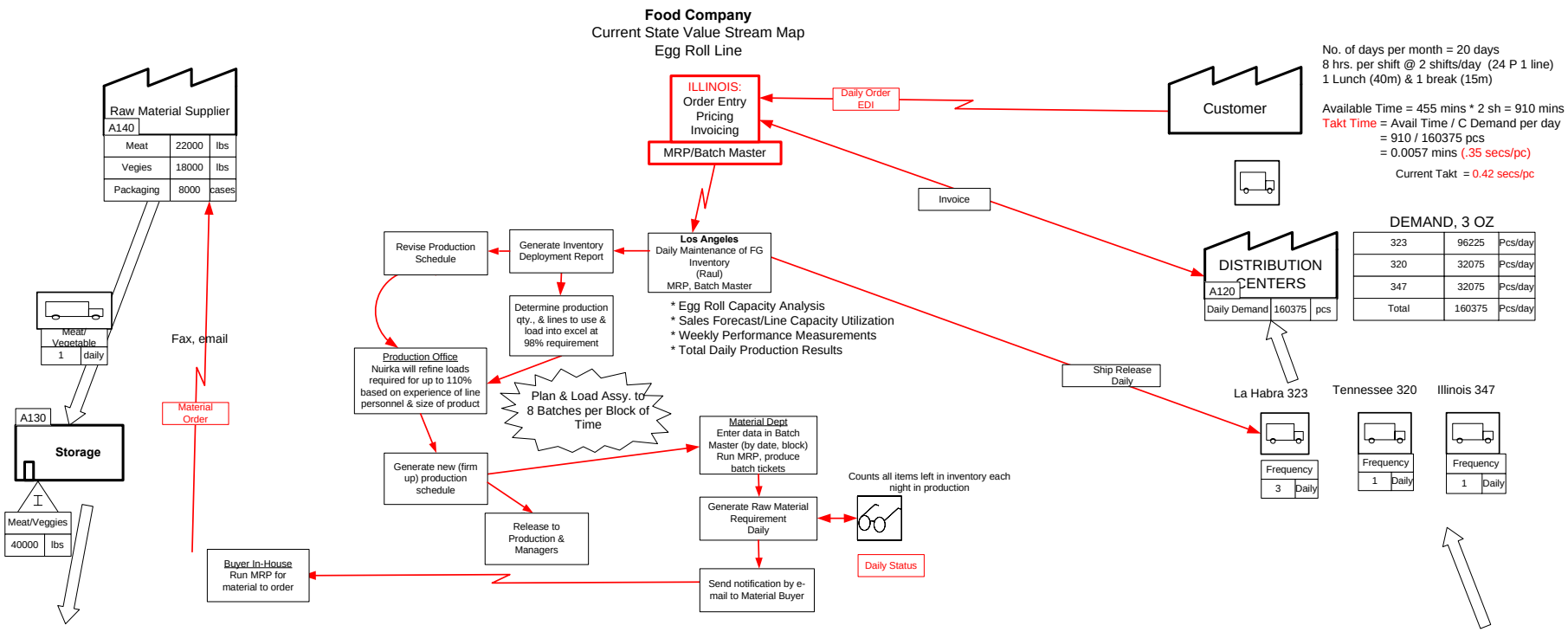
Value Added

Any activity that increases the market form or function of the product or service. These are things the customer is willing to pay for.

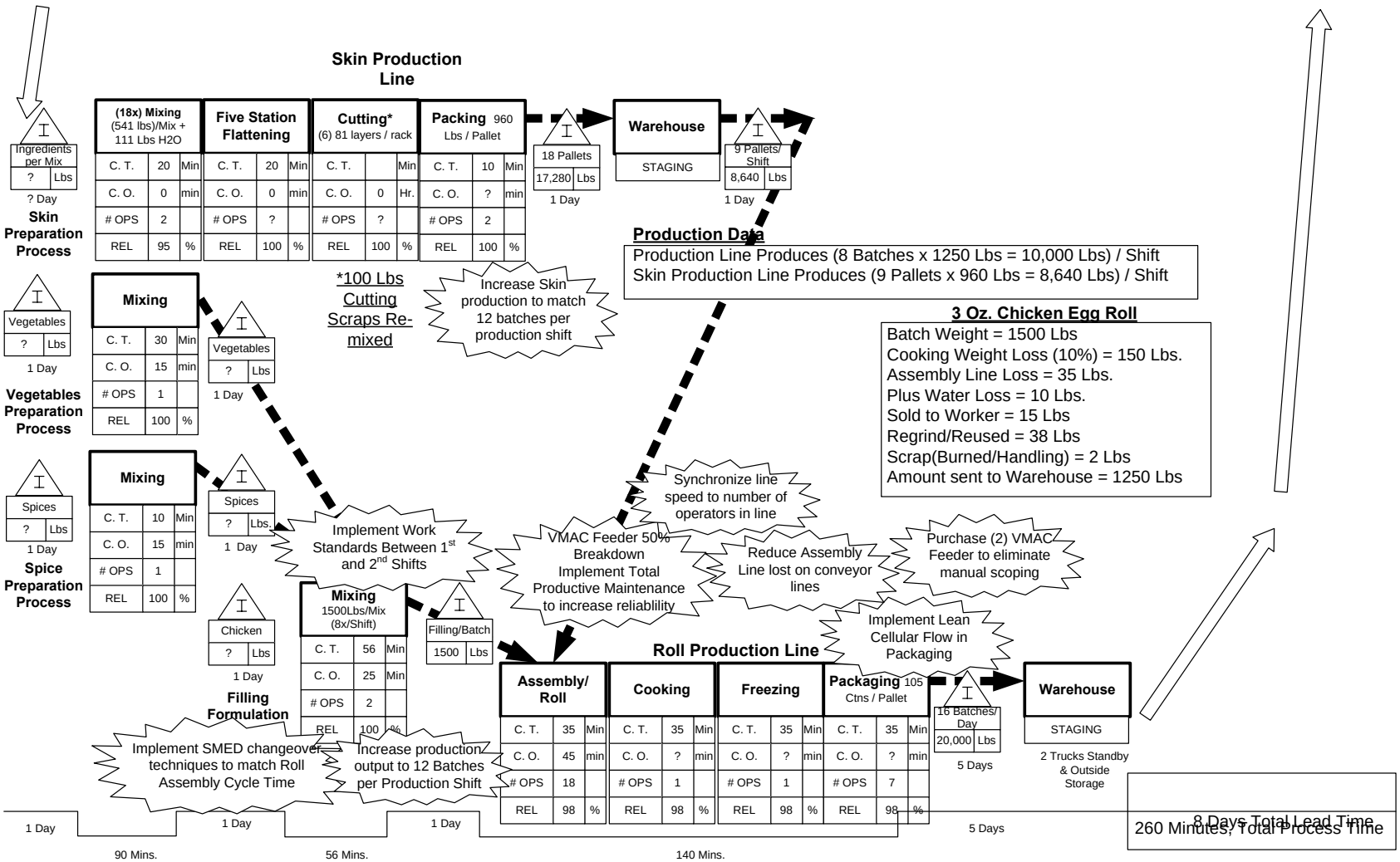
VALUE STREAM MAPPING BENEFITS

- **Helps you visualize more than the single-process level**
- **Links the material & information flows**
- **Provides a common language**
- **Provides a blueprint for implementation**
- **More useful than quantitative tools**
- **Ties together lean concepts & techniques**

VALUE STREAM MAPPING



VALUE STREAM MAPPING



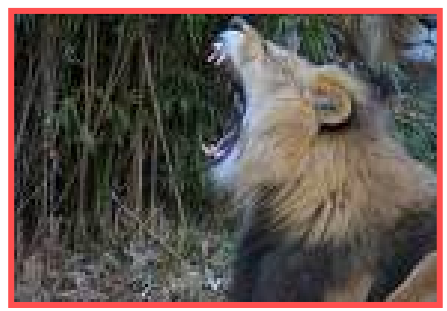
AFTER VALUE STREAM MAPPING – WHAT NEXT?

CONTINUOUS IMPROVEMENT

CONTINUOUS IMPROVEMENT IS MARKET DRIVEN!

Every morning in Africa, a Gazelle wakes up. It knows it must run faster than the fastest lion or it will be killed.

Every morning a lion wakes up. It knows it must outrun the slowest gazelle or it will starve to death.



It doesn't matter whether you are a lion or a gazelle - when the sun comes up, you had better be running!!

EIGHT WASTES OF CONTINUOUS IMPROVEMENT

overproduction

motion

Inventory

Waiting

Transportation

defects

Underutilized People

Extra Processing

CONTINUOUS IMPROVEMENT = ELIMINATING WASTE

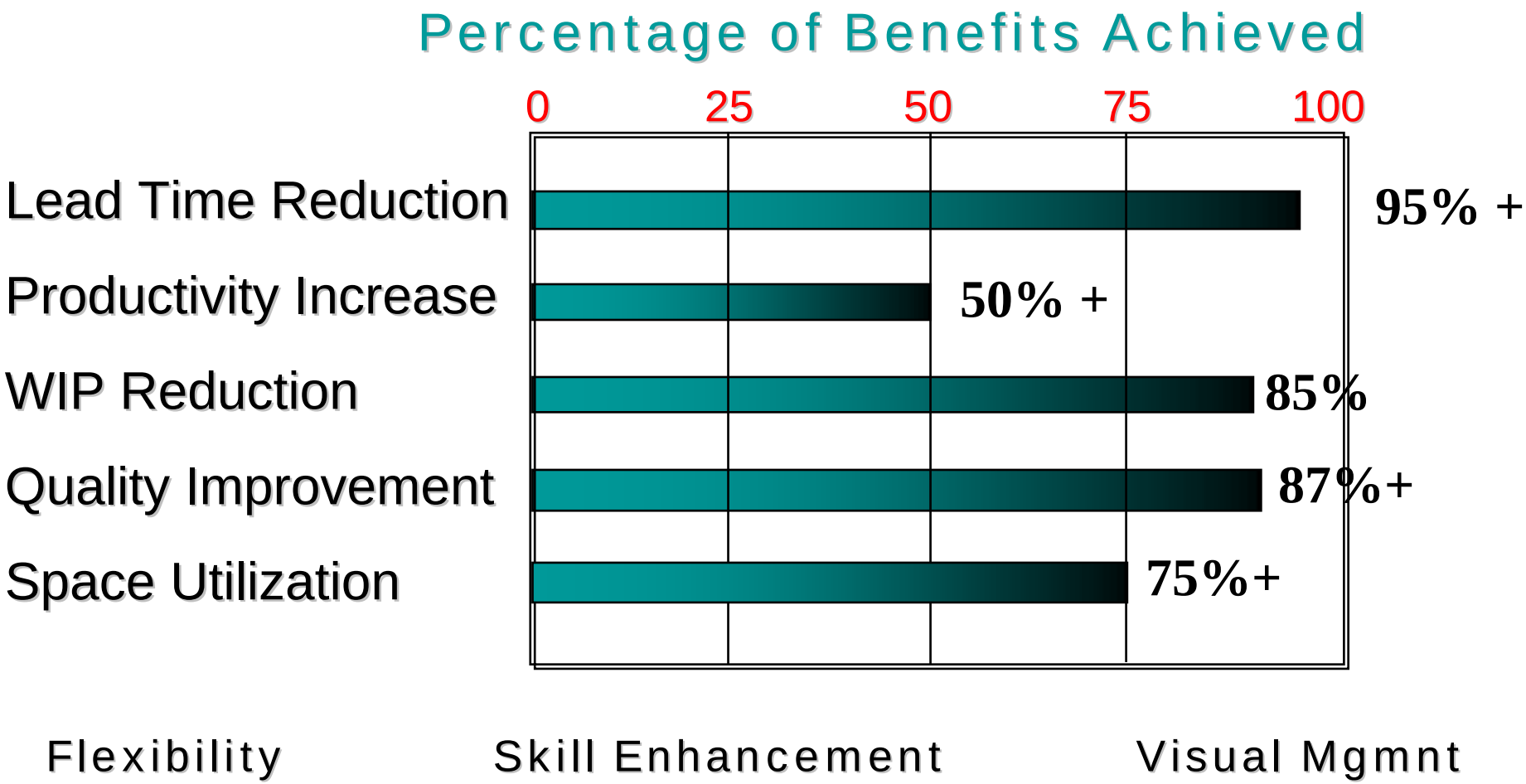
Typically 95% of <u>Total Lead Time</u> is Non-Value Added!!!

RUN TIME	Order Processing, Transport, Storage, Waiting, Rework, Machine Setup, Inspection, Machine Breakdowns, etc...

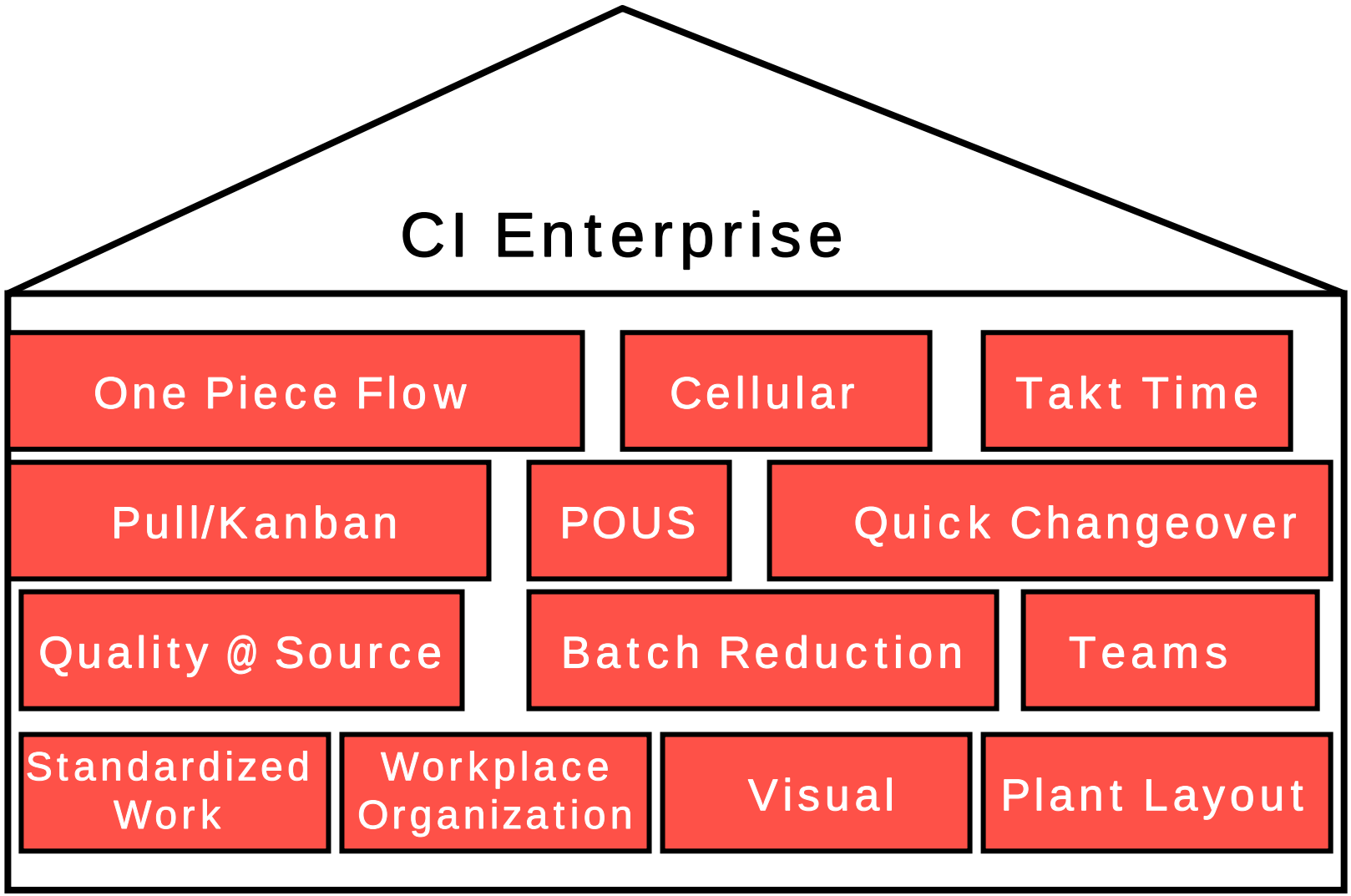
Total Lead Time

←→

BENEFITS OF CI – PERFORM BETTER!

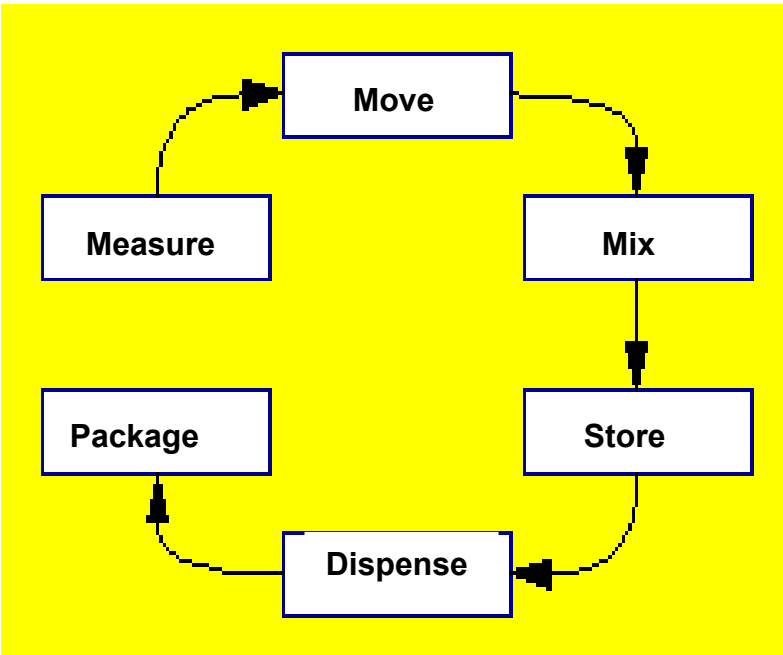


CONTINUOUS IMPROVEMENT BUILDING BLOCKS

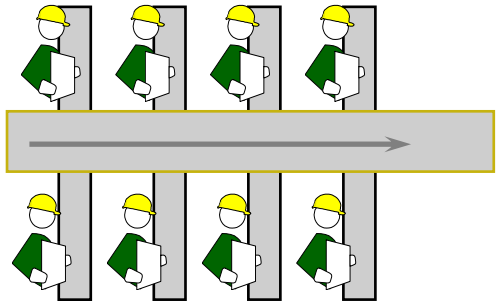


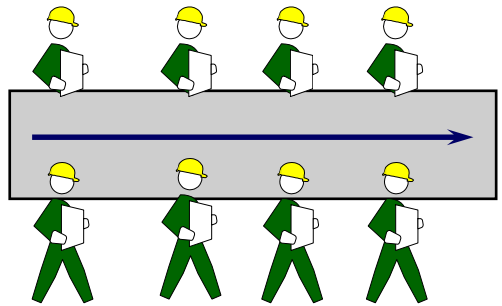
CELLULAR MANUFACTURING

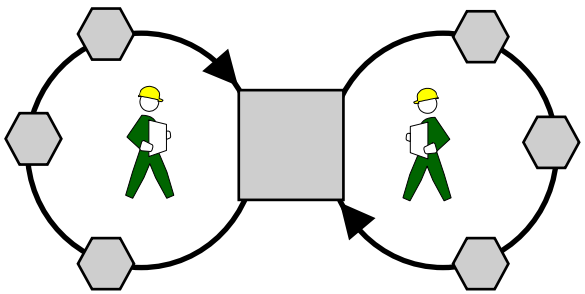
- Linking of manual and machine operations into the most efficient combination to maximize value-added content while minimizing waste

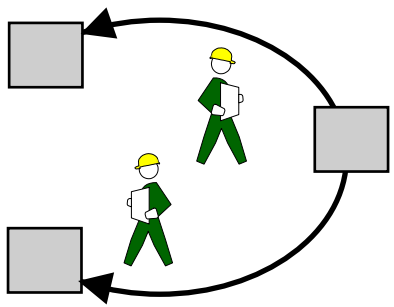


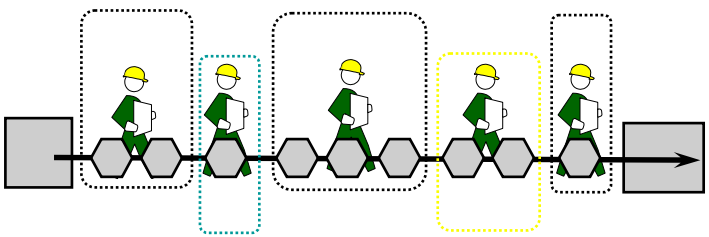
FLEXIBLE LAYOUTS FOR VARIABLE WORK CYCLES

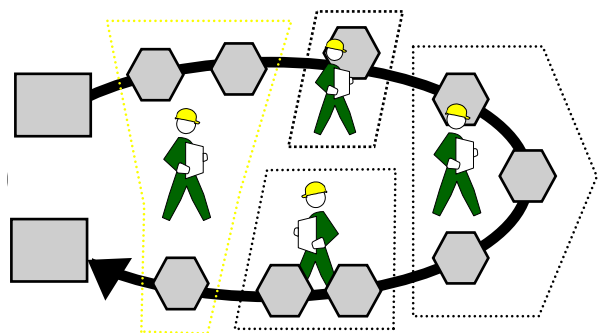










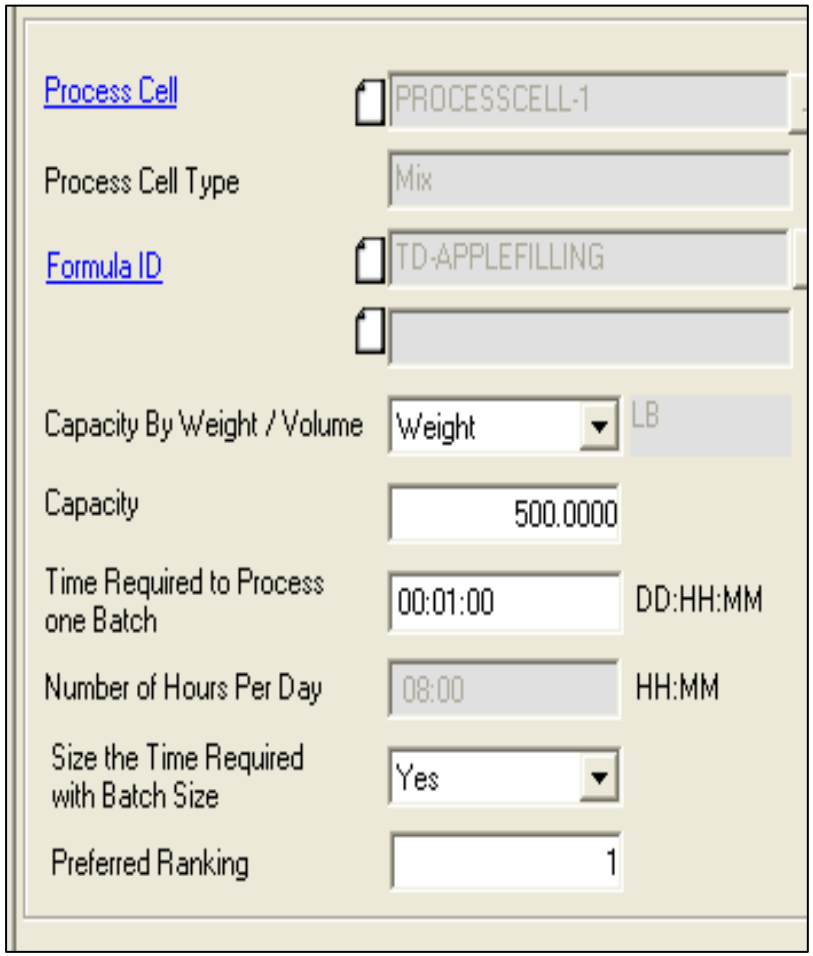


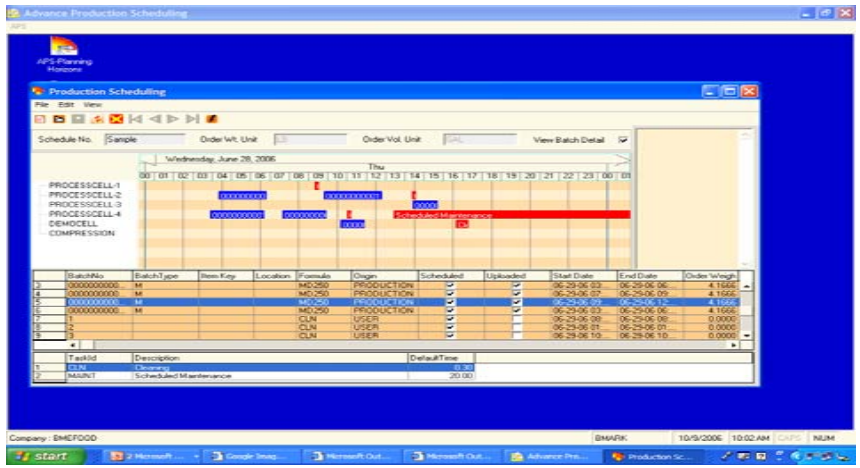
Optimal

MAPPING PROCESS TO PLANT

- Define scope of cells
- Evaluate labor & up-time
- Determine Capacity
- Map to systems
- Leverage in MRP & Advanced Planning
- Apply domain expertise

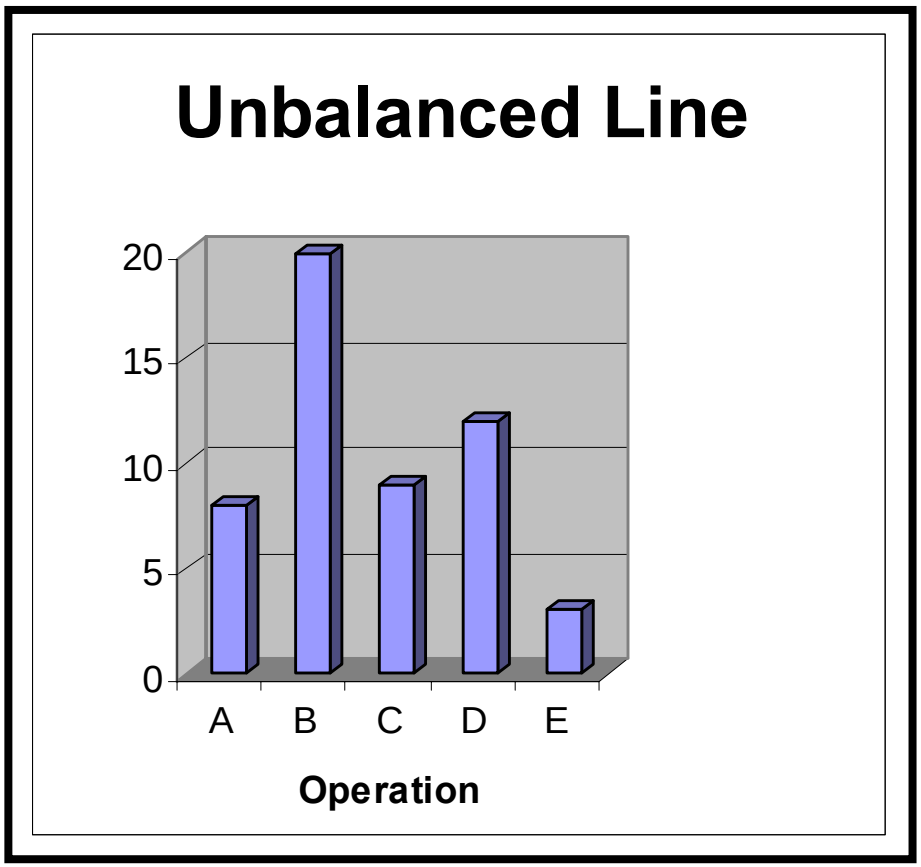
MODELING CELLS IN SYSTEMS

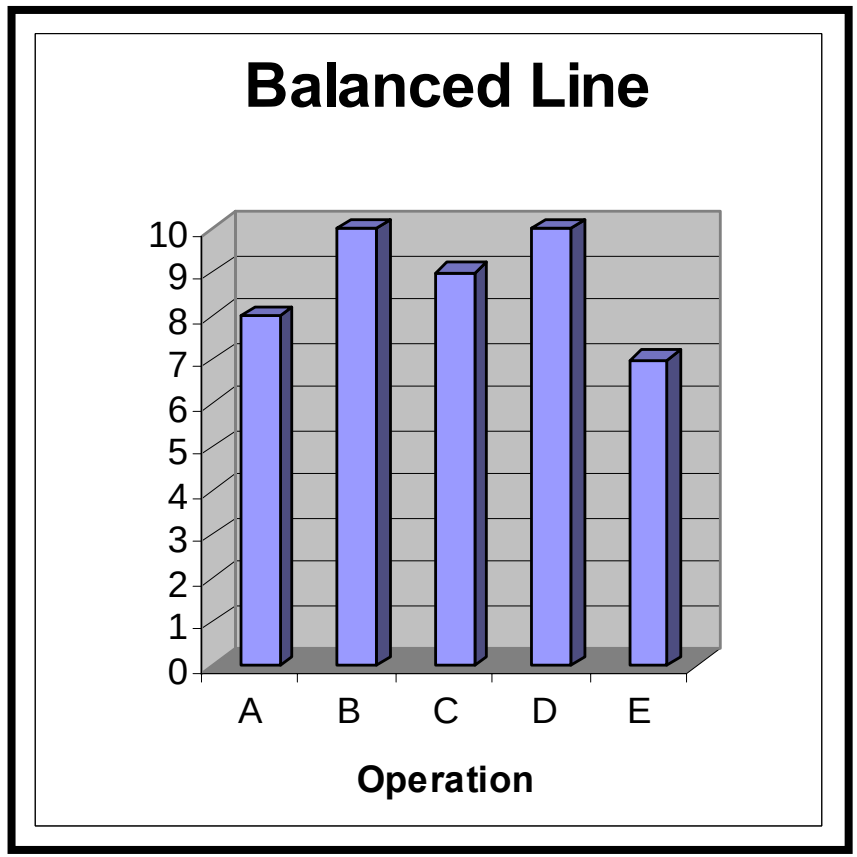




- Systems can equate multiple conditions in availability
- Planning becomes dynamic

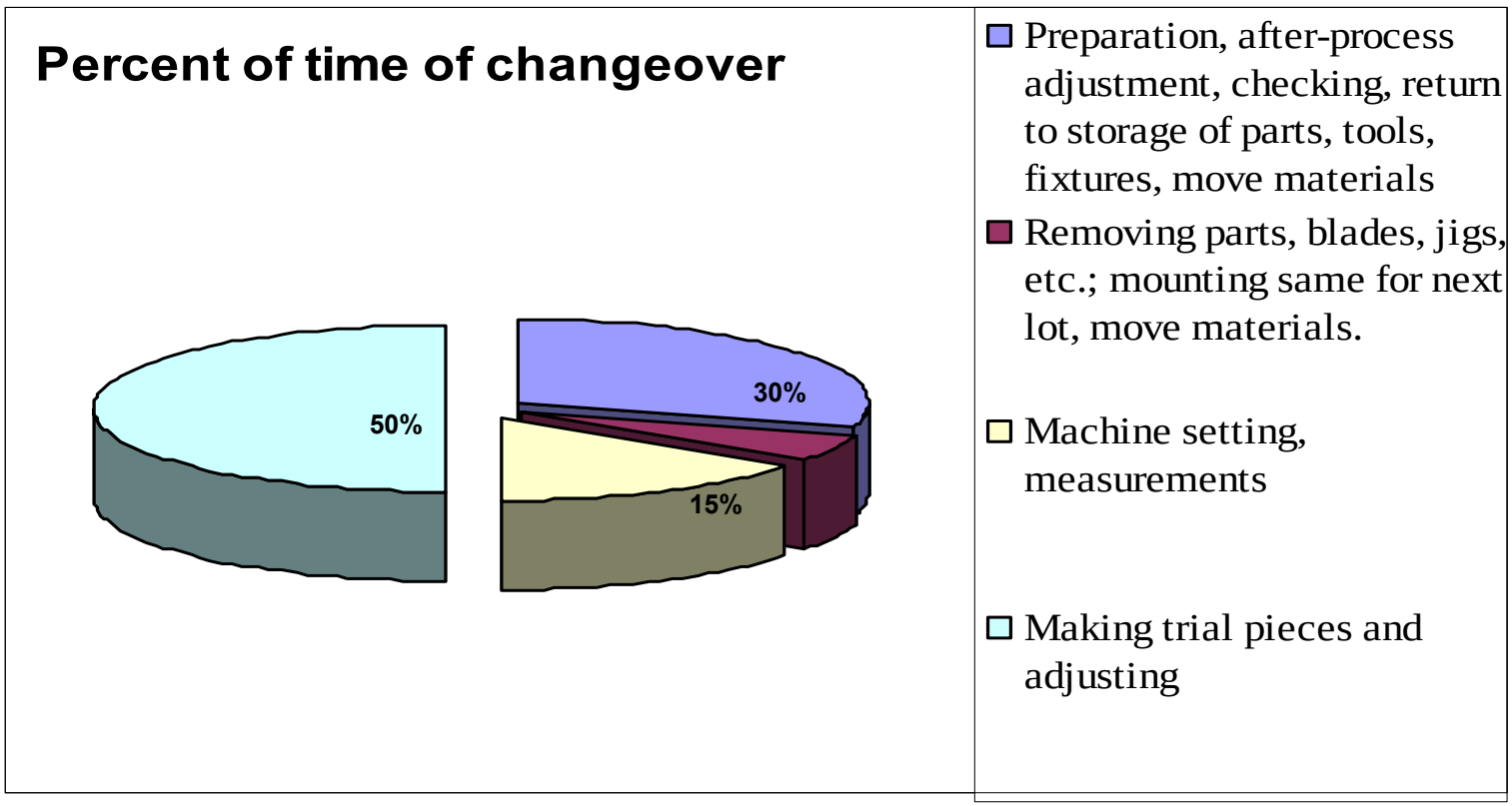
COMBINE WORK TO BALANCE PROCESS





QUICK CHANGEOVER

- Definition: Changing over a process to produce a different product in the most efficient manner.



REGULATORY COMPLIANCE: CATALYST FOR MANUFACTURING COST REDUCTION AND INCREASED SALES

DISCUSSION OUTLINE:

- √ **Bio-toxin attack simulation**
- √ **Top ten - (10) critical issues: Food Engineering**
- √ **Buzz word bingo**
- √ **Bioterrorism Act, record keeping**
- √ **HACCP**