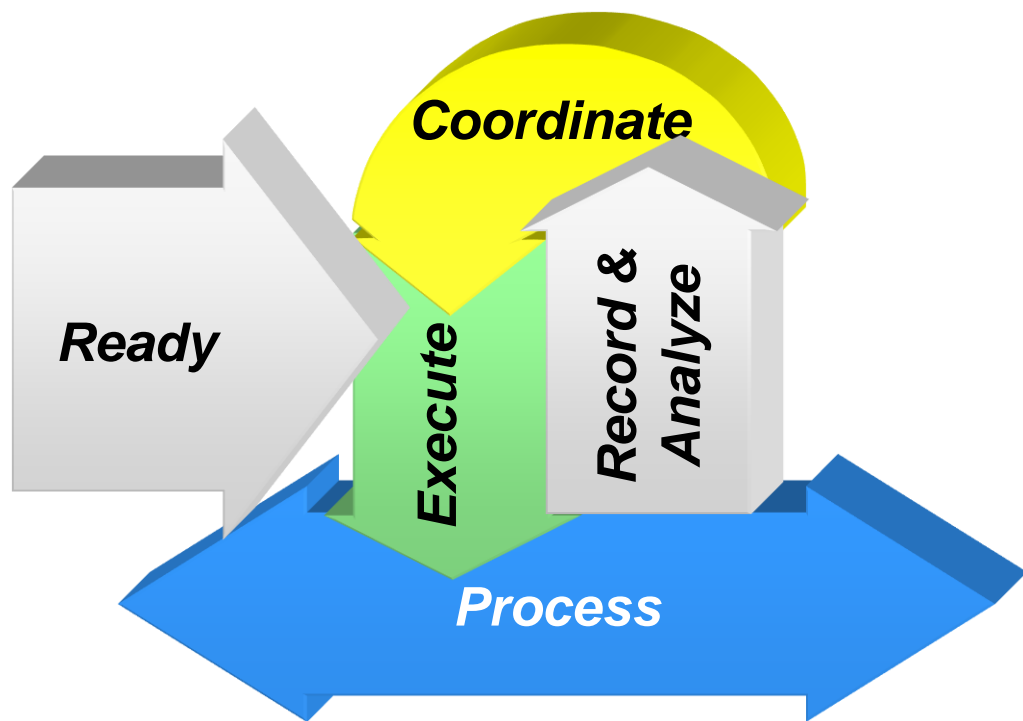


# *Machine automation / a User view on Standardization / OMAC & Make2Pack*

## ***What are our drivers and needs?***



## **DAu konference**

**OMAC Make2Pac**

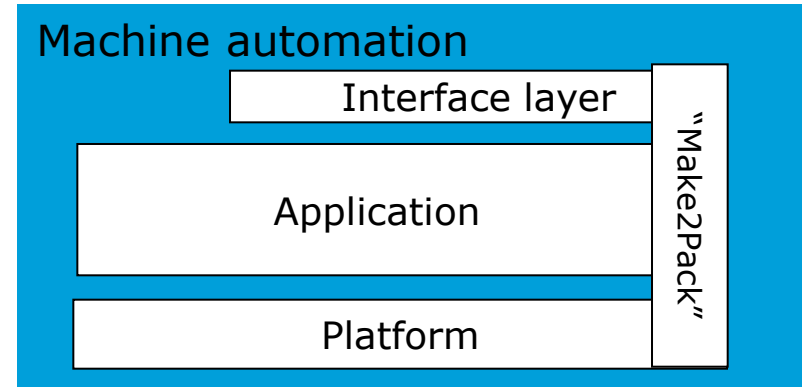
**2010 11 09**

**Ernst Madsen**

**Product Supply IT**

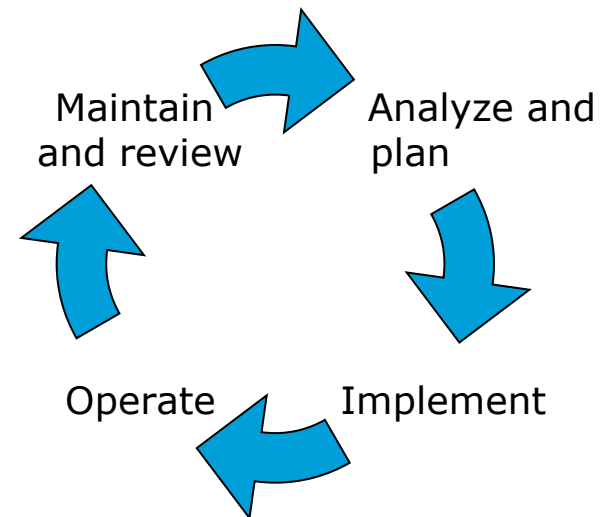
# Machine automation at Novo Nordisk

- Many applications
- From standard equipment/low cost e.g. simple packaging
- To very customized/high cost e.g. assembly lines
- Different architectures
- PLC (many vendors, many types)
- User interface (none, HMI, SCADA)
- MES/EBR integration (customized if any)
- Performance monitoring (none, simple, light, full OEE)
- Infrastructure integration



# Requirements

- Allow high automation levels with a minimum of cost and risk
- Not first movers but fast followers
- Fast to market
- Life cycle requirements:
  - Operational
  - Maintenance and support
  - Analyze and implement



# Operational requirements

- Ease of use
  - Standardization for operators
- Efficient workflows and quality reporting (MES/EBR)
  - Recipes and order information
  - QC sampling
  - Alarms and warnings
  - Reporting / electronic batch record
  - Material control (quality and advanced transport control)
- Performance monitoring (OEE)
- Infrastructure
  - Security
  - Users
  - Time
  - Narrow close down windows

# Maintenance requirements

- Disaster recovery
- Configuration management
- (Backup)



# Analyze and implement

Novo Nordisk need:

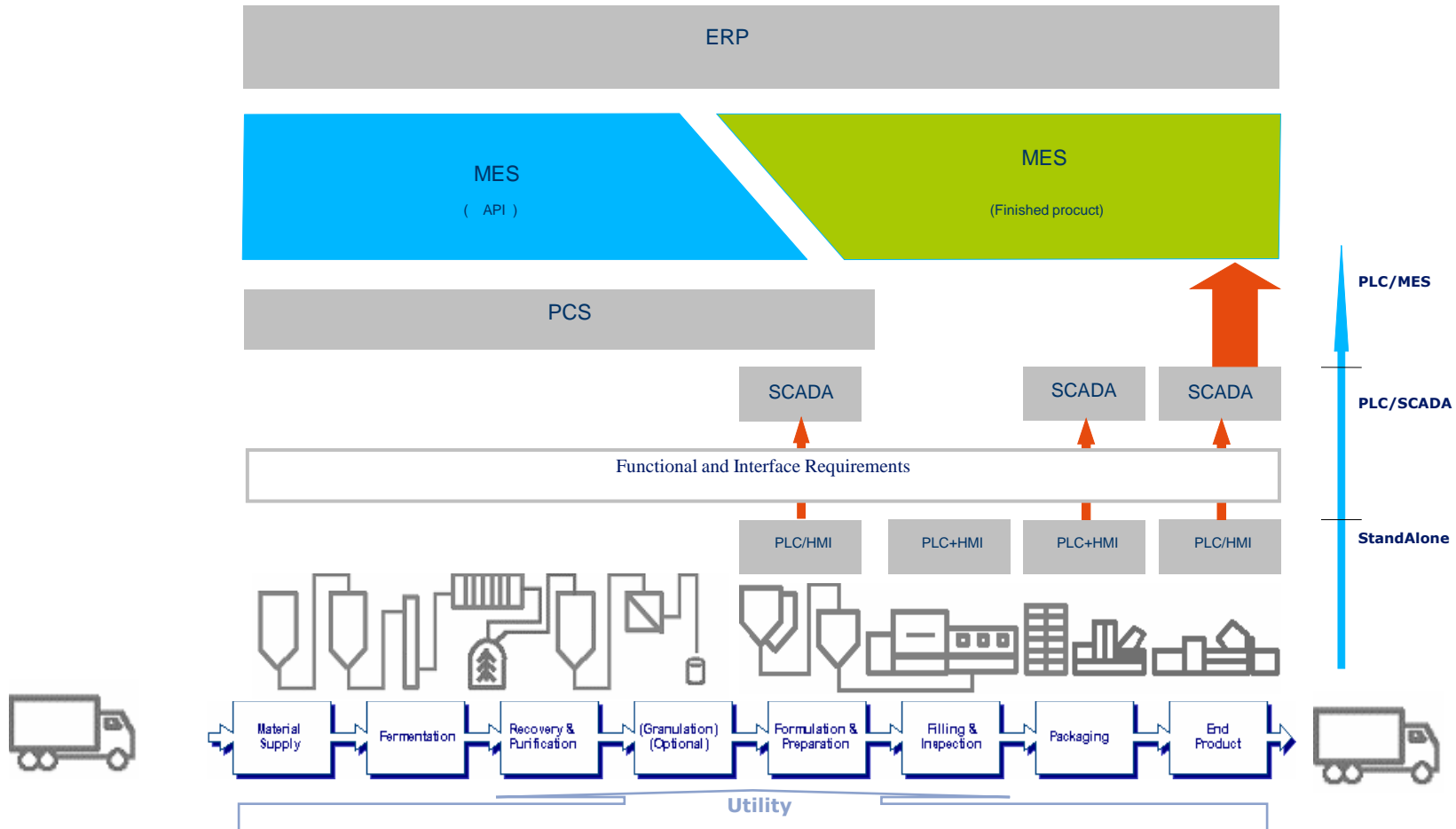
- Terminology
  - Ability to communicate complex projects
- Standard building blocks
  - Things should not be reinvented
- Standard interfaces
  - Solutions should be plug-and-play

# Standardization

Novo Nordisk need and support industry groups:

- We don't want to start from scratch every time
- We don't want to reinvent the wheel

# Processes and Systems





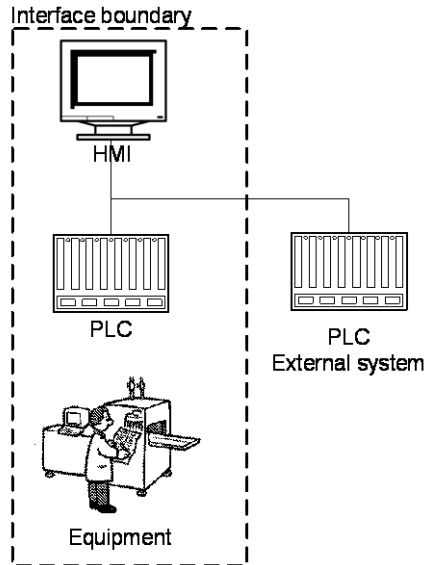
# Types of unit Processes

The types of equipment that this report focuses on are:

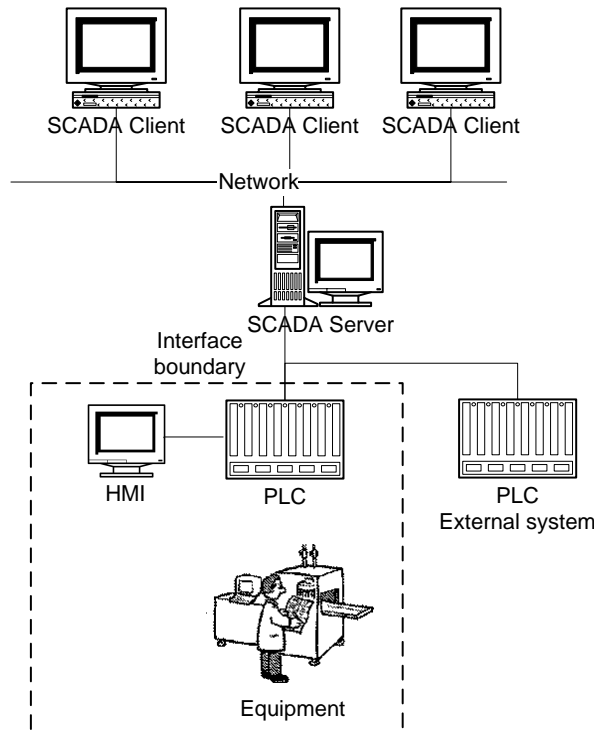
- Washers
- Sterilizers
- Autoclaves
- Filling lines
- Inspection machines
- Freeze driers
- Packaging lines
- Assembly lines
- Utility, WFI-distribution
- Formulation
- Weighing
- Granulators
- Facility Monitoring Systems
- Building Management Systems
- Black utilities and other auxiliary systems

# Infrastructures in finished Products

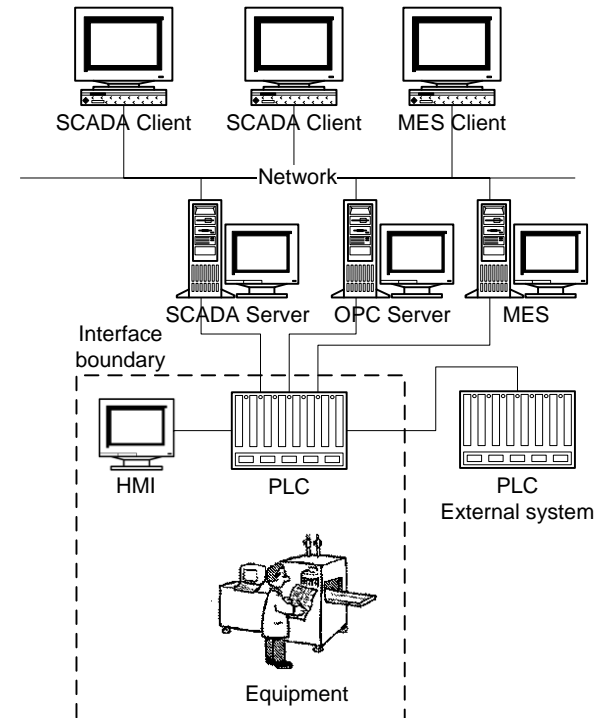
**PLC Stand alone system**



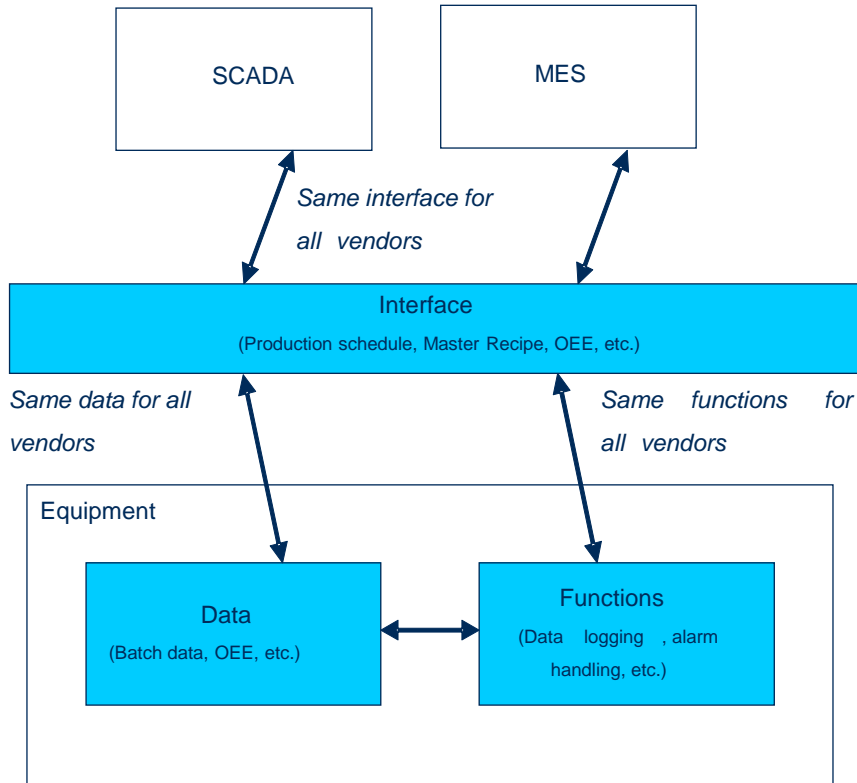
**PLC with interface to a SCADA**



**PLC with interface to a MES**

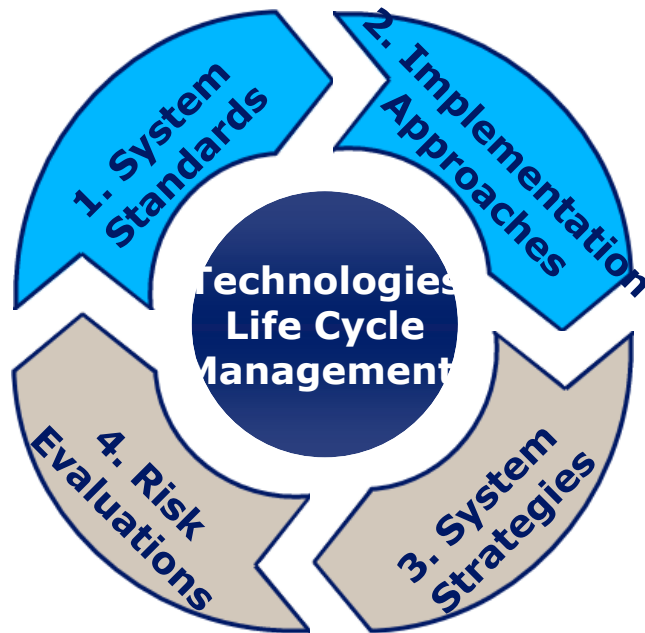


# Strategy & standard goals



- Change of paradigm
  - Equipment suppliers can choose its preferred PLC platform
  - Equipment suppliers must fulfil functional and interface requirements
  - A global and agile support and maintenance organization must exist

# Approach to standards



## The Technology Standard covers:

Description of relevant system configurations

Relevant functionalities and interfaces

Maintenance and support

Generic functional and interface requirements

In future development of Unit Process specific interface requirements

# Recommendations

## •Functional

- Development of unit process specific (“PLC”) requirements
- Make requirements suitable for central library storage to impose direct harmonization and reuse (testable)
- Gradual implementation of the Make2Pack standard as it matures and vendors start to comply with the standard

## •Competences

- Development of support and maintenance organization supporting multiple PLC platforms
- Enable knowledge sharing across sites and countries
- Develop procedures for support and maintenance
- Enable remote service capability for use by equipment suppliers and supporters

# Functions (Generic)

- Scan materials at the destinations
  - Download recipe to equipment
  - Categorization of recipe parameters
  - Download batch information
  - Equipment control Batch execution
- Log / Verify materials that have been received
- Transfer of process parameters to equipment
- Recipe parameters must be split in Production / Machine recipes and individually version controlled
- Transfer of batch information to equipment
- Send execution commands on the unit level (must comply with S88). Also includes receiving of status changes

# Functions cont.

- Equipment control Batch execution S88 OMAC  
Phase/operation/sequence control
- Equipment control - S88 OMAC  
em/cm module operation mode  
(AUTO, MANUAL...)
- Equipment control - S88 OMAC  
em/cm module control commands  
(OPEN, CLOSE...)
- Equipment control - S88 OMAC  
Module control - Control Values
- Time synchronization Synchronize the system time  
on equipment
- Line clearance, before production Include in batch report

# Functions cont.

- Operator assignment log (Electronic records) Log which operators was working on the machine
- Critical alarm log (Electronic records) List of critical equipment alarms
- Non-Critical alarm log (Electronic records) List of non-critical equipment alarms
- Log book (Electronic records) List of events occurring during a batch e.g. parameter change, etc.
- Process data (ER) Data that must be logged in order to approve a batch
- Manage IPC Sampling Take and record in-process samples as specified
- Line clearance, after prod. Include signatures for line clearance in batch report
- Reconciliation report Log number of produced goods in categories e.g. Good, Rejects, Manually removed, etc.



# Functions cont.

- Prepare batch report  
Generate production batch report (containing data specified above or by user)
- Evaluate equipment  
(Manual OEE data logging) Log manual OEE data to OEE database (stop causes). **Compliant with MAKE2PACK and OMAC standards.**
- Evaluate equipment  
(Automatic OEE data logging) Log automatic OEE data to OEE database (from e.g. critical alarms). **Compliant with MAKE2PACK and OMAC standards.**
- Data analysis  
(OEE data) Analyze OEE data and optimize production
- Data analysis  
(KPI data) Analyze KPI data and optimize production

# Functions cont.

- Prepare OEE/KPI data report
- Issue preventive maintenance job
- Change management
- Disaster recovery
- Documentation standards
- Programming standards
- Data communication interface

Generate OEE data report (containing data specified above or by user)

Send notification when preventive maintenance is required. Scheduling or operation counters

A well defined baseline of critical items must be supplied

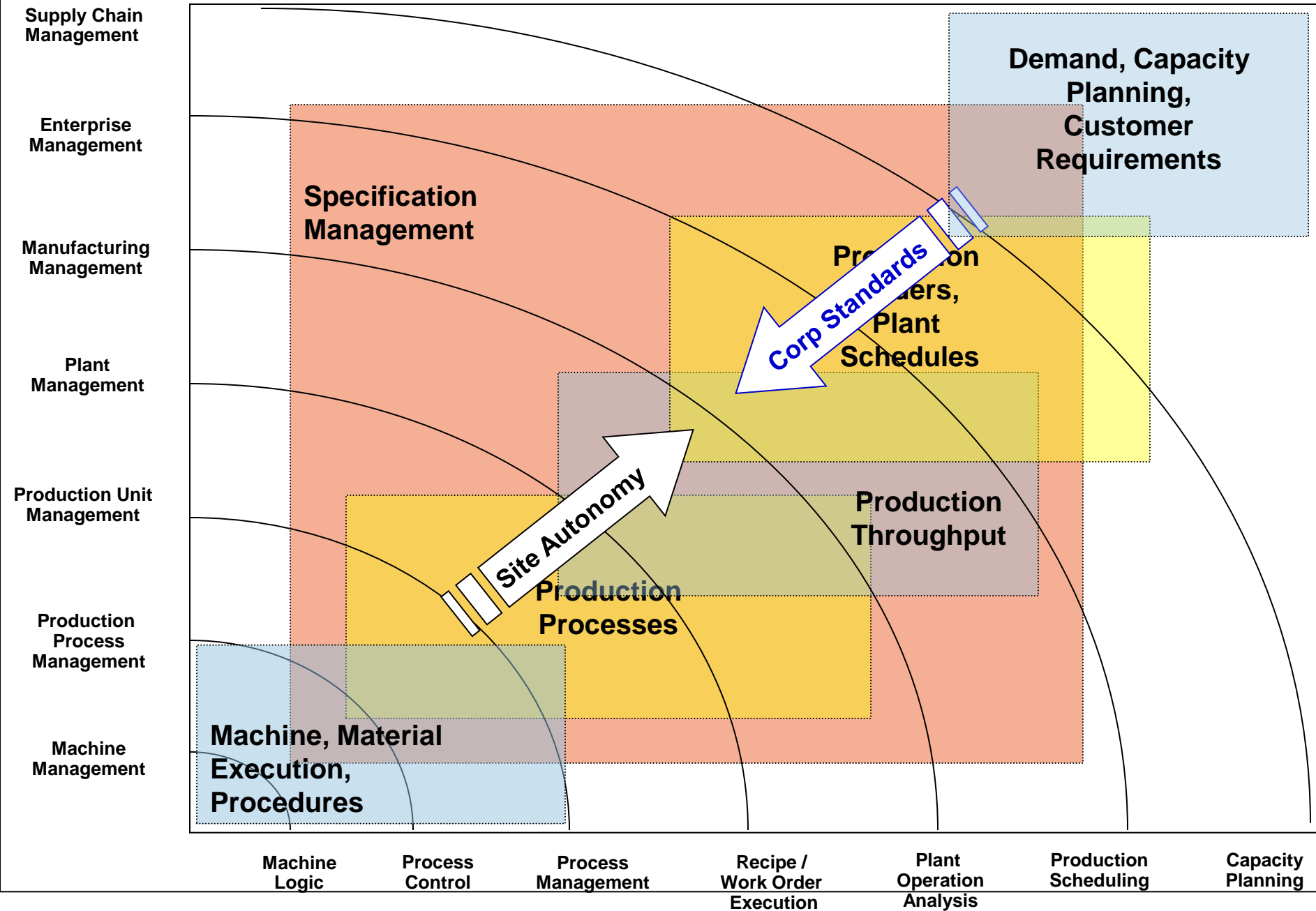
A disaster recovery plan and installation media must be supplied (incl. definition of critical data)

The documentation supplied must fulfill e.g. standards for engineering

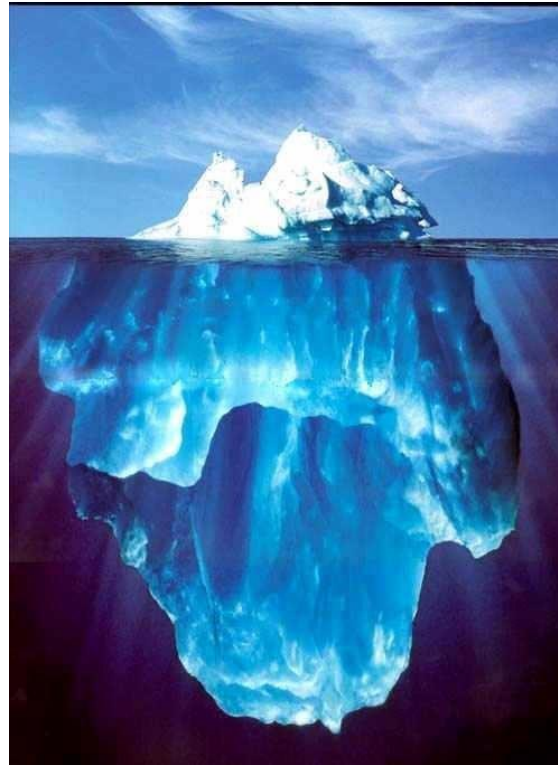
All programming must fulfill listed standards

Communication protocol used by PLC to communicate with external systems

# Agreeing on Point of Sameness – The balance central versus local



# Questions - ?



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Functions, Data, Interfaces  
& Dataflow is production  
EndUser Domain – Input to std.  
Organisations

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Machine standards  
as OMAC & Make2Pac  
is supplier and integrator  
Domains (and of partial EndUser  
maintenance interest)

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