ENGINEERING PHARMACEUTICAL INNOVATION

Process Automation Challenges

Managing complexity in requirements definition, architecture, and implementation.

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Overview

- History of Automation
- What does a control system do?
- What do Automation people do?
- Automation architectures – hardware and software components
- Defining and communicating Requirements
- Lessons Learned
- Acknowledgements

A History of Automation
(with some personal perspective)

Non-Computerized Examples:

Albacore (launched 1953 with 3000psi hydraulic controls)

1955 Buick

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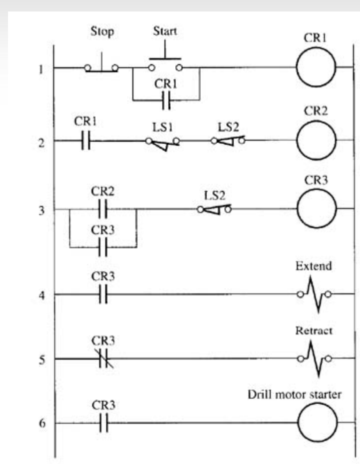
Relays and Pneumatics to Computers

Relay and pneumatic logic to control drilling operation



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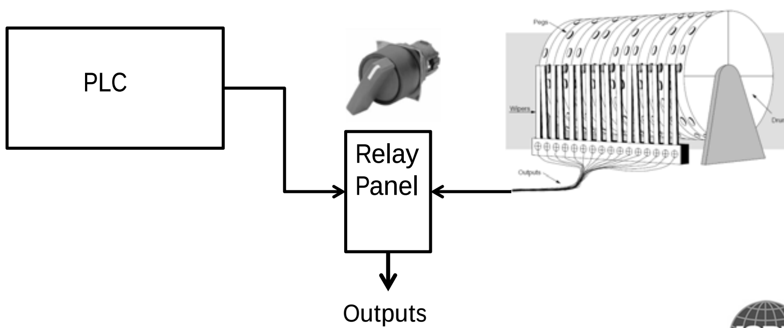
Drum Controller and Early PLC

Ice Cream batching system with Drum Controller kept as backup for first Early PLC. First Modicon PLC was 1968 (in Andover, MA).



Early Computerized Control Systems

HP 1000 (1974 – 2000)

A basic system cost just $3927.* And gives you features like 4K MOS RAM memory, memory parity, 128 instruction set, user microprogammability, floating point, ROM bootstrap loaders, and a unique front panel.

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Early Computerized Control Systems

HP 1000 (1974 – 2000)

Tritium inventory system (1978)

Distributed Control (1980) for load cell testing

- Multiple test stations from one HP1000 Processor
- IEEE-488 Communications
- Inter-process communications with assembly language access to common memory used for Communication and Device Drivers (modular implementation)

Jet engine data collection system

Light bulb manufacturing

Core Functional Requirements for Control Systems

A control system manipulates valves, motors, linear actuators, lights, etc. to achieve continuous control of temperature, level, pressure, etc., and to execute sequences. Simple, but …

- Need Sensors with DIs and AIs for control
- User Interface (push buttons, pots, lights and meters or a processor based panel)
- Alarm Annunciation

With reliability, repeatability, and a way to program.

Core Functional Requirements for Control Systems (continued)

Additional requirements for modern systems:
- Security
- Process data and alarm logging
- Operator action logging
- Auto / Manual Capabilities
- Interlocks – and the ability to see interlock status

Very nice to have:
- Centralized data logging to support PAT, batch reporting, etc.
- Integrated automation including at least status information for each unit
- Batch tracking through the facility
- Recipes for multiple products
- Modularity necessary to support straight forward validation of changes
- Environmental monitoring

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What does Automation do?

Automation does:
- Whatever is needed by Process Engineering and Manufacturing
- Follows procedures established by Validation and Quality

Automation also develops a control system infrastructure including:
- Standards for automation hardware and software
  - Using known good products
  - Consistent user interfaces
  - Improved maintainability
- Libraries of documented and tested reusable modules
- Building, Site – or Multi-site systems including IT infrastructure
  - Automation Networks
  - Utility Systems
  - Historians

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What's on the Menu?

Decisions made with Automation … (why Automation is hard)

- Which automation platform?
  - Reputation, quality of product, quality of service, availability of expertise
  - Company and personal experience, maturity of product, market share
  - Price, sales effectiveness
- Islands of Automation vs. integrated system
  - Islands are easier to buy, can require consistent hardware
  - Can specify integration requirements of islands
- Field Busses vs. hard wired (or sometimes both)
  - DeviceNet VFDs, Profibus Skid Interfaces, Modbus devices, Foundation Fieldbus and Hart I/O
- Number of Processors and Distributed I/O Communications
- Software Architecture - From Control Modules to Batch to Manufacturing Execution Systems

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Software Considerations

General Principles:

- Divide and conquer – so that each code module is only as complex as necessary
- Write once and reuse
- Never lose sight of the goal of achieving "simplicity on the other side of complexity". Systems have to "just work".
- Use industry standards to support development and implementation including S88, S95, GAMP, etc.

S88 defines a structure for recipe management and batch processing

- A way of thinking that provides a foundation for building systems
- The ANSI/ISA-88 set of specifications and follow up documents
- S88 separates what the equipment can do from product recipes

S95 defines a way to model an enterprise and system interfaces

- Having the same names for departments, products, etc. across the enterprise is a foundation for building interfaces

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Control Modules

A Control Module type is created for each type of device in a system.

- Discrete valve with limit switches
- Single Speed Motor with feedback
- VFD with speed setpoint, On/Off control and feedback
- General Analog input (sensors)
- Flow Meter (with totalization)
- Etc.

Analog Input CM Functionality

- Scaling – conversion of signal to engineering units
- Analog alarming with alarms and warnings, alarm timers, deadbands, severities and alarm areas, acknowledgments, etc.
- Simulation – ability to set to an entered value
- Calibration Mode – inhibiting alarms
- Specified criteria and behavior for bad input

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Control Modules (continued)

Motor CM Functionality

- Auto / Manual capability
- Mismatch Alarms with mismatch timers
- Inhibit timers to prevent rapid restarts
- Interlock list with the status of each item
- Run timers and start counts
- Option for current feedback and alarms

Control Modules have to be rock solid – everything else in a system is built on top of the CMs.

- Each CM has an associated HMI faceplate
- A CM can be a library type that is instantiated for each device, or a function block, or subroutine that is called for each device.
- Objective is to build as much functionality and flexibility as possible into CMs – while keeping them efficient. It is ok to a point – to create similar or special case CMs.

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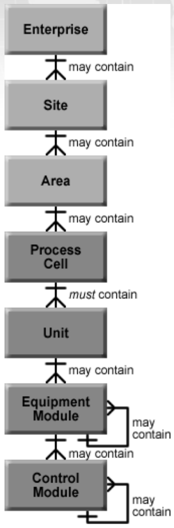
S88 Equipment Model



The Enterprise, Site, and Area are part of the model.

A Process Cell is a logical grouping of equipment needed to product batches.

A Unit is often a tank or a skid. There's flexibility in determining what exactly a unit is.

An Equipment module is a group of control modules that work together to perform a specific function, for example:

- Temperature Control
- Material Addition
- Transfer Out and Recirculation

Equipment modules can have just one CM – or can include for example several pumps and a large number of valves.

S88 Recipes

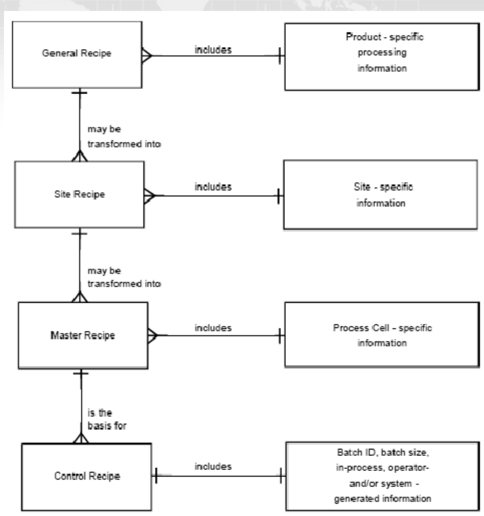


Figure 8 — Recipe types

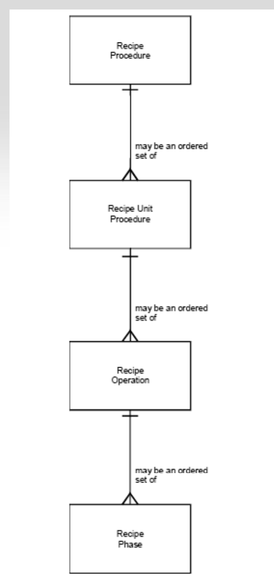


Figure 10 — Master recipe procedure

S88 Recipe – Operation Example

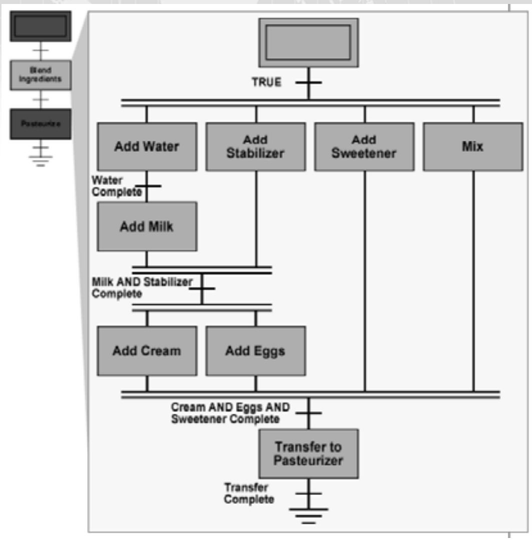


Figure from www.batchcontrol.com

- This is a "Blend Ingredients" Operation.
- Each step is a Phase.
- Manufacturing or Process Engineering can take ownership of Recipes (while Automation is responsible for providing the platform for execution).
- Example: Shampoo system – where the customer modified operations to significantly reduce cycle times

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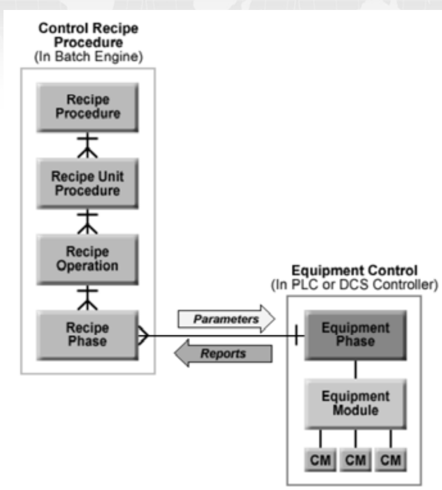
S88 Batch Execution



Typical Practice:

- Recipes executed in Batch Engine
- Phases executed in PLC or DCS controller

Note: some vendors moving batch engine to controller.

- Parameters are passed to phase
- Report parameters passed back to batch engine
- All parameters logged by batch engine

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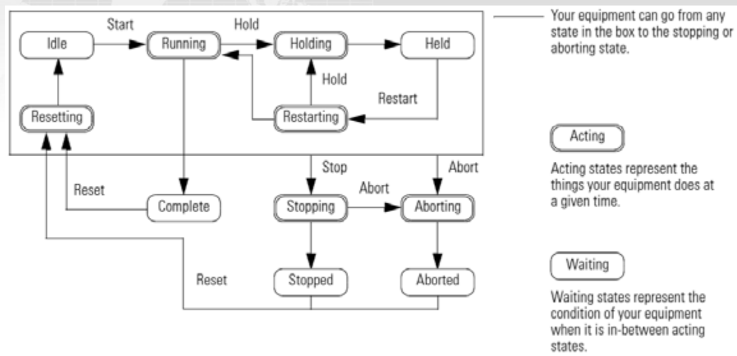
S88 Batch Execution – Phase Manager



- Software in the controller is written for each of the “Acting” states.
- Batch software provides an environment for building recipes and the equipment structure as well as the batch execution environment.
- Some controllers support the use of a phase manager without “Batch”.

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GAMP 4 Requirements

GAMP 4 Requirements Documentation includes:
- User Requirements Specification (URS)
- Functional Specification (FS)
- Hardware Design Specification (HDS)
- Software Design Specification (SDS)
- Software Module Design Specifications (SMDS)

GAMP 4 Challenges
- More rigid than GAMP 5 (example procedures vs. guidance, and regulated company vs. supplier roles)
- Duplication from URS to FS to SDS
- Completion of an SDS before starting development
- Where do Firmware specifications go?

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GAMP 5 Requirements

From GAMP 5: “The extent and detail of requirement specification should be commensurate with associated risk, complexity, and novelty of the system.”

GAMP 5 Requirements Documentation includes URS and FS plus additional Design and Configuration documents as needed – depending on regulated company standards and the nature and complexity of each system.

Opportunity:

- More detailed, living document FS – detailed enough for validation
- Software module specifications used for multiple systems
- Separate documents for IT and Control System infrastructure (consider system boundaries)
- Possible combined Design and Configuration Specification, including using audit trail controlled electronic files for Configuration

Reference: http://www.ispe.org/jett for sample documents including bioreactor URS, and a documentation package for a filling system.

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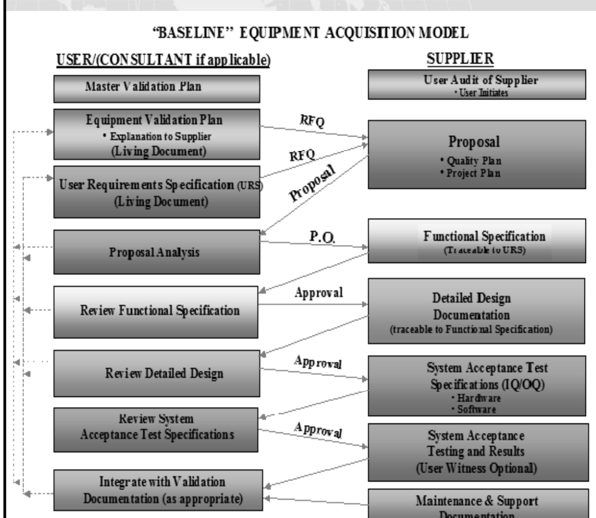
Need for Collaboration



Communication and collaboration is often underemphasized.

Milestones and Timelines from ISPE JETT Wide Range Liquid Filler URS Example

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Clear Specifications?

Consider the following sequence …

1. Add 10 gallons of sugar at a preset flow rate
2. Heat to 57 degrees for one hour
3. Request manual popcorn addition
4. Mix for 5 minutes
5. Cool to 40 degrees
6. Enjoy

Clear Specifications are a Challenge

Considering the following:

1. Add 10 gallons of sugar at a preset flow rate
2. Heat to 57 degrees for one hour
3. Request manual popcorn addition
4. Mix for 5 minutes
5. Cool to 40 degrees
6. Enjoy

What temperature should the vessel be at when adding sugar?

(how is the 10 gallons measured?, how is the flow rate set?, how is the flow controlled?)

Is the vessel heated to 57 degrees and then held at temperature for an hour – or does the heating time count as part of the hour?

What if the vessel never gets to 57 degrees? How long should system wait for popcorn addition? How do we know manual addition is complete?

Enjoy? With all those calories and grams of sugar per serving?

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Specifications and Learning Styles

Specification development is a collaboration.

- Automation needs to understand the process and the detailed process engineering requirements
- Process engineering needs to understand the feedback from automation

People have different learning styles:

- Visual learners work best from lists and written directions
  - Getting it down on paper helps remove ambiguity
  - Gives people something to refer to and time to respond
- Auditory folks work best when they hear instructions and can discuss how a system works
  - Taking the time to talk about the assumptions, intentions, and details really pays off
- Kinaesthetic learners do best with practical hands-on experience
  - If there's a prototype plant, definitely take the time to visit
  - Actually stepping through the process on a screen is huge. Consider creating the HMI screens early if there's a way to set up a simulation. Consider using Visio.
  - Lots of changes are made at FAT. Better at FAT than after the first engineering run.

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New "Opportunities"

The good old days:

- Push Buttons, dials and gauges, and alarm annunciation
- Closed systems – one set of manuals
- Logging data electronically was innovative
- KVMs – accessing multiple servers from one keyboard and monitor
- Stand alone networking

Today's environment:

- Transition from firewalled network to VPNs (2 types of VPNs)
- Active Directory security
- Redundant Controllers – with variable levels of redundancy
- Many different types of equipment interfaces – Profibus, Modbus, etc.
- Configurable I/O subsystems, solenoid valve packages, etc.
- Use of virtualization in production with vSphere
- Multiple redundant Batch, HMI, Database, Historian, and Terminal Servers
- HMI thin clients with ACP ThinManager (redundant)
- MES / ERP interfaces
- Web based and wireless interfaces
- Multiple Reporting options and piggyback applications (PAT, CMMS, etc.)

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Lessons Learned

Build or Buy a strong automation background

- Experience is huge
  - Field Devices and types of equipment
  - Automation project management
  - IT (Servers, Networks, etc.)

- Need for a code base – good development is iterative
  - Control Modules
  - “Experienced” architectures and phases
  - Ask – what are we starting with? Where is it currently being used?
  - If it’s not a code base that you have direct experience – don’t assume that all expected requirements are met

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Lessons Learned (continued)

- Involve Automation as early as possible. Agree on formats for requirements, collaborate on overall architecture, evaluate vendors, etc.
- Get up-to-date stable versions of applications – not the latest and greatest
- Make sure that when an automation platform has the required capabilities that all equipment, software AND engineering required is included in the platform pricing
- Vet both the vendor and the vendor’s personnel that will be committed full time – Project Managers and Technical Leads
- Check vendor references with the folks that are actually using the product
- Make sure that project success is important to your automation vendors
- Work with process engineering and your skid vendor to develop integration requirements. Adding an good interface to a standard skid works better than requiring a one-off automation solution.
- Communicate and Collaborate – partner for success
- Consider trade-offs between Time and Materials and Fixed Price

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