

Capture Your Best Automation Practices

To Generate

Pharmaceutical Automation Model

With

PFS Definition CAE Tool

1 - SCOPE

SPEC-Soft introduces a Batch process Pharmaceutical Automation Model (PAM).

The PAM goals are to fully specify and document **Best Automation Practices** of an enterprise for global deployment as automation standards in both equipment and procedures to optimize its best practices for pharmaceutical batch process automation.

The PAM model is intended to provide the users with the foundation of a corporate template for pharmaceutical batch process automation projects.

The PAM benefits include:

- Reduction of engineering costs.
- Faster development of the automation systems resulting in reduced time-to-market.
- Save validation time and cost.
- Optimize change management over the life cycle of the process.

The PAM initiative will employ PFS Definition and PFS Review CAE tools to create comprehensive generic S88-based Process Functional Specifications.

The PAM effort primary activities include:

- Prepare generic P&IDs for all typical Units and Process lines.
- Standardize nomenclature methodology.
- Define default conventions.
- Create a Physical Model for each Unit and Transfer.
- Define detailed procedural specification for Phases and Recipes.

Use of PFS Definition and PFS Review CAE tools will provide the following benefits:

- Substantial reduction in implementation time of individual project instances.
- Electronic, project-wide dissemination of automation practices and know-how.
- Effective link between process design and process automation, high levels of data integrity.
- High degree of change management for the project.
- Automatic project and validation documentation.

PAM can provide significant cost-benefits to its users:

- It is estimated that the use of generic templates (Classes) will result in future time and costs savings of 40% and higher when individual projects are “instantiated” from the PAM.
- Savings are expected to grow with every project by continuous perfection of the PAM.
- Further development of the PFS CAE tool will transform major parts of the Functional Specification into controller code and will add considerable extra time/cost savings.

SPEC-Soft is ready to accommodate customer needs with partial implementation of any aspect of this PAM Proposal. The following sections include S88 highlights and a general description of the PAM.

2 - INTRODUCTION

Often times, users request SPEC-Soft to provide insight into the value of PFS Definition software and the different aspects involved in employing S88 based methodology to transfer the Best Practices currently employed in batch process automation and create Global Project Methodology (GPM) based on enterprise-wide standards.

Critical to the success of a GPM initiative is the creation of detailed process design templates (“Classes” in S88 terminology) and the associated detailed functional specification of each Class.

Such initiative would create major benefits to its potential users:

- Optimize the labor-intensive tasks required to generate the specification requirements, typical of manually converting P&ID and other process data into specifications.
- Reduce human errors associated with manual operations.
- Create a global Change Management system and dramatically overcome the limitations typical of manual based record keeping systems.
- Optimize communication between project team disciplines
- Have the ability to conduct design reviews electronically by simulating the process automation specification document prior to committing resources to generate PLC/DCS code.

To help its customers meet the challenges in arriving to the above benefits, SPEC-Soft has created the Pharmaceutical Automation Model (PAM).

The PAM goals include:

- Applying S88 consistently and uniformly for all known process cells.
- Increase enterprise standardization level.
- Guarantee application of best practice engineering solutions.
- Reduce engineering cost for projects that will be based on PAM.
- Reduce project cycle time.
- Reduce costs impact of design changes through rapid communication of changes and evaluation of their impact on the current state of design (Total Project Cost of Ownership).

PFS software is a Computer Aided Software Engineering (CAE) tool that can support and enhance S88 object-oriented design.

The **PFS Definition** and **PFS Review** tools provide the following main features:

- Integrated link between the CAE tool and Process design (P&ID's and other design data).
- Sophisticated Class definition facility and rapid Instantiation for all procedure levels.
- Multi-Project & Multi-user capabilities.
- Flexible and extensive data representations.
- Change management.
- Automatic document generation.

3 - PHARMACEUTICAL AUTOMATION MODEL (PAM)

Pharmaceutical Automation Model is a generic detailed S88 model of a complete pharmaceutical batch manufacturing process or facility.

The proposed PAM project phases include:

3.1 Identify Best Engineering Practice for Process Units

This stage consisted of breaking down the customer design modules into (S88 based) Units, Equipment Modules and Control Modules.

3.2 Naming & Numbering Standardization

For an object-oriented project it is essential to define a naming & numbering methodology that will be understood by all future users of the CAM. Hence it has to express clearly the nature of the object; it's process context and the relation between class and instance.

3.3 Drawing Generic P&IDs

Based on the first two steps, a generic P&ID is created for each Process Unit. Units are identified by a generic name. Control Modules (i.e. valves, pumps, transmitters etc.) are identified by a generic **role** that expresses its functionality within the Unit (e.g., CIP_Valve).

3.4 Control Conventions & Definition Criteria

In order to avoid miss-interpretations and redundant definitions, a set of general control conventions and definition criteria for the complete project is outlined.

Often, this is a rigorous process involving different engineering disciplines.

Some of the conventions include general rules and answers to questions such as:

- How to define a Unit? What are the Unit boundaries?
- Default definition for Phase Restart from Hold
- How to interpret an SFC (Note: The S88 standard, IEC 1131-3 standard and the different Batch Engine software packages are not consistent on this issue);
- Exception Handling etc.

In some cases, these issues have been dealt with and clear guidelines already exist. In other cases, when the development of PAM coincides with introduction of S88 methodologies - this phase of the project is very important.

3.5 Pilot Project Definition

A pilot project is selected to challenge the conceptual definitions, classes, instantiation procedure and CAE tool compatibility with customer requirements.

The pilot project should consist of:

- Definition of Control Module Classes
- Definition of Equipment Module classes
- Definition of Unit Classes
- Definitions of Phases for EM and Unit Classes to support one typical Process
- Definition of Unit Procedures & Operations for Unit Classes
- Definition of a Cell Procedure representing a typical Process.
- Generation of Functional Specification documents in the CAE tool.

The Process Functional Specification documents are then reviewed by an independent (internal) engineering group, after which definitions and format can be accepted and improved.

3.6 Full Project Definition

An automation project can then be divided in to sub-projects in order to enable concurrent engineering. Since all projects are using the same Class definitions - design consistency is guaranteed.

4 - S88 HIGHLIGHTS

To highlight the S88 attributes of this proposal the following is discussed:

CAE Tool Benefits

- Control Module Class Definitions
- Unit Class Definitions
- Procedure Class Definitions
- Classification Challenges
- Instantiation Procedures
- Attributes of Using a CAE Tool
- Benefits of Using a CAE Tool

4.1 CAE TOOL BENEFITS

The PFS Definition CAE tool can produce significant benefits:

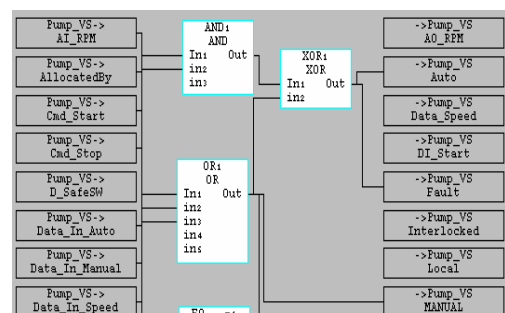
- A. The use of the PFS tool will impose a standard object-oriented (S88) methodology for the project, which can be deployed across the enterprise to future projects (note that S88 compliant methodology is not a requirement of the PFS CAE tool).
- B. Build well-defined structured Class hierarchy producing a modular design of the Project with reusable objects to facilitate future project execution.
- C. Common Class library will enable a multi-discipline team to work on multiple phases of the projects, at different sites, concurrently, while maintaining compliance with the project baseline design.
- D. Using the same tool by all project team disciplines will improve data and technology transfer, speed up the design process and prevent miss understanding and ambiguities.
- E. Batch application design processes are iterative by nature. The integrated Change Management facilities of PFS support and document frequent changes and enable the application of the required change all over the project effectively and safely.

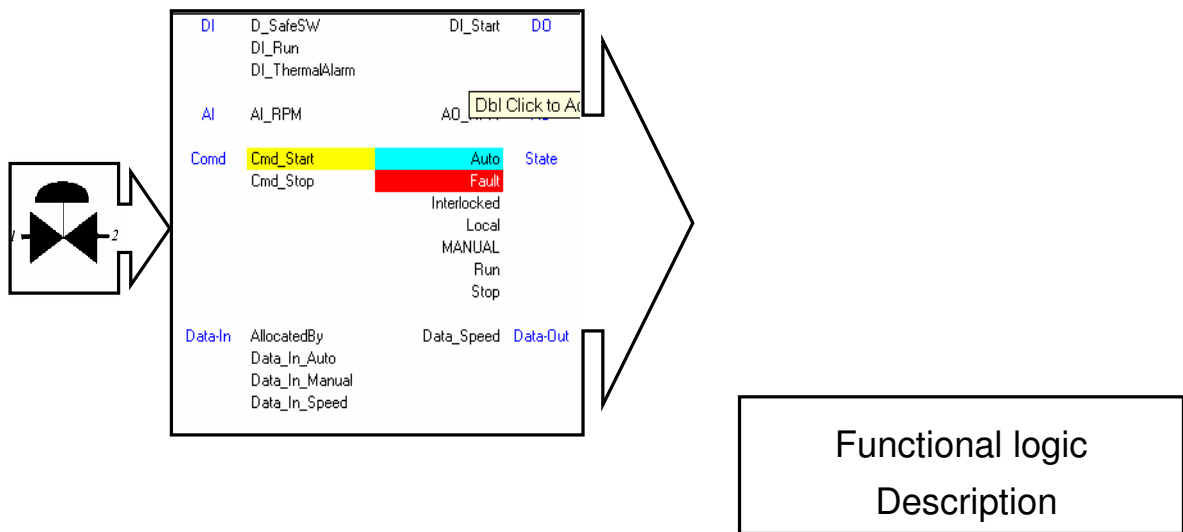
4.2 CONTROL MODULE CLASS DEFINITION

CM Classes represent generic types of Control Module such as Transmitter, Variable Speed Pump, Normally Closed two-way Valve etc. The CM Class definition consists of the CM physical I/O, Logical I/O (Commands, States and Data in/out). The Basic control logic of the CM Class may be specified in Function Block Diagrams or by attaching a textual description.

A CM Instance that is based on the Class will automatically inherit the Class Function Block structure and logical interpretation of Commands, States and I/O.

FIGURE 1 - CONTROL MODULE CLASS DEFINITION





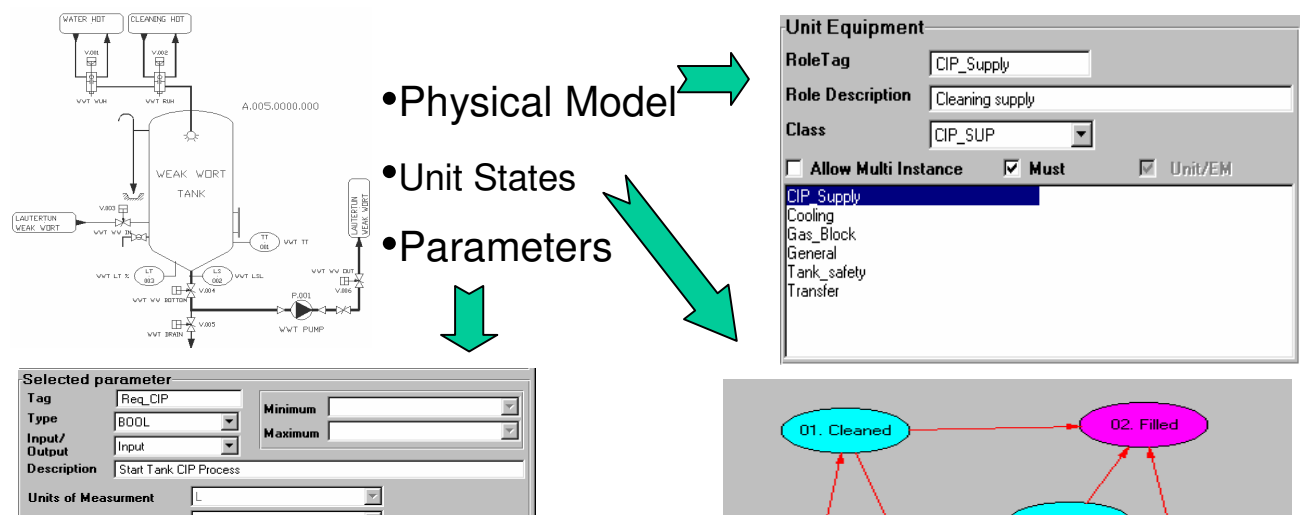
4.3 UNIT CLASSES DEFINITION

A Unit Class is a generic definition of a typical Process Unit. Unit Class definition consists of three elements:

- **Physical Model** - lists all CM Classes and EM Classes associated with the Unit Class. Each CM associated with a Unit Class is identified by the **Role** it performs within the Unit Class (i.e., Inlet Valve, Bottom Valve etc.).
- **States** - Logical Status of a unit at a given time (e.g. Clean, Empty, Heating etc.). States may be used for Logic definition (e.g., if Unit_1 is in Heating State OR CM_1234 is in Fault.....).
- **Parameters** – Variables associated with the Unit Logic (e.g., Level, Pressure, Temperature, Is Ready etc.). Unit parameters are used as Set Points for process actions or as Input/Output for other logical conditions.

A customer may choose to implement the S88 physical model to the letter, (e.g., a unit is composed of equipment modules and equipment modules are composed of control modules), or may opt for S88 style without complete adherence to the S88 rules.

FIGURE 2 - UNIT CLASS DEFINITION



4.4 PROCEDURE CLASS DEFINITION

A Procedure Class is a generic definition of a typical Process. Procedure Class may be defined for a Phase or for higher-level Procedures (Operation, Unit or Cell).

- **Phase Class**

A Phase Class is associated with a Unit Class. The generic logic is defined by referencing to the Unit Class Roles. For Phase Class the following elements may be defined:

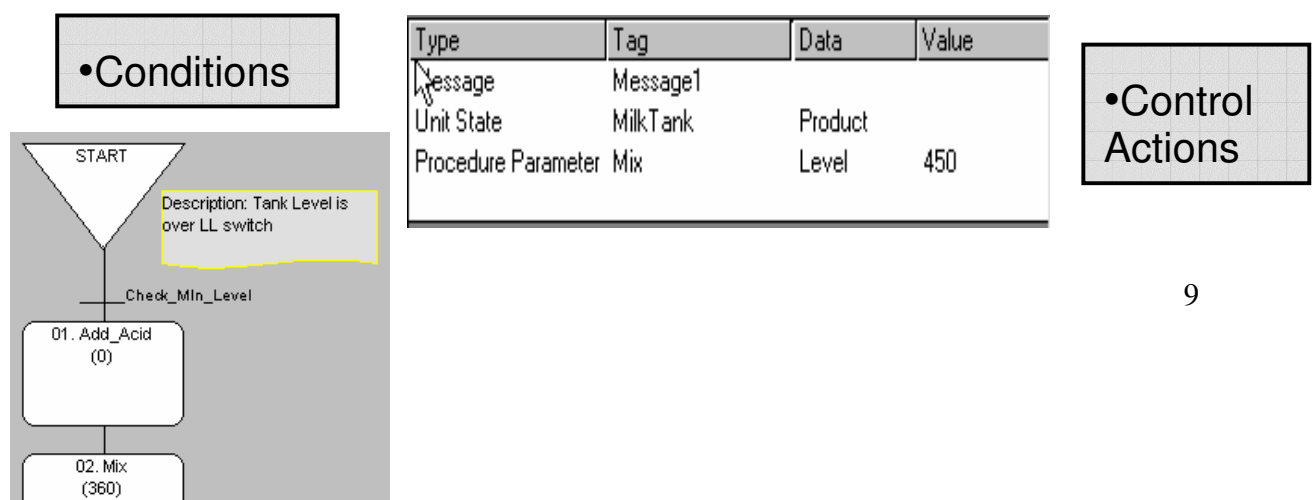
- ✓ Phase Parameters.
- ✓ Phase Steps - including Step Sequence Flow Chart (SFC) and transition logic.
- ✓ CM Activations for each step.
- ✓ Control Actions for each step.
- ✓ Alarms to be monitored in each step.

- **Classes for Higher-level Procedures**

Higher level Procedure Class logic is defined by creating an SFC that is composed of lower level Procedure Classes. For High level Procedure Class the following elements may be defined:

- ✓ Procedure Parameters
- ✓ Procedure Sequence Flow Chart (SFC) and transition logic.
- ✓ Procedure formula.

FIGURE 3 - PHASE CLASS DEFINITION



CM	Property	Condition
MilkTank - AG	Run	
MilkTank - CoolValve	Cmd_Open	
MilkTank - Input_V	OpenCommand	

•CM
Activation

Tag	Description	Property
MilkTank - AG	Fault in Agitator MilkTank - AG	Fault
MilkTank - CIP_V_F	Fault in Valve MilkTank - CIP_V_R2	LatchFault
MilkTank - CoolValv	Valve Fault MilkTank - CoolValve	Fault
MilkTank - HL	Fault in Switch MilkTank - HL	Fault
MilkTank - Input_V	Fault in Valve MilkTank - Input_V	Fault
MilkTank - LL	Fault in Switch MilkTank - LL	Fault
MilkTank - LT	Fault in Transmitter MilkTank - LT	Alarm-H
MilkTank - LT	Fault in Transmitter MilkTank - LT	Alarm-HH

•Alarms

4.5 THE CHALLENGES OF “CLASSIFICATION”

Issues and problems concerning Class definitions for batch process modeling have been raised and discussed in the past, primarily in conjunction with the physical model of a project. In this section we focus on typical issues that must be dealt with when employing **Procedure Class** definitions:

- ◆ **Defining logical conditions**
- ◆ **Defining logic for material transfer between Units (Transfer Phase).**
- ◆ **Definition of Exception Handling.**
- ◆ **MES Integration**

The following will discuss the above issues:

Generic Logical Condition

Logical condition may refer to an object’s internal or external to a specific Unit, e.g., if two units from the same class participate in a process, and a process action is conditioned by one of the CMs of the Unit Class, there is no way to distinguish between the Unit Roles since they belong to the same class.

To overcome this problem, generic Conditions (Condition Classes) can be specified by descriptive text and not by direct referencing to a Class property.

Transfer Logic

Transfer Units are Units that are responsible for transfer of material between processing units. They are very problematic to classify since they are **composed during Instantiation**, depending on the actual source and destination. For instance, it is almost impossible to define a unique Role for a valve within a CIP Valve matrix.

Some situations are further complicated by the control system when Transfer Units are automatically “assembled” in real-time, when a material transfer is required, based on the available routes and destination Units.

If the Physical Model Class can't be defined properly - there will be no way to define the procedural logic.

In order to solve this problem, an instantiated Transfer Unit can be modeled to its Class configuration (i.e., class source and destination units). In this case, every Role has only one occurrence and the transfer logic may be specified with no ambiguity.

Exception Handling

Comprehensive exception handling solutions for S88 based application are not a reality yet. At the Class level, the problem is even worse since in many cases exception-handling logic is based on events external to the Unit or based on other Units. It is, therefore, impossible to define complete exception handling logic on a Class level.

For Procedure Class definitions, exception handling can be specified only for Phase Classes and only for Phase associated Units.

Exception handling definition must be completed only after instantiation.

MES Integration

The Manufacturing Execution Systems are highly developed and integrated with the real-time control system. Thus, process modeling must comply with the MES to support that level of integration. In many cases the definition of a Unit can be dictated by the MES even though from “S88 point of view” a different Unit might have been defined. Since MES extensively use Unit State for process management, Unit States can be dictated by the MES, but implemented in the PFS Definition CAE tool.

4.6 PROCEDURE INSTANTIATION

Once a Unit instance is associated with a Procedure Class, the Procedure instantiation process must be executed automatically with minimal user interference. The Procedure instance inherits the Procedure Class structure (Steps and SFC). Unit Class Role activation and alarms are transformed to CM instances based on the Unit Instance modeling. Control actions are instantiated to the project instances.

4.7 PROCEDURE “INSTANTIATION” - HURDLES TO BE AWARE OF

The vision of automatic Procedure Instantiation is not automatic and “clear cut”:

- ◆ There may be cases where Unit instance is not fully compatible with its Class, i.e., a Unit instance does not have all Roles (CMs) defined for its Class or a case where a Unit instance requires a CM that has not been defined as Role at Unit Class definition.
- ◆ An instance where more than one CM is associated with the same Role (i.e., Multi-Instance Role).

- ◆ Condition Instantiation – A situation where descriptive text is not sufficient to define condition logic.
- ◆ When instantiating a high level Procedure – If a Procedure Class in the SFC has more than one Procedure Instance to associate with.

In all these case the user has to interfere during the Instantiation process and decide no the proper solution.

4.8 PFS - A TOOL FOR ALL DIFFERENT DISCIPLINES

The use of a CAE tool emphasizes several issues that have to be considered during Functional Specification definition.

◆ Functional Specification vs. Design Specification

Functional Specification is a document that transfers process operational data from the process engineer to the automation engineer. In many cases there is a disparity between these two different disciplines regarding type of data, level of details, design format and report format. This may result in **operation-oriented** vs. **programming-oriented** specification document.

To address this issue the PFS Definition CAE tool has the following capabilities.

- ✓ Allow the user to define the required level of details.
- ✓ Flexibility in representing the same functional logic in different ways.
- ✓ User-defined report format according to the report target.

5 - SPEC-SOFT PAM SERVICES

SPEC-Soft has developed with one of its global customers a PFS-based Automation Model for a pharmaceutical application. Based on this experience and expertise with the FFS software, the company is currently engages in the development efforts of such a model with one of the leading global pharmaceutical companies.

SPEC-Soft offers its customers a range of consulting and engineering services to accompany the development of the PAM:

- S88 Training and Consulting.
This training comes handy and most effective when an S88 Physical Model has to be developed including plant modularization. A thorough review of the different criteria is applied with the customer to arrive at the optimal model.
- PFS-Training.
A 5–day workshop provides detailed training on the Definition and Review tools with hands-on experience on a sample project.
- Equipment and Procedure Class development.
These engineering services are best performed in conjunction with customer process engineering personnel who know the process and can provide insight to the “minor” details of equipment and procedure behavior.

