Integrating Intermediate Bulk Containers (IBCs) Within An S88 Structure

Nick Taylor
Manager, Business Pursuit
Emerson Process Management
Meridian East
Leicester, LE3 2WU, UK
T +44-(0)116-282-2329
F +44-(0)116-289-2896
nick.taylor@emersonprocess.com

Pete Davies
Lead Engineer, Integration Projects
Emerson Process Management
Meridian East
Leicester, LE3 2WU, UK
T +44-(0)116-282-2822
F +44-(0)116-289-2896
peter.davies@emersonprocess.com

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ABSTRACT
An S88.01-aware automation system covers the control & management of activities carried out within plant equipment directly connected to it via hardwired, serial or fieldbus links. Batches begin and end within these confines.

Plant managers see a wider picture; eg Process fluid, the batch with its ID, maybe transferred from conventional reactors to Intermediate Bulk Containers (IBCs) and later returned to the piped plant.

This application uses soft (PC) phases within the S88 operation to deal with transfers to & from IBCs. Rather than implementing sequence logic in a plant controller the soft phases interface with an SQL database which tracks the batch ID as process fluid is transferred ‘out of the piped plant’.

The SQL server database interfaces in turn with radio barcode scanners, which identify IBCs, reactors, operators & IBC storage rooms used in each transfer.
Batch ID is preserved between transfers and the operator view from the automation system is of a batch held in a unit (the IBC). The status of any IBC, eg clean, batch ID inside, may be instantly determined via the barcode scanner.

The following benefits are realised:
Cycle time reduction, Reduction in abnormal occurrences, Production capacity increase, Improved safety
INTRODUCTION

This paper gives an overview of the features afforded by applications developed to meet the needs of three separate pharmaceutical manufacturers at primary manufacturing sites in Europe during 1999-2002. The paper includes features from each application. The technology employed is also discussed.

During the sales cycle with a number of pharmaceutical manufacturers recently it has become clear that they are increasingly looking to integrate the disparate ‘systems’, both manual & computerised, employed in the wide range of operations in the manufacturing facility. Many activities take place within the manufacturing plant that are not under control of devices or packages connected to the DCS.

In stark contrast with this reality the DCS vendor community has, for many years, been focussed upon supplying turnkey C&I solutions; HMI, historians, report packages, S88 batch engines, networks, controllers, sensors & actuators, almost entirely ‘within the DCS bubble’ (figure 1). The resulting disconnect between activities taking place inside and outside the bubble gives rise to inelegant solutions bridging the gap. At the most basic level Batch recipes give instructions to operators to carry out manual operations. The operator leaves the HMI screen carrying these instructions in his head and later provides feedback on the completed task to the procedure, again via the HMI. A more advanced approach has been to use bespoke code to communicate between the batch engine and operator via local terminals. The author has seen a number of sophisticated implementations using this approach and seek
in no way to decry what has been achieved. It should, however, be noted that such an approach does not sit well within the structure of most current S88.01 aware control systems. The bespoke code required to drive the various components is often in a different language, resides in a different node (with different operating system) and has a different look & feel to the phase algorithms which form the basic building blocks of S88 implementations.

The solution uses wireless barcode scanners controlled by softphases within the S88 procedure to prompt and track manual operations. Permanent barcodes are attached to IBCs, Drums Storage Rooms, Reactors, Dispensary & Operators. The statuses, contents, location etc, of IBCs, materials & storage rooms are tracked by a separate material tracking database linked to the DCS.

The notable difference between this approach and the pure bespoke code mentioned above is that the individual who wishes to edit a recipe need not be intimately aware of the application software architecture – he can simply choose the unit procedure or operation required.

All actions are carried by users in a single NT security system.

This paper uses a number of definitions as described below:

1. Direct DCS control – actions carried out by field devices, valves, pressure sensors etc connected to the DCS controller via hardwired, serial or fieldbus links
2. Piped Plant – ‘conventional’ process plant comprising units such as reactors connected together by pipes, whether fixed or flexible.

**PLANT OVERVIEW**

The part of the plant focussed on here comprises a Dispensary, two Reactors, a Dryer, multiple IBCs and IBC storage rooms. The processing actions carried out in these locations are part of a larger set of operations in the real plant but these few elements are the key items of interest to us here.

**OPERATIONAL OVERVIEW**

An overview of the operations as seen by the plant manager is as follows.:

1. A Campaign of Batches is defined including the selection of raw material lot numbers to be included in each Batch.
2. A suitable IBC is selected and placed on the Dispensary then charged manually with solid raw materials from Drums.
3. The IBC is then transferred to the Reactor 1 and placed on the Reactor’s top dock. Under direct DCS control the IBC contents are charged into the Reactor 1.
4. Under direct DCS control a series of conventional process actions are carried out; Heat, Charge, Agitate etc. Once these are complete the batch is transferred to the Dryer.
5. Under direct DCS control a series of conventional process actions are carried out in the Dryer.
6. Once drying is complete an IBC is manually placed in the Dryer’s bottom dock.
7. Under direct DCS control the Dryer contents are charged in to the IBC. The IBC is manually undocked and placed in a storage room. At this point the batch is located 100% in the IBC (or several IBCs).
8. Later, when the plant manager wishes to move the batch forward, the required IBC is found amongst those in the storage rooms and placed manually on the top dock of Reactor 2.
9. Under direct DCS control the IBC contents are charged into Reactor 2 and processing continues.

The suitability of each step to be controlled directly by an S88 batch engine under direct DCS control using equipment ‘within the DCS Bubble’ is noted on the right.

<table>
<thead>
<tr>
<th>Campaign of Batches to a particular recipe decided upon</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material lots to be used by the Campaign and member Batches nominated</td>
<td>Maybe</td>
</tr>
<tr>
<td>Individual Batches given batch Ids</td>
<td>Yes</td>
</tr>
<tr>
<td>Batch begins life when an IBC is chosen from the IBC community and placed on Dispensary</td>
<td>No</td>
</tr>
<tr>
<td>IBC placed on Dispensary</td>
<td>No</td>
</tr>
<tr>
<td>Operator takes material from Drums containing nominated Lot numbers and adds to IBC</td>
<td>No</td>
</tr>
<tr>
<td>IBC removed from Dispensary and placed on top-dock of Reactor 1</td>
<td>No</td>
</tr>
<tr>
<td>IBC contents charged into Reactor 1</td>
<td>Yes</td>
</tr>
<tr>
<td>Reactor 1 carries out various process actions: Agitate, Heat, Charge</td>
<td>Yes</td>
</tr>
<tr>
<td>Batch transferred from Reactor 1 to Dryer through pipe</td>
<td>Yes</td>
</tr>
<tr>
<td>Dryer carries out process actions</td>
<td>Yes</td>
</tr>
<tr>
<td>Suitable IBC selected from IBC community and placed in Dryer bottom dock</td>
<td>No</td>
</tr>
<tr>
<td>IBC charged from Dryer</td>
<td>Yes</td>
</tr>
<tr>
<td>IBC removed and placed in storage</td>
<td>No</td>
</tr>
<tr>
<td>Procedure calls for a particular IBC containing the appropriate Charge ID(^1)</td>
<td>Yes, prompt</td>
</tr>
<tr>
<td>Operator finds IBC containing correct Charge ID</td>
<td>No</td>
</tr>
<tr>
<td>Operator places IBC in top dock of Reactor 2</td>
<td>No</td>
</tr>
<tr>
<td>Reactor 2 charged from IBC</td>
<td>Yes</td>
</tr>
<tr>
<td>Reactor 2 carries out various process actions: Agitate, Heat, Charge</td>
<td>Yes</td>
</tr>
</tbody>
</table>

It is clear that many stages of the overall manufacturing process do not sit well within the DCS bubble. Of course this is nothing new — many implementations include batch operations of this nature undertaken using a combination of manual batch sheets, S88 automated recipes including screen prompts & SOPs\(^2\). The coincidence of increased regulatory pressure in the shape of 21 CFR Part 11 and ever more capable technology made this an area ripe for development.

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\(^1\) Charge ID used rather than IBC ID. Possibility of IBC damage and transfer of charge from one IBC to another is thus catered for.

\(^2\) SOP Standard Operating Procedure
OPERATIONAL DETAIL

Having previously looked at the plant operation from above we now consider it in detail at each stage:

1. A Campaign is defined: Recipe, number of batches, lot numbers of raw materials.
2. The Campaign is started – the Batch Engine begins to execute the first batch according to the procedure.
3. The procedure calls for a suitable IBC i.e. dispense this charge
4. The operator browses a hierarchy: campaign (list of batches), batch, charge on the barcode scanner screen. He selects an IBC and scans its barcode. The IBC state is checked with the material tracking database to see if it is suitable (ie clean, not in use, – or compatible to optimise washing)
6. Selects drums, scans barcode, if lot number is correct (matches lot selected during campaign definition) he charges solids from Drums into IBC
7. Confirms action taken on barcode scanner keyboard by re-entering password (21 CFR Part 11) Part 11 Verification also catered for: second user login/badge scan & password

8. Material Tracking Database knows the empty weight (tare weight) of the IBC. OPC link from the DCS controller (inside the bubble) provides actual weight from Dispensary weighscale so is aware of the total charged weight.

9. Operator browses barcode scanner screen for IBC movement required. Next location (Reactor 1) is determined by the Procedure.
10. Operator takes IBC to Reactor 1

11. Operator scans barcodes on: his badge, Reactor 1, IBC & enters his password

12. S88 procedure at this point comprises parallel Phases; hard & soft.
13. Hard - contains controller code controlling devices to receive the IBC solid charge eg valves on top-dock (inside the bubble)
14. Soft - contains PC code executed inside the bubble which bridge out to the material tracking application and onto the radio barcode scanners

15. Batch Processing in the Reactor - S88 procedure now has only one operation comprising hard/controller phases running ‘conventional processing steps’ entirely within the bubble.

16. Processing in Reactor 1 completes and batch is transferred to the Dryer through pipes under Direct DCS control.

17. Processing carried out in Dryer under Direct DCS control.

18. Procedure calls for IBC
19. Operator selects IBC (empty IBC must be compatible to prevent contamination but does not need to be clean) Material Tracking database has this information
20. Scans himself, IBC, Dryer & enters his password
21. Hard & Soft Phases work together to charge IBC with solid from Dryer.
22. Material Tracking Database tracks Batch ID against IBC ID
23. Operator prompted to remove full IBC to storage
24. Full IBC will be retrieved later by the procedure

**APPLICATION ARCHITECTURE**

**SOFTWARE ARCHITECTURE**

The application comprises a number of modular components layered on top of the standard facilities found within the DCS bubble.

The DCS in question has an integral Campaign Manager on top of the S88 Batch Engine, which has soft phase capability.

Data is stored from the Procedure in the Batch Historian Database and from the Control (& Equipment Modules in the Continuous Historian Database.

The Material Tracking solution comprises an SQL Server Material Tracking database and associated Material Tracking application, which communicates with the Procedure via Soft Phases.

The wireless barcode scanners are driven by the Material Tracking application and present information to the Operator from the Procedure & Material Tracking database.

The Material Tracking application also communicates with Equipment & Control Modules directly via OPC.

Campaign Manager loads predefined Campaigns into the Batch Engine.

Campaign Studio allows the definition of Campaigns including the raw material lot numbers to be used. Campaign Studio is linked to the Material Tracking database.

The additional applications described below have been developed as toolkit solutions to ease re-use on future projects. This toolkit approach considerably reduces the level of development and testing required but it should be realised that the nature of possible applications in this area are extremely diverse so extensive customisation will always be required. For example, the first project using this technology
focussed upon the use of IBCs and material tracking as described in this case study. A current project uses the same toolkit but is concerned primarily with manual steps associated with various consumables used in the process (e.g., filters) rather than the process material itself.

The data flow sketch below is shown as an overview of the application specific elements of the bar-coding strategy. The software packages used have been omitted for simplicity. The conventions used include:

- A circle represents a process
- A connecting line with an arrow shows a flow of data
- A solid horizontal line shows a data store.
- A rectangle represents external input or output.

**REPORT SUBSYSTEM**
Batch reports are ‘assembled’ using data from Continuous & Batch Historians plus the Material Tracking database.

**HARDWARE ARCHITECTURE**
The primary operator interface to the material tracking system is via a handheld bar-code terminal. The particular wireless barcode scanner used has alphanumeric keypad and LCD display (16 lines of 21 characters). This device is available for hazardous areas. The wireless barcode scanners communicate via Ethernet access points. These are housed in Ex enclosures where appropriate.
DCS VIEW

From within the bubble, i.e. on the operator HMI screens, various views are available:

Reactor Graphic with IBC Detail
IBC Faceplate

IBC Status

These displays are driven by OPC from data contained in the Material Tracking Database.
ECONOMIC BENEFITS

CYCLE TIME REDUCTION
Batch cycle times are significantly reduced as the operator is led through manual operations with very little leeway for error.

REDUCTION IN ABNORMAL OCCURRENCES
The transfer of process material, both fluid & solid, between IBC and piped plant is closely controlled and recorded. An incorrect IBC cannot be charged as IBC ID / batch ID referential integrity is maintained by the material tracking database.

Ad hoc use of the barcode scanner to identify the contents of IBCs improves housekeeping of the process area.

PRODUCTION CAPACITY INCREASE
As well as the contribution from reduced cycle time the plant capacity is improved as the plant manager has good information concerning the status & whereabouts of IBCs. He can quickly determine how many are clean, dirty, in use and plan usage, cleaning etc to maximise availability of suitable IBC.

IMPROVED SAFETY
Ad hoc identification of IBC contents reduces the risk of incorrect action, use of dirty IBC etc.

TRACEABILITY
‘Manual Operations’ are now closely ‘controlled’ by the DCS from within the S88 Procedure. Information collected in the batch record comes from barcodes read directly from raw material lot containers rather than being input from operators’ notepads or memory. The requirements of 21 CFR Part 11 are met in several areas: a) records are input directly into secure ERs, b) Actions requiring Confirm or Verify login can be carried out via the barcode terminal, c) A single login user environment covers all actions.

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SUMMARY

The use of IBCs rather than conventional piped plant allows extremely flexible plant configuration. It is, however, possible to deliver incorrect material. To ensure that this does not happen the IBCs are tracked. By tracking their status & usage and referring to material compatibility tables IBC re-use is achieved without constant cleaning.

Reusable recipe building blocks accessible to process engineer or chemist eg top dock reused on reactor, mill etc

To ensure GMP compliance each transfer of material is recorded along with user confirm & verify signoffs. The collection of raw material lot numbers as an integral part of the S88 recipe provides material tracking beyond the scope normally encountered within the DCS bubble.