BATCHLINE

We are very excited to be agents for "BatchLine"; A leading new software concept that provides a level of system support for manufacturing batch records that until recently has been only been available to a few of the leading global pharma corporations.

Whether you are looking to take your first steps on the Manufacturing 4.0 / Pharma 4.0 journey or simply looking to improve your "Batches Right First Time", BatchLine

Execution
Batch Review
Report Analytics

offers intuitive and extensive functionality which is simple to implement and deploy, providing significant return on investment within a remarkably short period of time (as little as 1 month, but for GxP environments we expect the full benefit to be leveraged within 3 to 6 months from beginning of initial deployment).

The system has been designed and built with Pharmaceutical Manufacturing as the intended user base from the product's inception. As a result, the functionality is fully compliant with pharmaceutical regulatory requirements and has been engineered against quality standards that are expected of a targeted GxP software vendor.

2 - Verify Crimper Operation

Enter Crimp Height
(Executed by Operator One Jun 15, 2020 18:53:24)

Enter Crimp Diameter
(Executed by Operator One Jun 15, 2020 18:53:30)

Enter Canister Height
(Executed by Operator One Jun 15, 2020 18:53:49)

All user actions, such as operator execution activities or QA review activities are timestamped and logged against the users' ID, supporting full compliance with the principles of ALCOA+, and the system provides a major improvement over paper batch records with regard to Data Integrity standards and compliance.

We offer a compliant Software as a Service (SaaS) hosting provision; either single tenant or multi-tenant. Alternatively, if required, we can supply the packaged software for "on-premise" installation and operation. With our SaaS provision, you can be developing you own implementation with a few days as you build your initial prototypes and develop your understanding of the approach in the intuitive and easy to use environment.

All Batch Specifications (Recipes) are version controlled and must follow the in-built release process to make them available to operators. The tool also allows draft specifications to be uploaded and verified in "Verification mode" within the tool itself, prior to approval and release for production use.

Batch Specification (ID : Name)	Material (ID : Name)	Active	Approval Status	Version
Search...	Search...	Any ▼	Any ▼	Search...
MDI_GEN_SPEC_001 : Generic MDI	MDI_GEN_001 : MDI Generic		Rejected	1
MDI_FULLSPEC_001 : MDI - Full Spec	MDI_GEN_001 : MDI Generic	☐	Approved	1
MDI_GEN_SPEC_001 : Generic MDI	MDI_GEN_001 : MDI Generic	☐	Approved	2
MDI_FULLSPEC_001 : MDI - Full Spec	MDI_GEN_001 : MDI Generic	☑	Approved	2

It comes with support for 8 in-built roles designed to fully support segregation of duties and to allow full Supervisor and Quality review of operator actions and deviations / exceptions. The use of the roles is fully configurable on a recipe by recipe basis.

It would be easy to jump to the conclusion that the tool is simply a "paper on glass" system, but that would be to miss some of the fundamental functionality. The system supports automated calculations, including Dates, Times, Measurements, BOM items, together with support for "yields and reconciliation".

Tolerances of actual values can be set in terms of absolute values or as percentages of expected values; Any values which are outside of configured tolerances will automatically raise exceptions which can be configured to support a range of criticalities. In addition, any changes to previously manually entered data values will also raise automatic exceptions. Operators are free to raise "for information" notes (also by way of exceptions) as they execute their actions in order to record any minor observations as they would when annotating a paper batch record.

All batch execution actions and exceptions can be seen by Supervisors and Quality Assurance roles *in real-time* and they can be *reviewed and assessed in parallel* with the continued batch manufacture. Not only does this allow the quality resources (QA or QP for example) to be comfortable with current batch execution and quality, it also allows them to intervene immediately if necessary and thus avoid lengthy, post execution investigations or batch rework.

All of which increases the percentage of Batches Right First Time and reduces the time from completion of manufacturing to batch release by up to 75%.

Photographs and other attachments can be added to the record at any point by an operator (The system works very well on devices such as Microsoft Surface notebooks allowing instant data capture of items such as balance printouts and carton labels) and all attachment uploads are themselves timestamped.

The system provides a comprehensive pdf Batch Report which is generated automatically by the system at the end of batch manufacture and does itself become subject to a review and approval process to complete the activities. All BOM related entries are clearly highlighted. Exceptions are grouped together and clearly marked to support the concept of "Review by exception", though to some extent, the ability to continually review the operator actions during manufacture minimises reliance on the batch report.
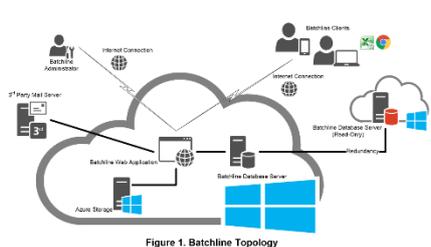

Being fully web enabled, the system can be accessed securely from anywhere and allows for full remote access where Quality Assurance and QP's are working remotely and with the unfortunate events of the recent viral outbreak the ability to generate, review, store and retrieve batch records electronically, has never been more relevant.

Creation of the recipes (Batch Specification) is via an MS Excel template which is provided with comprehensive control features to guide the author through the authoring process. Once generated, the spreadsheet is loaded to the system where it is automatically parsed for errors and when satisfactory, can be tested in the system prior to approval and release for use.

Phase ID	Phase Description	Phase Seq	Step ID	Step Description	Step Seq	Instruction ID	Instruction Seq	Instruction Description	Type	Sub-Type	Expected Result	Decimal Places	UOM	Limit type	Lower limit	Upper limit
2	Crimping & Filling Setup	1														
			1	Vacuum Crimp Setup	1											
						1	1	Setup Vacuum Crimper in accordance with SOP-xx-xxx.	Instruction							
						2	2	Set Crimp Height (Target Height = 8.46mm)	Instruction							
						3	3	Set Crimp Diameter (Target Diameter = 19.8)	Instruction							
						4	4	Set Canister Height (Target Height = 67.45mm)	Instruction							
						5	5	Verify Crimper Operation by crimping 2 cans.	Instruction							
			2	Verify Crimper Operation	2											
						1	1	Enter Crimp Height	Value	None	8.46	2	mm	Number	8.42	8.5
						2	1	Enter Crimp Diameter	Value	None	19.8	2	mm	Number	19.7	19.9
						3	1	Enter Canister Height	Value	None	67.45	2	mm	Number	66.95	67.95

All recipes (Batch Specifications) are stored within the system and automatically version controlled. Existing recipes can be downloaded to ensure any updates are made only against the existing, version controlled, instance.

Generation of the recipe requires some familiarisation with the notation conventions and syntax rules of the tool, but anyone with a quite basic level of Excel experience can be generating their own recipes with a single day's training.

The system can be used to support any batch manufacturing or workflow process, whether this be actual manufacturing of the product or specifically focused on activities such as Line Setup, Line Clearance, Equipment Sterilisation or actual Batch Review / Release workflow in support of Annex 16.

Our professional services team can supply support for any aspect of your deployment from training, through to business change management or system deployment and validation, though the need for this support is limited due to the COTS nature and modular design of the system.

Key Features and Benefits

	Traditional Paper Batch Records	BatchLine EBRS		Traditional Paper Batch Records	BatchLine EBRS
Parallel Review of Exceptions by QA	✗	✓	Meets expectations of "Current Good Practice"	✗	✓
Immediate Visibility of Exceptions to QA	✗	✓	Minimises End of Batch Rework	✗	✓
Remote Review of Batch Record Execution	✗	✓	Minimises Batch Release Timeframe	✗	✓
Ability to automate Yields and Reconciliation	✗	✓	Support for ALCOA+ Principles	✗	✓
Automatic calculation of API for batch potency	✗	✓	Automated Trending of CQAs and CPPs	✗	✓
Compliant with Data Integrity Expectations	✗	✓	E-Signatures with automated Timestamp	✗	✓
Support for "Release by Exception"	✗	✓	Automated Sequence Enforcement	✗	✓