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**Response to RFP for
Electronic Manufacturing Systems
29 Aug 2025
BATCHLINE Lite MES System
(Electronic Batch Record & Equipment Management)**

PREPARED FOR: BRUDER CONSULTING ON BEHALF OF
CUSTOMER

PREPARED BY: BATCHLINE CO., LTD.

RFP RESPONSE NUMBER: RFP-20250918-001-01

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APPENDIX A STANDARD TERMS OF BUSINESS OF BATCHLINE CO., LTD.

APPENDIX B BATCHLINE PACKAGE AND PRICE LIST



In response to your request regarding a Lite MES solution, Batchline Co., Ltd. (Hereinafter "Batchline") is pleased to submit this response to RFP to Bruder Consulting, United States of America (hereinafter "CUSTOMER") with the details described below.

1. Introduction

Batchline is pleased to submit this proposal in response to the Request for Proposal (RFP) for Electronic Manufacturing Systems, issued on 29 August 2025. This document outlines a comprehensive solution designed to address CUSTOMER's strategic objectives of improving manufacturing efficiency, reducing operational costs, and minimizing process deviations through the implementation of a modern electronic system. It is understood that CUSTOMER seeks a modular, scalable, and "right-sized" platform to replace its current paper-based and "paper on glass" batch record systems, recognizing that a full-scale Manufacturing Execution System (MES) is not justified for its production volume.

Batchline Lite MES is specifically engineered for exacting demands of the biotech and pharmaceutical industries. Its design avoids the excessive complexity, lengthy implementation timelines, and high total cost of traditional large-scale MES solutions. It is designed to deliver immediate and tangible strategic advantages:

- ✓ Ensuring a fully compliant electronic batch record (EBR) and equipment management (e-logbook) system.
- ✓ Compliance through right first-time manufacturing including automated checking on input.
- ✓ Increased production capacity and output through shorter cycle times and robust processes.
- ✓ Review and Approval online and by Exception.
- ✓ Less risks of waste and losses due to quality documentation and production errors.
- ✓ Fully GAMP 5 validated and FDA 21 CFR Part 11 compliant
- ✓ Seamlessly integrate with third-party LIMS and IM systems via a robust REST API.

The RFP outlines a scope that includes Electronic Batch Record (EBR), Laboratory Information Management Systems (LIMS), and Inventory Management (IM). Batchline's core lies in its EBR and Equipment Management (EQM) modules. For LIMS and IM functionalities, Batchline presents a modern, REST API and webhook architecture designed for seamless and robust integration with leading third-party systems. This approach provides CUSTOMER with superior flexibility to select best solutions for laboratory and inventory operations without being constrained by a single vendor's ecosystem. This modular strategy is not a limitation but a deliberate design choice that empowers a dynamic biotech company to build a flexible, powerful, and cost-effective digital manufacturing environment.

This proposal details two distinct implementation options as requested, providing itemized pricing and comprehensive project plans for both a flagship product rollout and a full product line implementation.

2. Scope of a proposal

This section defines the scope of the solution and services included in this proposal, directly addressing the requirements outlined in the RFP.

Proposed Product Package

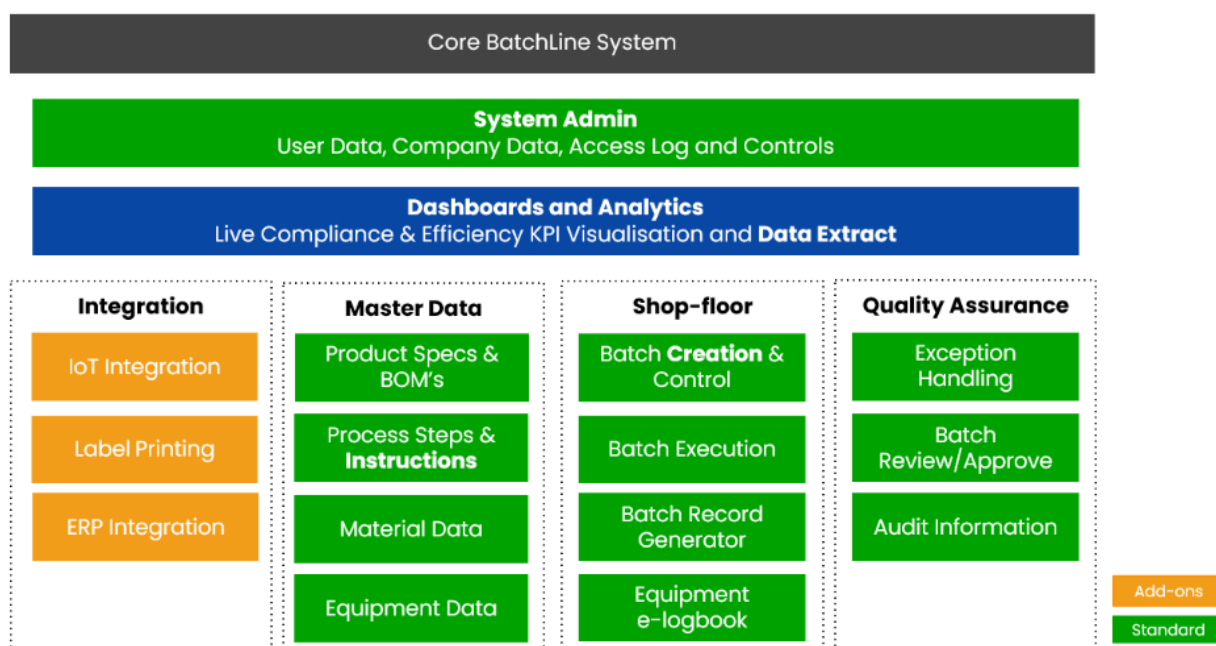
For CUSTOMER, we have selected the Pro MT package to provide essential EBR and Equipment management functionalities that will facilitate the transition from paper-based systems to digital batch record management. This package includes standard integration modules to ensure seamless connectivity with 3rd party LIMS and IM systems using REST API and Webhook.

The product includes:

- BatchLine product Pro MT package license with interface connector to LIMS, ERP, and IoTs.
 - Implementation Option1: 20 x BatchLine concurrent user (CCU) licenses.
 - Implementation Option2:
 - Small campus: 10 x BatchLine concurrent user (CCU) licenses.
 - Mid-Size Campus: 30 x BatchLine concurrent user (CCU) licenses.
 - Large Campus: 50 x BatchLine concurrent user (CCU) licenses.
- Multi-tenant (MT) cloud hosting service managed by Batchline hosted in the United States (USA).

Core Batchline Solution: Electronic Batch Records (EBR)

Batchline Lite MES is a comprehensive platform built upon a powerful core of Electronic Batch Records (EBR) and Equipment Management (EQM), supported by a robust framework for integration with external systems.



The EBR module digitizes and streamlines the entire batch manufacturing lifecycle, significantly reducing the time and effort required for production, review, and approval. The platform's capabilities are specifically designed to meet the functional requirements detailed in the RFP.

- **Master Batch Record (MBR) Management:** Batchline simplifies the creation, approval, and change control of MBRs. The recipe modeling process is performed using a user-familiar tool, macro-controlled Excel template, which is then uploaded to the application. This approach empowers CUSTOMER's subject matter experts to author and modify complex recipes without requiring any coding skills or extensive training. The system enforces robust version control to ensure that operators always use the latest approved version.
- **Workflow Guidance:** The system guides operators through manufacturing processes with configurable and enforced workflows which support both **sequential and parallel steps**. This eliminates ambiguity and ensures procedural adherence. Work instructions are enriched with multimedia content, **including images and embedded videos**, and can contain hyperlinks to external Standard Operating Procedures (SOPs) or other reference documents. Integrated checklists and automated calculations further reduce the risk of human error. A key differentiating feature is the **integrated camera function** which allows operators to capture and attach photographic evidence directly to a batch record step.
- **Materials Management within EBR:** While Batchline integrates with dedicated Inventory Management systems for enterprise-wide logistics, the EBR module provides essential material tracking at the batch level. The Bill of Materials (BOM) is an integral part of the MBR, and the system records the consumption of each material, capturing the Material ID, Lot ID, and expiry date. Data entry can be performed manually or streamlined via barcode scanning, ensuring accurate traceability of all materials used in a specific batch.
- **Deviations/exceptions management:** Batchline features a powerful "Review by Exception" capability that significantly accelerates batch review and release cycles. The system can be configured with critical process parameters and quality attributes. Any data entry that falls outside predefined limits automatically triggers an exception. Operators can also manually raise an exception or atypical event at any point in the process. A dedicated dashboard provides real-time visibility into all pending exceptions, allowing production supervisors and Quality Assurance (QA) personnel to review and close them out concurrently while the batch is still in progress.
- **Equipment Management within EBR:** Complementing the EBR, the dedicated EQM module provides a centralized system for managing the lifecycle and status of all manufacturing and laboratory equipment. This module allows administrators to define equipment classes and custom status models (e.g., Clean, Dirty, In Use, In Calibration) and to track critical dates for preventative maintenance and calibration. The module generates a comprehensive, auditable electronic equipment logbook that automatically records all status changes and usage events, providing a complete history for each asset.
- **Data Reporting and Analytics:** The platform provides real-time dashboards for monitoring the progress and status of all active batches. For deeper analysis, all tagged process data can be easily extracted into a CSV format for use in third-party analytics tools like PowerBI, allowing for trending of exceptions, cycle times, and process parameters. The system also includes an **in-**

app time-series trending feature for in-process check parameters and can publish execution data to an MQTT stream for continuous, real-time process monitoring and integration with data historians.

The following table provides a direct mapping of the EBR requirements from the RFP to the supported features within the Batchline platform.

RFP Requirement	Batchline EBR Capability
Master Batch Record management (creation, approval, change-control)	Fully Supported. MBRs are authored in a user-friendly Excel template and managed with robust version control, configurable approval workflows, and a complete audit trail for all changes.
Workflow guidance	Fully Supported. The system provides enforced sequential/parallel workflows with multimedia instructions, checklists, and automated calculations to guide operators and reduce errors.
Materials management	Fully Supported. The EBR manages the batch-level Bill of Materials, recording material ID, lot number, and consumption with full traceability. Integrates with external IM systems for enterprise-level management.
Deviations/exceptions management	Fully Supported. Features a "Review by Exception" model with automatic flagging of out-of-spec data, manual exception logging, and concurrent review and approval by QA.
Equipment management	Partially Supported. Equipment usage is recorded directly within the EBR by scanning the equipment QR code, linking specific assets to the batch. Complemented by a dedicated EQM module for lifecycle management.
Electronic signatures	Fully Supported. The system captures electronic signatures for all critical actions in full compliance with FDA 21 CFR Part 11 requirements.
Integration with the existing eQMS	Fully Supported. Integration can be achieved via Batchline's REST API and webhook capabilities to link batch exceptions or records with events in an external eQMS.
Data reporting and analytics capabilities	Fully Supported. Provides real-time dashboards, in-app trending, and data export to CSV for analysis in external tools. Publishes real-time data via MQTT for continuous monitoring.



Integration Framework for Laboratory Information System (LIMS) and Inventory Management (IM)

CUSTOMER requires a "right-sized" solution that can adapt and evolve, avoiding the restrictions of a monolithic system. To achieve this, Batchline provides a powerful, open, and standards-based framework that integrates with best-of-breed systems. Instead of locking CUSTOMER into proprietary LIMS and IM modules, our approach allows to select the market's best solutions for each function. This ensures every area is supported by a specialized, high-performance application, eliminating compromises, and future-proofing your digital ecosystem.

The integration frameworks are built on modern, widely adopted, and robust technologies:

- **REST API:** Provides the primary mechanism for transactional data exchange. This can be used to pull in-process control results from a LIMS directly into the EBR, send sample information to the LIMS, or push material consumption data to an IM or Enterprise Resource Planning (ERP) system upon batch completion.
- **MQTT (Message Queuing Telemetry Transport):** Enables real-time, event-driven data streams from IoT-enabled devices, sensors, and laboratory equipment. This is ideal for automatically capturing data from the types of equipment listed in the RFP, such as flow cytometers, plate readers, and HPLCs, directly into the batch record without manual transcription, thereby eliminating errors and ensuring data integrity.
- **Webhooks:** Allows Batchline to push automated, real-time notifications to other systems when key events occur. For example, a webhook can notify an eQMS when an exception is raised in a batch or inform an ERP system that a batch has been completed and is ready for the next stage of the supply chain.

Batchline has successfully integrated with major ERP systems like SAP via middleware and has utilized tools like Node-RED as an IoT gateway to connect a wide array of manufacturing and lab equipment. This demonstrates a mature and reliable capability to create the connected digital plant that the RFP envisions.

In-Scope Services Overview

The implementation of the Batchline Lite MES is a comprehensive project delivered by our experienced team of operations managers, customer success managers, and compliance consultants. The scope of services includes the following key components.

- **Implementation and Configuration:** We will deploy the Batchline system on our secure cloud environment and perform the initial configuration. This includes setting up user accounts, defining roles and access rights, and customizing system settings to align with your operational requirements.
- **Training and Workshop:** To ensure rapid user adoption and long-term self-sufficiency, we provide extensive training. Our program includes role-based training for key users following a "train-the-trainer" model. We also conduct a hands-on Recipe Design Workshop, where we collaborate with your subject matter experts to build out your first product specification, providing them with the skills to manage future recipes independently.
- **Validation Support:** Our service includes a streamlined validation package based on GAMP5 best practices to significantly reduce your team's validation effort. Through a series of expert-led

workshops, we provide a complete set of documentation templates and guidance to ensure an efficient and compliant Computer System Validation (CSV) process.

- **Maintenance & Support:** The project includes our standard Service Level Agreement (SLA), providing ongoing technical support and maintenance at no additional cost for this cloud-based deployment. Extended support packages such as 24/7 support are also available if required. Additional services, such as further recipe design or on-site support, can be provided upon request.

Out-of-Scope Items

To ensure clarity, the following items are explicitly considered out of scope for this proposal:

- **LIMS and IM Software:** Batchline does not provide its own Laboratory Information Management System (LIMS) or Inventory Management (IM) software modules. The scope is limited to the seamless integration of the Batchline platform with CUSTOMER's selected the best LIMS and IM systems.
- **Replacement of Enterprise Systems:** This project does not include the replacement of existing enterprise systems such as the eQMS or ERP. The scope is focused on providing a dedicated EBR solution that integrates with these platforms.
- **Hardware and Client-Side Software:** The provision of physical hardware (servers, tablets, barcode scanners) and standard client-side software (e.g., Microsoft Excel, Google Chrome) is the responsibility of CUSTOMER.
- **Third-Party System Configuration:** Programming or configuring any part of third-party systems and middleware, machines, sensors, or hardware is not included unless explicitly stated.
- **Network Infrastructure:** Setting up or configuring CUSTOMER's network infrastructure is not included.

Any out-of-scope services will require a separate agreement and will be calculated on a Time & Materials basis.

3. Implementation

Batchline employs a proven, structured methodology to ensure a predictable, efficient, and successful implementation. The plan is tailored to the two distinct scenarios requested in the RFP, leveraging data and experience from numerous successful deployments in GxP-regulated environments.

Implementation Option 1: Flagship Product Implementation

This option focuses on the initial implementation of the EBR system for CUSTOMER's single, flagship product at one manufacturing location, establishing a foundation for future expansion.

- **Scope and Complexity:** The scope includes the full EBR functionality for the flagship product at a single manufacturing location.
- **Project Team:** A successful project requires a collaborative partnership. The Batchline team will consist of a dedicated Project Manager, a Lead Technical Consultant, and a Validation Specialist. It is anticipated that the CUSTOMER team will include a Project Manager, Subject Matter Experts (SMEs) from manufacturing and QC, and representatives from IT and QA.
- **Phased Approach:** The project will be executed in distinct phases to manage risk and ensure a smooth transition:
 - **Phase 1:** Standalone EBR Implementation (Estimated Duration: 4-5 Months)

- Cloud Application Deployment and Configuration (2 Weeks): Infrastructure workshop (service and end-user devices), setup, and configuring the system in the customer-specific cloud based on infrastructure requirements.
- Initial key user and MBR training (1 week): Train operators and end users on using the cloud-based EBR, including MBR building and master data. Ensure all shifts are proficient in using the cloud system.
- Process mapping and MBR build (4-6 weeks): Define and document the manufacturing processes, identify critical process parameters and specifications, build the MBR templates in the EBR, and initial testing.
- CSV and MBR verification / testing of the recipe (4-6 weeks): Standard CSV package, workshop, and drafting for the project. Fully validate the recipe and user acceptance testing.
- Go-Live (1-2 week): Transition to full production use of the cloud-based EBR for one product.

Activity / Purpose	Week																							
Environment Preparation	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Kickoff meeting / alignment of all stakeholders on plan, scope and resources																								
Deploy Batchline Test & Production environment on Azure cloud																								
Initial key users training / set base knowledge of EBR functions																								
Customer master data + configuration / Customer specific config																								
CSV Validation/ Validation of Batchline application																								
MBR team training / ready MBR authors for design																								
1 product SKU MBR build / prepare MBR design for Flagship product																								
MBR review workshop / review actual MBR																								
MBR finalization / Finalization and verification of Flagship product																								
Local infrastructure / ready IT devices and network																								
End-user training / ready operations for production run																								
Go-live / use of EBR alongside production for 1 product SKU																								
	Procurement time				Project Effort																			

- **Phase 2: LIMS and IM Integration** (Estimated Duration: 1-2 Months per system): Following the successful go-live of the standalone EBR, work will begin on integrating with CUSTOMER's selected LIMS and IM systems. This will be a sequential process, including interface design specification, API configuration and testing, and formal integration validation.
 - Integration setup and configuration (2-3 weeks): LIMPS and IM integration workshop (protocols, messages, adaptations). Define into Interface Detailed Design Specifications on both server and client sides.
 - Message configuration (3-4 weeks): Engineering to prepare the interface on both server and client sides.
 - Update to MBR Build (1-2 weeks): Update the MBR templates in the EBR with any related changes and initial testing.
 - Integration qualification and testing of interfaces (3-4 weeks): Update to CSV package, workshop, and drafting for IDS/IAT, SAT/UAT. Interface testing and user acceptance testing.
- **Scalability:** This initial implementation is strategically designed as a scalable template, creating a repeatable model that de-risks and accelerates future expansion. The MBR and CSV documents become reusable assets that significantly reduce future design and compliance efforts. Simultaneously, your project team develops the hands-on expertise to form an internal Center of Excellence (COE), empowering them to lead subsequent rollouts with greater independence. This entire foundation is built upon a future-proof cloud architecture and is



supported by flexible licensing models, ensuring that adding new products or sites is both technically and commercially seamless.

Implementation Option 2: Full Product Line Implementation

This option provides a comprehensive program to implement EBR for the full suite of CUSTOMER's products, manufactured at up to **three locations** in the United States.

- **Program Structure:** A multi-site rollout of this scale will be managed by a central Batchline program management team to oversee planning and governance, working with dedicated site-level deployment teams. The strategy is based on a proven model of targeting a go-live for up to three sites in 7-8 months.
- **Site Prioritization and Phasing:** A phased rollout is strongly recommended to maximize success and incorporate learnings.
 - **Pilot Phase:** The program will begin with the flagship product at the primary site, exactly as described in Implementation Option 1. This will serve as the pilot, validating the MBR templates, integration strategies, and training approach.
 - **Rollout Wave 1:** Following the successful pilot, the implementation will be deployed in parallel at the two remaining sites. Learnings and validated templates from the pilot phase will be leveraged to accelerate the deployment and ensure a consistent, harmonized approach across all locations.

4. Customer Resource Requirements

Infrastructure

As CUSTOMER will deploy BatchLine on BatchLine's multi-tenant cloud environment, BatchLine shall provide necessary infrastructure for the system, as well as maintain regulatory compliance, availability, security, and reliability of the infrastructure that host the system. BatchLine offers unlimited storage and will automatically scale its computational power (CPU, RAM, etc.) to match expected performance and server-side response time (excluding data transmission time or ping that may cause by internet connection). All infrastructure cost on the server side is included to the subscription fee.

Client workstation

As BatchLine is a web-based SaaS. The only hardware required on the client side to use BatchLine is the devices with internet connection and a compatible web browser.

- PC Computer/ Laptop – recommended for stationed unit e.g., admins and MBR creators.
- Tablets – recommended for mobile units e.g. operators.

Components	Windows	Android	iOS
Computer/ Processor	Windows 10 or higher (64-bit) with Intel® Core i5, or Microsoft Surface Go recommended	Android Devices which support version 10 or higher	iOS Devices which support iOS 14.4 or higher
Memory	The computer must have approximately 16 GB of RAM (Recommended for maximum performance) 8 GB of RAM (Minimum specification for optimal performance)		
Hard Disk	100 GB of free hard disk space		
Screen Resolution	XGA (1024 x 768 pixels) or higher resolution monitor with 16 bits colour settings		
Input Device	Keyboard and Mouse. (On Surface Go – Those will be unnecessary)		
Internet Connections	Network using 20 Mbps or higher speed network adapter and/or WLAN. 100 Mbps (<200 Users), 1 Gbps (<1,000 Users)		
Components	Windows	Android	iOS
Web Browsers	Any web browser. Recommended the latest version of Chrome.		
MS Excel 64 Bit Version	MS Excel Eng. Version only 2016 (Recommended)	N/A	N/A

Human resources

To ensure the efficiency and precision of the project, a close co-operation from CUSTOMER is essential. You must assign a group of people as representatives to the following roles to work together with Batchline Project team.

- **Executive Sponsor:** This senior staff member is responsible to the business for the success of the implementation project and will serve as the primary contact in cases where an escalation might be necessary.
- **Project Lead:** Senior management will assign this person to drive the project forward, which includes the arrangement of all your actions regarding the new system and is main contact person for Batchline. One of the most important tasks of this role will be detection, classification and, if applicable, elimination any threats that may cause delay, problems, or failure to the project.
- **Subject Matter Expert(s):** One or more experts from each department e.g. QA, Operation, etc. are required to participate different sessions across the project.
- **Validation Resources:** At least two people will need to oversee validation from your side: one validation approver will ensure the system is valid and the other person will support the approver and participate in validation activities as required.
- **IT Resource:** At least one internal IT expert is required to support the technical setup e.g., set up client-side device, set up IoT gateway, coordinate with 3rd party system SI, etc.
 - CUSTOMER must heartfully support all activities during the implementation and any on-site activities (if any).
 - CUSTOMER's representatives must acquire necessary information before and send to Batchline project team in a timely manner.
 - After the Implementation is completed, CUSTOMER must allow Batchline to access the entire system environment in the necessary extent for configuration, testing, validation, and support free of charge.
 - CUSTOMER agree to provide necessary internet connections to their internal for any off-site and remote activities across the project (if any).
 - CUSTOMER are responsible for all required tasks, e.g. facility preparation, internet connection, etc. for any on-site activities e.g. system validation, trainings, etc. (if any).

5. Training

Key User Training

Training will be delivered remotely by Batchline consultants for different groups of people based on their roles and following a train-the-trainer approach. Up to 8 participants can attend each course to ensure highest effectiveness.

- BatchLine system administration, attended by System Admin
- Batch Record management and review, attended by QA and Supervisors
- Batch Record execution, attended by end users e.g., operators, researchers, etc.

Recipe Design Consulting Workshop

Batchline offers a Specification Authoring Workshop for SME's who will be responsible for creating specifications within BatchLine. Our team will use CUSTOMER existing process specification and convert into Batchline application along with providing knowledge and techniques needed. Once the creation is complete, our team will also validate the specification and teach SME how to do it themselves for other products.

Up to 5 participants can attend each workshop to ensure highest effectiveness.

- Workshop for 1 product of CUSTOMER's choice
- Batchline will lead the design process, while the customer will shadow the activities and receive on-the-job training.
- The design process will be limited to 2 (two) design reviews and change rounds to ensure efficient and timely completion ***unless stated otherwise within the contract.***

Delivery Method: Remote workshop plus Online consulting sessions via Microsoft Teams' Meeting (or equivalent) platform

Training Materials: Training documents will be provided before each training session, and training records after the training is complete.

Language: English

6. Validation

The BatchLine Lite MES is validated using a modern, risk-based and supplier centric approach as it is installed and managed by BatchLine on a cloud environment. BatchLine is a fully standardized system which the customer accesses using only a web-browser connected to the internet and Batchline provide a complete Validation package to assist customers with the method and document templates to ensure the system is specified and tested according to best practice (GAMP5).

The BatchLine functionality and underlying infrastructure is tested and controlled by BatchLine's QMS and qualification work as a supplier, leaving a much-reduced amount of validation effort for the customer.

To assist with the validation, a comprehensive set of documents are provided to the customer as standard which can be used to help ensure the validation is done efficiently and in compliance with regulations.

The following Qualification documents are included to provide details and evidence of the work BatchLine completed to verify the system meets its requirements and specifications, and is therefore qualified for use following appropriate customer validation activities:

- Qualification Report (QR)
- Requirements Traceability Matrix (RTM)
- User Requirement Specification (URS)

The following section outlines the Computer System Validation (CSV) deliverables and activities that will be conducted as part of the project.

Sessions	Deliverables	Duration
Workshop 1	<ul style="list-style-type: none">• Batchline Qualification• Validation Plan• High Level Risk Assessment (HLRA)	3 hours
Workshop 2	<ul style="list-style-type: none">• URS• Process and Risk Assessment (PRA)	3 – 6 hours
Workshop 3	<ul style="list-style-type: none">• Infrastructure Design and Configuration Specs (ID&CS)	1 hour
Workshop 4	<ul style="list-style-type: none">• Infrastructure Design and Configuration Acceptance Test (ID&CAT)• User Acceptance Test (UAT) Plan and Specifications	3 hours
Workshop 5	<ul style="list-style-type: none">• SOP Master Batch Record (MBR) Verification Operational SOPs	3 hours
CSV Execution	<ul style="list-style-type: none">• ID&CAT• UAT	Customer's responsibility
Workshop 6	<ul style="list-style-type: none">• Validation Report	1 hours
Pre-Go-live activity	<ul style="list-style-type: none">• MBR Verification	Customer's responsibility

We provide a complete set of templates, designed for the validation team to use and follow. These provide an efficient and compliant approach which we strongly recommend customers utilize, as they have been designed by leading international CSV experts and GAMP5 certified trainers with extensive experience of US FDA, EU, and PIC/s GMP's.

- Validation Plan
- High Level Risk Assessment
- User Requirements Specification
- Process and Risk Assessment
- Infrastructure Design & Configuration Specification Template
- Infrastructure Design & Configuration Verification Template
- User Acceptance Testing Specification Template
- Validation Report
- SOP Batch Specification (MBR) Verification
- Standard Operating Procedure (SOP)'s
 - SOP Batch Specification (MBR) Verification
 - Customer specific – standard templates available on request

Batchline will assist the client in the first validation using the CUSTOMER configuration and the infrastructure to be used to access it (i.e., a pc/tablet and internet connections).

7. Data Migration

Our approach to data migration is structured to ensure a seamless and efficient transition to the Batchline EBR. Our standard implementation scope focuses on the comprehensive migration of all necessary Master Data to ensure the system is fully operational from go-live. We recommend a separate strategy for managing historical records to maintain data integrity and project efficiency.

Master Data Migration

This process involves the structured transfer of core operational data into the Batchline system. The scope of Master Data migration includes:

- **Master Batch Records (MBRs):** The conversion of existing manufacturing instructions, process parameters, and specifications into the Batchline digital format. This is facilitated through Batchline's Excel-based authoring tool.
- **Material Master Data:** A comprehensive list of all raw materials, intermediates, and components required for the Bill of Materials (BOM), including material IDs, descriptions, and units of measure.
- **Equipment Master Data:** A complete registry of all manufacturing and testing equipment configured within the Equipment Management module.
- **User and Role Profiles:** The configuration of all user accounts (e.g., Operators, QA, Supervisors) with the appropriate roles and system permissions.

8. Pricing

This section provides a transparent and detailed breakdown of all costs associated with the Batchline solution, delineated as requested in the RFP.

This proposal projection is based on a **5-year total cost of ownership**. The scale-up of concurrent users is calculated on certain assumptions and static figures derived from our current pricelist.

Once we move into the next stage of discussions and refine the proposal, the following will be included:

- **Annual Price Adjustment Review** – As part of our commitment to transparency and long-term partnership, any potential price adjustments will be reviewed jointly with the customer during the annual business review. This ensures that pricing remains aligned with agreed service levels, actual system usage, and evolving business requirements, while providing a clear and collaborative framework for any necessary adjustments.

8.1 OPTION 1: Flagship Product Implementation

Cost structure	Quoted Quantity	Year #1	Year #2	Year #3	Year #4	Year #5	TOTAL
License Subscription Fee	Pro MT Package for 20 CCU at 1 manufacturing facility. (Including Azure Hosting Fee) @ \$2,500 / CCU	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 250,000
Deployment Service (One-Time)	Batchline deployment, Training, Recipe design consulting and CSV Validation	\$ 35,900	-	-	-	-	\$ 35,900
Implementation of Flagship product design & verification at a single manufacturing location	Turnkey recipe design & verification for Part A and Part B of the Flagship product design including design, 4 review sessions with customer SME and recipe verification ready for production go-live.	\$ 89,100	-	-	-	-	\$ 89,100
TOTAL	Total Cost of Ownership over 5 years	\$175,000	\$50,000	\$50,000	\$50,000	\$50,000	\$ 375,000

8.2 OPTION 2: Full product line implementation

Cost structure	Quoted Quantity	Year #1	Year #2	Year #3	Year #4	Year #5	TOTAL
License Subscription Fee	Pro MT Package at 3 manufacturing facility with a total 100 CCU, full scale up on 2 nd year onwards (Including Azure Hosting Fee)	\$ 63,000	\$ 183,000	\$ 183,000	\$ 183,000	\$ 183,000	\$ 795,000
Deployment Service (One-Time)	Batchline deployment, Training, Recipe design consulting and CSV Validation	\$ 35,900	-	-	-	-	\$ 35,900
Implementation of Flagship product design & verification at a single manufacturing location	Turnkey recipe design & verification for Part A and Part B of the Flagship product design including design, 4 review sessions with customer SME and recipe verification ready for production go-live.	\$ 89,100	-	-	-	-	\$ 89,100
Implementation of Full Product Suite, manufactured at up to 3 locations in the United States	Turnkey recipe design for Full product suite including design, 3 review sessions (each recipe) with customer SME and recipe verification ready for production go-live.	-	\$ 198,000	-	-	-	\$ 198,000
TOTAL	Total Cost of Ownership over 5 years	\$ 188,000	\$ 381,000	\$ 183,000	\$ 183,000	\$ 183,000	\$ 1,118,000

Subscriptions – Recurring cost

Annual Platform Licensing: (OPTION 1: Flagship Product Implementation)							
Proposed License	Description	Unit Price / CCU	Year #1	Year #2	Year #3	Year #4	Year #5
Batchline Pro MT Subscription Fee	Pro MT Package includes: <ul style="list-style-type: none"> • Batchline licensing for 20 Concurrent Users (CCU) • Electronic Batch recording (EBR) and Equipment management (EQM) module • Integration capabilities (REST API) connections to ERP, LIMS • Connectivity with (<i>unlimited</i>) IoT devices • Microsoft Azure VPC hosting • Standard Maintenance support (upgrade, update, patches) 	\$ 2,500	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000
License Cost Model/Drivers	Quoted Quantity						
BatchLine uses a concurrent users licensing model	A concurrent users licensing model allows multiple users to access a software application simultaneously up to a predefined limit, with licensing fees based on the maximum number of users accessing the system concurrently rather than individual user accounts.						
The number of Concurrent Users (CCU)	20 CCU - serving about 60-70 unique users						
MS Azure hosting	Microsoft Azure hosting cost is included as part of the Pro MT package.						



This proposal is based on certain assumptions regarding the sizing of each site. We have used this opportunity to illustrate how subscription fees scale as additional users are added per site. For projection purposes, the 2nd and 3rd sites are assumed to commence in Year 2, following the successful implementation of the 1st pilot site (flagship product).

Annual Platform Licensing: (OPTION 2: Full product line implementation)							
Proposed License	Description	Unit Price / CCU	Year #1	Year #2	Year #3	Year #4	Year #5
Batchline Pro MT Subscription Fee	Pro MT Package includes: <ul style="list-style-type: none">Batchline licensing for 50 Concurrent Users (CCU) <i>(Large Campus - 50 CCU)</i>	\$ 1,760	-	\$ 88,000	\$ 88,000	\$ 88,000	\$ 88,000
Batchline Pro MT Subscription Fee	Pro MT Package includes: <ul style="list-style-type: none">Batchline licensing for 30 Concurrent Users (CCU) <i>(Mid-Size Campus - 30 CCU)</i>	\$ 2,100	\$ 63,000	\$ 63,000	\$ 63,000	\$ 63,000	\$ 63,000
Batchline Pro MT Subscription Fee	Pro MT Package includes: <ul style="list-style-type: none">Batchline licensing for 10 Concurrent Users (CCU) <i>(Small Campus - 10 CCU)</i>	\$ 3,200	-	\$ 32,000	\$ 32,000	\$ 32,000	\$ 32,000
License Cost Model/Drivers		Quoted Quantity					
BatchLine uses a concurrent users licensing model		A concurrent users licensing model allows multiple users to access a software application simultaneously up to a predefined limit, with licensing fees based on the maximum number of users accessing the system concurrently rather than individual user accounts.					
Pro MT Package features		<ul style="list-style-type: none">Electronic Batch recording (EBR) and Equipment management (EQM) moduleIntegration capabilities (REST API) connections to ERP, LIMSConnectivity with (unlimited) IoT devicesMicrosoft Azure VPC hosting Maintenance support (upgrade, update, patches)					
MS Azure hosting		Microsoft Azure hosting cost is included as part of the Pro MT package.					

Standard Policy

Batchline application operates on a year-to-year contract structure. All agreements will be automatically renewed for subsequent terms unless either party provides written notice of termination prior to the end of the current term.

All prices will be valid through 2027; Batchline reserves the right to review the subscription and will notify Customer at least 120 days before next recurring date in case the price needs to be adjusted.

One-time service cost

Annual Platform Licensing: (OPTION 1: Flagship Product Implementation)			
One-Time Services	Quoted Quantity (Person Days)	Unit Price / PD	Year #1
Deployment of Test & Production environment on Multi-Tenant (MT) (Includes IDS & CS documentations)	10 PD	\$ 990	\$ 9,900
Training (Key users, Admin, Operator and QA)	5 PD	\$ 1,400	\$ 7,000
Recipe design consulting	3 PD	\$ 1,200	\$ 3,600
CSV Validation workshops & deliverables	7 PD	\$ 1,200	\$ 8,400
Project Management (PM)	5 PD	\$ 1,400	\$ 7,000
Total Deployment Services	30 PD	\$ 1,197	\$ 35,900

Annual Platform Licensing: (OPTION 2: Full product line implementation)			
One-Time Services	Quoted Quantity (Person Days)	Unit Price / PD	Year #1
Deployment of Test & Production environment on Multi-Tenant (MT) (Includes IDS & CS documentations)	10 PD	\$ 990	\$ 9,900
Training (Key users, Admin, Operator and QA)	5 PD	\$ 1,400	\$ 7,000
Recipe design consulting	3 PD	\$ 1,200	\$ 3,600
CSV Validation workshops & deliverables	7 PD	\$ 1,200	\$ 8,400
Project Management (PM)	5 PD	\$ 1,400	\$ 7,000
Total Deployment Services	30 PD	\$ 1,197	\$ 35,900

Flagship product design & verification at a single manufacturing location

(OPTION 1: Flagship Product Implementation) Implementation of Flagship product design & verification at a single manufacturing location			
Part A	Quoted Quantity (Person Days)	Unit Price / PD	Year #1
Process 1 Number of Pages: ~165 Number of Operator Entries: ~2000	20 PD	\$ 990	\$ 19,800
Process 2 Number of Pages: ~430 Number of Operator Entries: ~2700	50 PD	\$ 990	\$ 49,500
Part B	Quoted Quantity (Person Days)	Unit Price / PD	Year #1
Process 1 Number of Pages: ~150 Number of Operator Entries: ~2500	20 PD	\$ 990	\$ 19,800
Total	90 PD	\$ 990	\$ 89,100

This is a breakdown of a turnkey recipe design & verification for Part A and Part B including design, 4 review sessions with customer SME and recipe verification ready for production go-live.

Full Product Suite design & verification at 3 manufacturing location

(OPTION 2: Full product line implementation) Implementation of Flagship product design & verification at all 3-manufacturing location			
Part A	Quoted Quantity (Person Days)	Unit Price / PD	Year #1
Process 1 Number of Pages: ~165 Number of Operator Entries: ~2000	20 PD	\$ 990	\$ 19,800
Process 2 Number of Pages: ~430 Number of Operator Entries: ~2700	50 PD	\$ 990	\$ 49,500
Part B	Quoted Quantity (Person Days)	Unit Price / PD	Year #1
Process 1 Number of Pages: ~150 Number of Operator Entries: ~2500	20 PD	\$ 990	\$ 19,800
Total	90 PD	\$ 990	\$ 89,100

This is a breakdown of a turnkey recipe design & verification for Part A and Part B including design, 4 review sessions with customer SME and recipe verification ready for production go-live.

Full Product Suite	Quoted Quantity (Person Days)	Unit Price / PD	Year #1
Product 2 Number of Pages: ~30 Number of Operator Entries: ~400	3 PD	\$ 990	\$ 2,970
Product 3 Number of Pages: ~30 Number of Operator Entries: ~350	3 PD	\$ 990	\$ 2,970
Product 4 Number of Pages: ~30 Number of Operator Entries: ~700	7 PD	\$ 990	\$ 6,930
Product 5 Number of Pages: ~30 Number of Operator Entries: ~650	7 PD	\$ 990	\$ 6,930
Product 6 Number of Pages: ~30 Number of Operator Entries: ~550	5 PD	\$ 990	\$ 4,950
Raw Material Intermediate 1 Number of Pages: ~40 Number of Operator Entries: ~1400	15 PD	\$ 990	\$ 14,850
Raw Material Intermediate 2 Number of Pages: ~200 Number of Operator Entries: ~7250	25 PD	\$ 990	\$ 24,750

Production Solutions (~30) Number of Pages: ~9 each Number of Operator Entries: ~130 each	35 PD	\$ 990	\$ 34,650
MCB-1 Number of Pages: ~175 Number of Operator Entries: ~3300	20 PD	\$ 990	\$ 19,800
WCB-1 Number of Pages: ~400 Number of Operator Entries: ~6500	50 PD	\$ 990	\$ 49,500
MCB-2 Number of Pages: ~100 Number of Operator Entries: ~1400	10 PD	\$ 990	\$ 9,900
WCB-2 Number of Pages: ~140 Number of Operator Entries: ~2650	20 PD	\$ 990	\$ 19,800
Total	200 PD	\$ 990	\$ 198,000

This is a breakdown of a turnkey recipe design for Full product suite including design, 3 review sessions (each recipe) with customer SME and recipe verification ready for production go-live.

Project cost summary

Total Cost of Ownership over 5 years			
Additional Ongoing Services	Quoted Quantity	OPTION 1: Flagship Product Implementation	OPTION 2: Full product line implementation
License Subscription Fee	Pro MT Package (Including Azure Hosting Fee)	\$ 250,000	\$ 795,000
Deployment Service (One-Time)	Batchline deployment, Training, Recipe design consulting and CSV Validation	\$ 35,900	\$ 35,900
Implementation of Flagship product design & verification at a single manufacturing location	Turnkey recipe design & verification for Part A and Part B of the Flagship product design including design, 4 review sessions with customer SME and recipe verification ready for production go-live.	\$ 89,100	\$ 89,100
Implementation of Full Product Suite, manufactured at up to 3 locations in the United States	Turnkey recipe design for Full product suite including design, 3 review sessions (each recipe) with customer SME and recipe verification ready for production go-live.	-	\$ 198,000
TOTAL	Total Cost of Ownership over 5-years	\$ 375,000	\$ 1,118,000

Additional support services 24/7 (Optional)

Additional (OPTIONAL) Support Services (OPTION 1: Flagship Product Implementation)						
Additional Ongoing Services	Quoted Quantity	Year #1	Year #2	Year #3	Year #4	Year #5
24/7 Support Structure	<i>additional 24% on-top of subscription fee. In-case customers operate and require support for 24/7 operation</i>	\$ 12,000	\$ 12,000	\$ 12,000	\$ 12,000	\$ 12,000

Additional (OPTIONAL) Support Services (OPTION 1: Flagship Product Implementation)						
Additional Ongoing Services	Quoted Quantity	Year #1	Year #2	Year #3	Year #4	Year #5
24/7 Support Structure	<i>additional 24% on-top of subscription fee. In-case customers operate and require support for 24/7 operation</i>	\$ 15,120	\$ 43,920	\$ 43,920	\$ 43,920	\$ 43,920

Person day rates for additional work

The following rates are offered to calculate any additional costs for work occur within 1 year after the project completion date on Time and Materials basis:

RESOURCE	RATE CARD (USD/Person Day)
Project Manager	\$ 1,400 /day
Senior Consultant / Senior Engineer	\$ 1,200 / day
Consultant / Engineer	\$ 990 / day

1 Person Day (PD) is equivalent to 8 working hours. The work will be performed during BatchLine's standard operating hours, which is Monday-Friday 09:00-18:00 (excl. public holidays). BatchLine reserves the right to adjust the rate if the work needs to be performed outside the standard operating hours or happen after the stated period.

9. PAYMENT TERMS

Project fee are payable within 30 (Thirty) days on receipt of invoice.

NO.	INVOICE ISSUEING	FEE
1	Signing of the contract	• 100% of subscription fee
2	Signing of the contract	• 50% of service fee
3	Completion of service delivery	• 50% of service fee

All Fees in this proposal should be paid in Full, except to the extent that any withholding of taxes is required by applicable law. If any taxes are required to be withheld, Customer is responsible to provide the appropriate receipt and valid withholding tax certificate issued by government authority to Batchline. Otherwise withholding taxes shall be under a responsibility of Customer. Please see [Appendix A: Standard Terms of Business of Batchline Co., Ltd.](#) for details.

RECURRING COST

- a. Recurring cost under this contract will automatically renew after the expiry of the subscription period unless BatchLine is notified in advance by Customer in writing.
- b. BatchLine operates a strict policy of no subscription refunds, and a 120-days' notice period is required if the Customer desires to terminate or change the renewal terms/scope.

10. Reference

HALO Pharma (Canada) – CDMO / Pharma

HALO Pharma, a contract manufacturing organization with over 40 years of experience, operates a highly versatile facility in Mirabel, Quebec. The site supports a wide range of dosage forms including solid dose, liquids (solutions and suspensions), semi-solids (lotions, creams, ointments), and suppositories. It also offers analytical development, microbiology testing, and packaging services.

Global Biotech Product (GBP) – Thailand – Vaccine.

It is a joint venture between the Government Pharmaceutical Organization, Substipharma Biologics and Siam Bioscience that strengthens vaccine capabilities and vaccine security policies in order to adequately support the country's immunization plan.

CYTO-FACTO INC. (Japan) - CAR-T Cell Therapy / MSC

Cyto-Facto Inc. is a cutting-edge biotechnology company based in Kobe, Japan, specializing in the development, manufacturing, and quality control testing of gene and cell therapy products. Founded in 2022, Cyto-Facto operates as a cell therapy research and development center, with a focus on commercial CAR-T therapies and mesenchymal stem cell products.

Vector BioMed (USA) – Cell Therapy / Viral Vector

Vector BioMed Inc. is a viral vector contract development and manufacturing organization (CDMO) based in Gaithersburg, Maryland. Founded in 2021, the company specializes in the design, optimization, and scalable production of lentiviral vectors for gene therapy applications.

Unison Laboratories (B.Grimm Group, Thailand)

Unison Laboratories, founded in 1956, is a leading pharmaceutical manufacturer in Thailand, now part of the B.Grimm Healthcare portfolio. The company maintains a portfolio of over 450 registered pharmaceutical products and operates under stringent quality standards, holding certifications such as PIC/S GMP, ISO 9001, ISO 14001, ISO 45001, and ISO/IEC 17025 for drug testing. Batchline is being used for commercial Production and QC lab testing procedure.



APPENDIX A: STANDARD TERMS OF BUSINESS OF BATCHLINE CO., LTD.

1. Services

Batchline Co., Ltd. ("BATCHLINE") will provide the services described in the attached letter.

BATCHLINE's work will be based solely on information provided by CUSTOMER. ("CLIENT"), the circumstances made known to BATCHLINE and any assumptions that may be set out in BATCHLINE's report. BATCHLINE will rely on CLIENT to bring to BATCHLINE's attention any changes in information that may impact on BATCHLINE's advice.

BATCHLINE's advice will be based on laws and practices in existence at the time its work is performed. Changes in the laws and practices may take place after BATCHLINE's advice is given but before its advice is acted upon. BATCHLINE will be responsible to inform CLIENT of such changes from time to time.

2. Timeline

BATCHLINE will use its best endeavour to carry out our services in accordance with the timeline set out in the attached letter.

BATCHLINE will use its best endeavour to commence services at the earliest available date for the selected consultants, within 8 weeks of the date of quotation acceptance.

3. Changes to Services

Each party may request changes to the proposed services or changes to the Standard Terms of Business, but no such changes take effect unless agreed in writing by both parties. CLIENT acknowledges that changes may impact on the costs, timing and any other aspects of the services.

4. Reporting

BATCHLINE will report to CLIENT in accordance with the terms set out in the attached letter. Unless specifically agreed, BATCHLINE accept no duty or responsibility to any third party that may seek to rely on BATCHLINE's report. In some cases appropriate releases from third parties may be required and requested by BATCHLINE.

5. Intellectual Property

Intellectual property rights and copyright in BATCHLINE's documentation, materials, methodologies, tools and processes brought to the assignment shall remain and be vested in BATCHLINE.

6. Information

Unless otherwise stated in the attached letter, BATCHLINE will not independently verify the accuracy of any information and documents provided by CLIENT and BATCHLINE will not be liable for any loss or damage arising from any inaccuracy or other defect in any such information or documents provided by CLIENT.

7. Fees

Fees for products and services will be charged by BATCHLINE on the basis set out in the attached letter. The fees and, where applicable, out of pocket expenses as defined in the letter above, are subject to applicable taxes. CLIENT is responsible to provide the corresponding withholding tax documentation to BATCHLINE. Where required this should be issued by a local government authority.

8. Expenses

Unless the attached letter states otherwise, our fees are exclusive of any travel, accommodation and applicable out of pocket expenses such as subsistence and document handling costs incurred in connection with the services. Such expenses will be charged monthly at cost upon receipt and as applicable will include BATCHLINE's standard Per Diem rate for each day worked onsite.

9. Reference

CLIENT agrees that BATCHLINE may refer to CLIENT's name and the solutions and services performed as a customer reference and used on BATCHLINE promotional materials.

10. Payment of Fees

CLIENT's obligation to pay the fees and expenses to BATCHLINE will not arise until BATCHLINE have issued an invoice to Customer. Unless otherwise stated, all invoices are due for payment within 30 (Thirty) days of the receiving date of the invoice by Customer.

11. Tax Responsibility

Exclusion of Taxes: All fees and charges outlined in this agreement are exclusive of any taxes, including, but not limited to, value-added taxes (VAT), goods and services taxes (GST), or withholding taxes, unless otherwise explicitly stated.

Customer Responsibility for Taxes: The CLIENT shall be solely responsible for the payment of any applicable taxes, levies, duties, or similar governmental assessments, including withholding taxes, associated with the fees and services provided under this agreement.

Withholding Tax Reclamation: If withholding taxes are applicable and can be reclaimed, the CLIENT agrees to provide all necessary documentation and assistance required for the reclamation of such taxes. This includes, but is not limited to, tax certificates, receipts, and any additional paperwork requested by the relevant tax authorities.

Non-Reclaimable Withholding Tax: If withholding taxes cannot be reclaimed or recovered, the CLIENT agrees to reimburse and pay such amounts to the Company in addition to the fees and charges stated in this agreement. The Company shall issue an invoice for any unreclaimed withholding tax, and the Customer shall remit payment as outlined in the payment terms of this agreement.

12. Term and Termination

The services described in the attached letter and these Standard Terms of Business will commence on the date specified in the attached letter, or where no date of commencement is specified, from the date of first performance of the services.

The assignment may be terminated if either party fails to remedy a material breach of these Standard Terms of Business. Otherwise, either party may terminate the assignment by providing written notice of termination.

13. Confidentiality

BATCHLINE will not disclose to any third party, without CLIENT's prior consent, any confidential information which is received during the performance of the services, which is marked confidential or confirmed in writing as being confidential, including but not limited to reports, briefs, projections, summaries, maps, drawings, memoranda, intellectual property, copyright, know-how and methodology.

This restriction will apply for a period of 5 (five) years from disclosure but will not apply to information that is or becomes generally available to the public through no violation to this confidentiality obligation, or is acquired from a third party who owes no obligation of confidence in respect of the information, or is required by law to be disclosed.

14. Liability

To the extent permitted by law, the liability of BATCHLINE for breach of any warranty, condition or term implied in fact or by law is limited to, at the option of BATCHLINE, either the re-supply of the services or payment for the cost of having the services re-supplied.

In all instances, other than as set out in the preceding paragraph, the total aggregate liability of BATCHLINE to CLIENT for loss or damage (including indirect and consequential loss or damage), caused by, resulting from, or in relation to the services, including whether arising from breach of contract, negligence, or any other tort, in equity or otherwise, and whether or not BATCHLINE was advised of the possibility of such loss or damage, is limited to the amount of the fees paid for the services.

CLIENT agree that if loss is contributed to or caused by CLIENT, then liability for loss will be apportioned according to respective responsibilities for the loss.

15. Transfer Rights and Obligations to the Third Party

Each party may not transfer to the third party any of its rights and obligations described in the attached letter and these Standard Terms of Business in whole or in part without the prior written consent of another party.

16. Agreement

The attached letter and these Standard Terms of Business comprise the Agreement between both parties relating to the services. In the event of any conflict between the attached letter and these Standard Terms of Business, the letter takes precedence.

17. Governing Law

The relationship between BATCHLINE and CLIENT is governed and interpreted in accordance with the laws of New York, USA. should any disputes arise between both parties, BATCHLINE will attempt to resolve the dispute in good faith

APPENDIX B: BATCHLINE PRO MT PACKAGE AND PRICE LIST PER MANUFACTURING SITE

# of CCU	Unit Price per CCU	Total Subscription Fee
5	\$3,600	\$18,000
10	\$3,200	\$32,000
20	\$2,500	\$50,000
30	\$2,100	\$63,000
40	\$1,900	\$76,000
50	\$1,760	\$88,000
60	\$1,500	\$90,000
70	\$1,350	\$94,500
80	\$1,300	\$104,000
90	\$1,280	\$115,200
100	\$1,200	\$120,000
110	\$1,150	\$126,500
120	\$1,100	\$132,000
130	\$1,080	\$140,400
140	\$1,050	\$147,000
150	\$1,020	\$153,000
160	\$990	\$158,400
170	\$960	\$163,200
180	\$930	\$167,400
190	\$910	\$172,900
200	\$890	\$178,000

**Priced per CCU in USD (\$), exclude tax*