



CONTRACT MODIFICATION

Date: November 12, 2024
Contract #: UCPJMU5198
Service: Pharmacy Operations System
Modification #: Two
Issued By: James Madison University Ph: 540-568-3137
Colleen Johnson, Lead Commodity Contract
Officer & Project Manager Fx: 540-568-7935
Contractor: Kalos, Inc.
Attn: Bryan Jakovcic
3418 SE 21st Street, Suite B
Topeka, KS 66607
Contract Administrator: Chris Ouren, University Health Center

Description of Modification Notice:

The attached proposal K-2507 dated 11/08/2024, with including product specific terms and conditions, for one time implementation services and annual subscription to Fusion360 for DSCSA ASN/EPCIS Repository is hereby added to contract UCPJMU5198.

Except as provided herein, all terms and conditions of Contract Number UCPJMU5198 as herefore changed, remain unchanged and in full force and effect.

Kalos, Inc.

By: Mark A. Lawrence
Mark Lawrence

Name (print)
Corporate Counsel 11/12/2024

Title Date Signed

James Madison University

By: Colleen Johnson
Colleen Johnson, CUPO

Name (print)
Lead Commodity Contract Officer & PM 11/12/2024

Title Date Signed



Proposal

Kalos Inc.
3518 SE 21st Street
Topeka KS 66607
United States

Date
Proposal #
Project

11/08/2024
K-2507

Bill To
Attn: Accounts Payable
James Madison University
MSC 5712, 1031 S Main St, Mass ...
Harrisonburg VA 22807
United States

Description	Quantity	Amount
One Time Professional Services Fee Fusion360 Implementation & Client Onboarding	1	350.00
Annual Subscription Fee Fusion360: DSCSA ASN / EPCIS Repository (per location) *3 year initial term	1	1,320.00
Please see subsequent pages of this document for the full statement of work.		

Total \$1,670.00

This quote is an approximation of charges and is not a guarantee of costs for services to be provided by Kalos. Quote is based on initial project information provided by the client and the actual cost may change once project elements are finalized. This quote serves as the minimum charge for the work to be performed. Should the work require more time than is estimated in this quote or should the scope of the work to be performed change, parties will mutually agree to a change order prior to any additional work, then the invoice will be updated to reflect the quoted price plus any additional accepted additional work. This quote is valid for thirty (30) days.

By signing this quote, the client understands and agrees to the terms and conditions detailed herein. And upon signature, the client authorizes Kalos to begin the work described in this quote and agrees to pay the total incurred invoice amount, upon completion. All special instructions and additions relative to this quote summary appear below and are accepted by the parties upon signature. All terms, products, and services requested by the client that are not listed in this quote are subject to additional charges or fees.

Signature: 

Name: Colleen Johnson

Date: 11/12/2024

Client: James Madison University
Requester: Chris Ouren
Date of Request: 11/08/24
Proposal #: K-2507

Scope of Services.

A. Summary of Requested Work

Kalos Inc, a subsidiary of Fusion Capital Management LLC ("Kalos") will provide to James Madison University ("Client") configuration of and support for the Track and Trace solution ("Fusion 360") to ensure compliance with mandates of the Drug Supply Chain Security Act (DSCSA).

B. Detailed Requirements

1. The Fusion 360 solution is comprehensive and tailored to address all 10 DSCSA mandates:
 - a. Validate Product Suppliers and Provide Suppliers Validation by Dispensers
 - b. Receive, Validate, & Store Historical ASN Data and now EPCIS Data
 - c. Quarantine Suspected Illegitimate Drugs in compliance with FDA Guidance as issued in March 2023
 - d. Notify FDA & Trading Partners of Suspect Illegitimate Drugs with Logging Tracked Form 3911 Submission
 - e. Provide Timely Response to Government Authorities and Trading Partners. Response Clock Time Decreasing from 48 Hours to 24 Hours
 - f. ATP Serialization Data Validation. Ensure Dispensers Only Buy and Sell Products Encoded with Product Identifiers (PIs)rec
 - g. ATP Lot Number Data Validation. Verify Every Product at the Product Package Lot # Level, Including the Serialized Numerical Identifier (SNI)
 - h. Integrate ASN/EPCIS Data Across Internal Operating Systems Within Each ATP
 - i. Provide Secure ATP Interoperability of DSCSA Compliance Data Exchange
 - j. Communicate Regulations and Establish Comprehensive Reporting of Enhanced Drug Distribution Security (EDDS) with Interoperable Electronic Tracing of Product at the Package Level in response to Onsite and Remote Inspection Requirements
2. Staff Support and Outsourced Services:
 - a. **Fusion 360 Systems and Services Training/trainer**
 - Kalos will provide monthly one-hour Fusion 360 System Training Sessions and record each session on continuous reel for review and replace the Training Sessions monthly due to anticipated continuation of FDA Guidance Updates.
 - Kalos will also provide monthly one-hour User Workshop [if on your web conference bridge do you have any limitations in number of participants, if you do we will need to offer this twice per month instead].
 - Kalos will provide Pharmacy Team Compliance Audit of, Kalos identified weekly "potential" suspect product examples and processes, to review and denote steps taken by the institution to document their DSCSA Compliance surveillance and compliance.
 - b. **Fusion 360 Systems and Repository Set-Up Fee**
 - c. **Kalos ASN Repository Monitoring and Mgt. Services**
 - d. **Kalos EDDS Configuration, Monitoring & Reporting**

- e. **Kalos EDDS Compliance System Maintenance and Management Updates**
 - f. **Kalos EPCIS Repository Monitoring and Mgt. Services (Includes 340B)**
 - g. **Kalos DSCSA CME Pharmacy Team Courses & Testing:**
 - Kalos conducts DSCSA Compliance CME Programs, Inspection Workshops, FDA Tabletop Audit Simulations. All of which can be provided on a continuous reel, maintained, and updated, and CE Records for 36 months from production date.
 - h. **Federal and State Inspection Preparation and Response Training and Education Programming:**
 - Federal and State Inspection Preparation and Response Training and Education Program and Advisory Services.
 - i. **24/7 Kalos Pharmacists and Operational Management emergency consultants available:**
 - Pharmacists and Operational Management consultants available 24/7 to assist during a scheduled or unscheduled inspection and assistance in preparation of the inspection response documentation after an inspection.
 - j. **Cross-Reference Corrections of ASNs/EPCIS Data:**
 - Rolling 6-year historical Cross-reference of "Amended" ASN/EPCIS corrections of ALL Suppliers errors, omissions, deficiencies by manufacturer by product and by product line.
 - k. **Customized Electronic DSCSA Compliance Standard Operating Procedures:**
 - Customized Electronic DSCSA Compliance Standard Operating Procedures constantly updated to integrate all FDA new guidance and requirement adjustments.
 - l. **Federal and State Licensure Clearinghouse:**
 - Federal and State Licensure Clearinghouse for all Current Suppliers and potential New Suppliers for Client Facilities to Exchange Licensures and Validated Certificates between Authorized Trading Partners through secure 24–48-hour data exchange.
 - m. **24/7 Pharmacists and Operational Management available for "Suspect" and "Illegitimate" product assessment support:**
 - Pharmacists and Operations Management available 24/7 to handle questions regarding potential "Suspect" products and potential "illegitimate" products before notifying Supplier and FDA and upon need to report, Pharmacists and Operational Management will assist in filing the report.
 - n. **Proactive notification of Product Recalls Received by Each Facility:**
 - Proactive notification of Recalls for products received by each individual Client facility and corresponding steps to take to return the product for credit.
 - o. **Product Serialized Codes and Lot Number Clearinghouse (1/2020-present)**
- 3. Step-by-step instructions will be provided for obtaining a GLN # (Global Location Number).
 - 4. Fusion 360 will be accessed through a link to a web application in the Kalos environment. There is not a direct integration between the PMS and Fusion 360 at this time.
 - 5. Client requests for training/maintenance/support requests will be submitted directly through the Kalos help desk.
 - 6. Client will have the ability to manage users and permissions for specific users within the application.
 - 7. Client will have the ability to manage and resolve ASN validation errors through Fusion 360.
 - 8. Real time audit support will be provided during a DSCSA audit.
 - 9. Client data will be stored in Fusion 360. It will be protected and be made available to the Client upon contract termination or expiration (and non-renewal) of a Client's subscription.

Terms and Conditions

Grant of Right to Use. Kalos grants Client a non-exclusive and non-transferable right to access and use Fusion 360.

Support Services. Technical support, help desk, upgrades, updates, bug fixes, and all similar support services for use of Fusion 360 shall be provided to Client solely in accordance with the Service Level Agreement attached hereto as Exhibit A.

INTELLECTUAL PROPERTY.

Product Ownership. Client acknowledges that (i) Fusion 360 and the related documentation are the exclusive property of Kalos and its licensors and (ii) Client has no right to transfer, sublicense or lease Fusion 360.

License Grant & Restrictions. Client is permitted to: (a) display content from Fusion 360 solely for Client's internal business operations, provided such operations will not include service bureau use, outsourcing, renting, or time-sharing of Fusion 360 and (b) copy and use on Client's computer system any object code generated by Fusion 360 for use by the Client. Client is expressly prohibited from modifying, distributing, preparing derivative works of, reverse engineering, reverse assembling, disassembling, or decompiling Fusion 360, any object code generated by Fusion 360, or any part thereof, or otherwise attempting to discover any source code, modifying Fusion 360 in any manner or form, or using unauthorized or modified versions of Fusion 360. Client must agree not to access Fusion 360 for purposes of monitoring its availability, performance, or functionality, or for any other benchmarking or competitive purposes. Client is not conveyed any rights or ownership in Fusion 360, or any source or object code generated by Fusion 360, or any intellectual property rights in Fusion 360, or any code generated by Fusion 360.

Access. Kalos shall provide Client with a unique login identification and password to gain access to Fusion 360. Client is required to keep all identification and password information strictly confidential and will only reveal such information to authorized users. Fusion 360 is subject to a maintenance period each week on Saturday or Sunday between 8:00pm(et) to 2:00am(et) and access to Fusion 360 may be limited or unavailable during such period.

Confidentiality. Client to maintain the confidentiality of Kalos (including third-parties) Confidential Information in the same manner as Client may receive confidential information as a receiving party under the SOW or Parent Terms. In no event shall Client disclose Fusion 360 to any third party which is a competitor of Kalos through the provision of a similar integration platform or related integration services. "Kalos Confidential Information" means all data and information of a confidential nature (including: Fusion 360 source code; documentation including technical, financial, strategic, marketing or product information, plans, and other documents; and Client's data) provided by, or prepared for, Kalos. Confidential Information does not include information: (a) already known or independently developed by the receiving party; (b) already in the public domain through no act of the receiving party; or (c) received by the receiving party from a third party authorized to disclose such information for which the receiving party has no obligations of confidentiality (d) for the avoidance of doubt this agreement and pricing are not Confidential Information.

TERM AND TERMINATION.

The term of Client's subscription rights to access and use Fusion 360 shall be as specified in the SOW and Parent Terms. If the SOW and Parent Terms do not identify a term, the term shall be for one (1) year and may renew for additional one (1) year terms each anniversary thereof by mutual written agreement. The term shall expire or terminate only in (i) accordance with the SOW or Parent Terms or (ii) following thirty (30) days prior written notice, or (iii) in the event of any breach by Client of the terms and conditions hereof related to Fusion 360 or other misuse of Fusion 360, in which case, Kalos may suspend and/or disable Client's access to Fusion 360 without Client's consent and without any liability therefor pending resolution of such breach or misuse or termination of the SOW or Parent Terms.

DISCLAIMERS.

KALOS MAKES NO REPRESENTATIONS OR WARRANTIES TO CLIENT CONCERNING FUSION 360, EXPRESS OR IMPLIED, WHETHER ARISING BY STATUTE OR OTHERWISE IN LAW OR FROM A COURSE OF DEALING OR USAGE OF TRADE, SUCH AS ANY WARRANTY OF ACCURACY, COMPLETENESS, PERFORMANCE, CURRENCY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR TITLE. KALOS DOES NOT WARRANT THAT FUSION 360 WILL BE ERROR-FREE. KALOS WILL HAVE NO OBLIGATIONS TO CLIENT IN THE EVENT CLIENT: (A) DOES NOT PROPERLY MAINTAIN ALL ASSOCIATED EQUIPMENT, SOFTWARE, INTERNET ACCESS, AND ENVIRONMENTAL CONDITIONS IN ACCORDANCE WITH APPLICABLE SPECIFICATIONS AND INDUSTRY STANDARDS; (B) INTRODUCES OTHER EQUIPMENT OR SOFTWARE CREATING AN ADVERSE IMPACT ON FUSION 360, (C) IS IN DEFAULT OF ANY MATERIAL PROVISION SET FORTH HEREIN THESE FUSION 360 TERMS AND CONDITIONS. FUSION 360 MAY BE SUBJECT TO LIMITATIONS, DELAYS, AND OTHER PROBLEMS INHERENT IN THE USE OF THE INTERNET AND ELECTRONIC COMMUNICATIONS, AND KALOS IS NOT RESPONSIBLE FOR ANY DELAYS, DELIVERY FAILURES, OR OTHER DAMAGE RESULTING FROM SUCH PROBLEMS.

LIMITATION OF LIABILITY.

IN NO EVENT SHALL KALOS BE LIABLE FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, PUNITIVE, SPECIAL, OR SIMILAR DAMAGES, SUCH AS DAMAGES FOR LOSS OF PROFITS, LOSS OF GOOD WILL, WORK STOPPAGE, COMPUTER FAILURE OR MALFUNCTION, LOSS OF WORK PRODUCT, WHETHER IN TORT, CONTRACT, OR OTHERWISE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

CLIENT'S INDEMNIFICATION.

Subject to and in addition to the right of indemnification of Kalos under the Parent Terms and to the process therefor, Client agrees to indemnify, defend and hold Kalos and its subsidiaries, affiliates, and assigns, harmless from and against any and all losses arising out of or in connection with a claim, suit, action, or proceeding brought by any third party against Kalos that arises out of or results from a claim by a third-party: (i) alleging that the Client's data or any use of Client's data infringes the intellectual property rights or other rights of a third party or has caused harm to a third party; or (ii) arising out of Client's breach of the Parent Terms or these terms.

Miscellaneous.

1. Kalos Staffing. Unless stated otherwise in writing by Kalos, all Services will be performed remotely by Kalos.
2. Parent Terms. To the extent possible, this SOW shall be incorporated into any master agreement or terms and conditions that were previously or concurrently executed by the Parties ("Parent Terms"). In the event of a conflict between any Parent Terms and this SOW, the terms of this SOW shall control.
3. Third Parties. Kalos may utilize third parties (subcontractors, consultants, vendors, or affiliates) in providing any and all goods or services identified in this SOW. Kalos shall be responsible for ensuring any third-parties used are in compliance with this SOW, Parent Terms, and applicable laws or regulations. Any reference to Kalos herein shall also refer to any third-parties used.
4. Performance of Services. The details of the method and manner for performance of the Services by Kalos shall be under its own sole control, Client being interested only in the results thereof. If Kalos' performance of its Services is prevented or delayed by any act or omission of Client or its agents, subcontractors, consultants or employees, Kalos shall not be deemed in breach of its obligations, withheld payment for Services provided, or otherwise liable for any costs, charges or losses sustained or incurred by Client. ALL SERVICES PROVIDED BY KALOS AND THE DELIVERABLES RESULTING THEREOF ARE PROVIDED AS IS.
5. Client agrees to:
 - a. Cooperate in all matters relating to the Services detailed herein;
 - b. Abide by any and all Kalos and third-party Terms of Use;
 - c. Provide, such access as may reasonably be requested by Kalos for the purposes of performing the Services;
 - d. Respond promptly to any requests by Kalos to provide direction, information, approvals, authorizations or decisions that are reasonably necessary for Kalos to perform Services;
 - e. Provide such materials and/or information as Kalos may request in order to carry out the Services, in a timely manner, and ensure that it is complete and accurate in all material respects;
 - f. back up all data, files and information prior to the performance of any Services and hereby assumes sole responsibility for any lost or altered data, files or information.
6. Relationship of Parties. The relationship between the parties is that of independent contractors. Nothing contained in this SOW shall be construed as creating any agency, partnership, joint venture or other form of joint enterprise, employment or fiduciary relationship between the parties, and neither party shall have authority to contract for or bind the other party in any manner whatsoever. It is also understood and agreed by both Parties that Kalos is under no obligation hereunder to proceed with or to complete any Services hereunder.
7. Commencement of Services is dependent upon Kalos resources allocation and availability at time of signing.
8. The SOW including Terms and Conditions included therein shall be governed in the event of conflict by the Commonwealth Agency Contract Form Addendum to Contractor's Form, dated September 25, 2017, and the JMU Information Technology Services Addendum, dated July 19, 2018, in the event of conflict.

Pricing and Payment.

1. Please see corresponding proposal for the pricing of Services identified in this SOW.
2. Unless stated otherwise by Kalos in the corresponding proposal, all invoices will be due and payable within thirty (30) days of Kalos' transmission date of the invoice to Client. Payments not received within thirty (30) days of invoice transmission to Client will be considered late and will accrue interest, to the extent permitted under law.
3. All amounts due to Kalos under this SOW or otherwise are non-refundable. In the event of cancellation service fees already performed to the date of cancellation will be invoiced and due for payment.
4. Hours quoted in the corresponding proposal have been identified as the minimum amount necessary to complete the services as defined herein. It is not a fixed, not to exceed amount, and this initial estimate shall be updated, only by mutual written agreement between parties, to reflect additional hours needed, where applicable.

Change Orders.

1. SOW may only be modified in writing and when signed by authorized representatives of both parties.
2. Services not included in this SOW are out of scope and subject to a separate price proposal issued by Kalos to Client for approval.
3. Requests for additional development or enhancements not included in this SOW shall be documented in writing by Client and submitted to Kalos' assigned project manager. Kalos will assess the requested change and consider the prioritization, estimated work effort, cost, resource availability, and impact on the project completion timeline.

Signatures on next page



STATEMENT OF WORK (SOW)

Client Sign-Off

By: Colleen Johnson

Name: Colleen Johnson

Title: Lead Commodity Contract Officer & PM

Date: 11/12/2024

Kalos Sign-Off

By: Mark A. Lawrence

Name: Mark A. Lawrence

Title: Corporate Counsel

Date: 11/12/2024

SOW

EXHIBIT A**Service Level Agreement for FUSION 360 Software Maintenance and Client Support Services****Support Services Section 1: FUSION 360 SOFTWARE MAINTENANCE PROVISIONS**

The following technical and functional improvements may be issued periodically by Kalos to improve Fusion 360 and will be seamless for Clients and notices will be sent to Clients who have embedded Fusion 360 into their operations with these defined terms:

- 1.1 Kalos Product Prior Releases will be archived for Client Questions on programming history of the system upon such questions being submitted to Kalos from Client. Previous Sequential Release is a prior release of Fusion 360, database, or documentation (usually delivered via an update) in a similar operating environment. Kalos will support a Previous Sequential Release for a period of twelve (12) months after release of the subsequent release. Kalos shall in its sole discretion distinguish among upgrades, options and new products.
- 1.2 Updates are repairs or replacements of source, object, or executable code versions of Fusion 360, the database, and documentation to remedy an error. Updates are typically issued when errors cannot be corrected using workarounds.
- 1.3 Upgrades are published revisions to Fusion 360, the database and documentation meant primarily to enhance existing features or functionality of Fusion 360 and is neither an option (as hereinafter defined) or a New Product (as hereinafter defined) for which Kalos charges additional fees. Options and New Products are technical or functional releases of Fusion 360, the database and documentation that provide capabilities outside the original intent and/or scope of Fusion 360. A separate fee may be charged upon Client consent at the discretion of the Client for each Option or New Product, and for any hardware required in connection with each Upgrade, Option or New Product.
- 1.4 Workarounds are changes in the procedures followed or data supplied to avoid an Error (as described in Section 5, below) without significantly impairing performance of Fusion 360 and the database.

Section 2: PRIORITY LEVEL OF ERRORS.

An Error means any failure of Fusion 360 or the database to function materially in accordance with its documentation. Kalos shall reasonably determine the priority level of Errors in accordance with the following protocols:

- 2.1 Level 1 (Critical) means an Error that: (1) renders Fusion 360 inoperative; or (2) causes the Fusion 360 to fail catastrophically. If a Level 1 Error is identified, Kalos will promptly initiate the following procedures: (1) assign a specialist to attempt to correct the Error; (2) provide ongoing communications to the system administrator on the status of the corrections; and (3) take reasonable measures to provide a Workaround, Update, or Upgrade.
- 2.2 Level 2 (Urgent) means an Error that affects performance of Fusion 360 but, does not prohibit Client's use of Fusion 360. If a Level 2 Error is identified, Kalos will promptly initiate the following procedures: (1) assign a Kalos specialist to attempt to correct the Error; (2) provide escalation procedures as reasonably determined by Kalos. Kalos will exercise commercially reasonable efforts to include the Update for the Error in the next Fusion 360 release.
- 2.3 Level 3 (Basic) means an Error that causes only a minor impact in the use of Fusion 360. Kalos may include the Update for the Error in the next Fusion 360 release.

Section 3: SUPPORT SERVICES.

Kalos provides a standard support package in accordance with this Support Agreement. This package covers the maintenance and support of Fusion 360, the database and documentation. Under no circumstances will Kalos provide Support Services for hardware, network or third-Party software not purchased through Kalos. This includes the re-installation, re-configuration, or re-setup of Fusion 360 on such hardware because of hardware failure, third-Party software failure, or network re-configuration.

Standard Support Plan. Web-based ticketing system monitoring provided between 8:00am to 5:00pm EASTERN Time (EST/EDT), Monday through Friday, excluding national holidays. Scheduled system upgrades between 9:00am to 6:00pm EASTERN Time (EST/EDT), Monday to Friday, excluding national holidays, subject to staff availability.