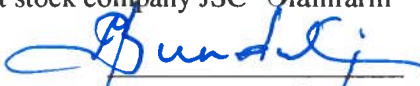




Confirm
Joint stock company JSC "Olainfarm"


Chairman of the Board Juris Bundulis
Olaime, May 27, 2024

Procurement procedure
ACQUISITION OF THE REGULATORY INFORMATION MANAGEMENT (RIM) SYSTEM
RULES

Procurement identification No 2024/05/3

1. GENERAL INFORMATION

1.1. Customer information

Name	JSC "Olainfarm"
Address	Rupnicas Street 5, Olaine, Olaine Nov., Latvia, LV-2114
Registration No.	40003007246
Contact person for technical issues	Project Manager of Information systems Division of Information systems Department Maria Rakova, phone No: +371 25632208, Email address: marija.rakova@olainfarm.com
Contact person for exchange of information	Project manager of Procurement and Project Department Signe Martinkrista, phone No.: +371 20208363, email address: signe.martinkrista@olainfarm.com

1.2. Subject-matter of procurement

- 1.2.1. **The object of the procurement is the acquisition** (hereinafter - procurement) **of the Regulatory information management (RIM) system** (hereinafter – RIM system).
- 1.2.2. Procurement shall be organised in accordance with Cabinet of Ministers Regulation No. 104 of February 28, 2017 "Regulation regarding the Procurement Procedure and the procedures for the application thereof for projects financed by the commissioning party".
- 1.2.3. Implementation/establishment of RIM system shall be performed in accordance with the information indicated in Annex No. 1 "Technical Specification" to the procurement rules, the address of delivery shall be: Rupnicas Street 5, Olaine, Olaine Nov., Latvia, LV-2114.
- 1.2.4. Where Annex No. 1 "User requirements specification" to the procurement rules indicates a specific manufacturer or a specific manufacturer's solution, the applicant may offer an analogue or equivalent product of another manufacturer or a functionally equivalent product with an alternative technological solution meeting the specified parameters. The commissioning party may request an assessment of analogous solutions.

1.3. Submission of offer

- 1.3.1. The offer shall be submitted by 11th June 2024, 16:30 p.m. in person or by post to: Rupnicas Street 5, Olaine, Olaines county, Latvia, LV-2114 or to an electronic mail address (signed with an electronic signature): signe.martinkrista@olainfarm.com
- 1.3.2. If the offer is sent by post, the tenderer shall be liable and bear the risk of the commissioning party receiving the offer within the specified time period.
- 1.3.3. When submitting the offer electronically, the tenderer is entitled to sign all documents as one set with one secure electronic signature.

1.4. Validity of the offer

- 1.4.1. The offer submitted by the tenderer shall be valid, i.e. binding to the tenderer and the contracting authority at least one month, but preferable until September 30th 2024, which is also the deadline for the execution of the subject matter of this procurement. The tenderer may set a longer period of validity for the offer.
- 1.4.2. If for objective reasons the date referred to in Paragraph 1.4.1 cannot be determined as the final term for performance of the procurement contract, the commissioning party may request in writing an extension of the term of validity of the offer. If the tenderer agrees to extend the term of validity of the offer without changing the content and price of his or her offer, he or she shall notify the commissioning party thereof in writing.

1.5. Design of offer

- 1.5.1. Together with the offer prepared in accordance with the requirements indicated in Annex No.1 "User requirements specification", the applicant shall submit completed forms, which are appended to the procurement rules - Annex No. 2 "Application for participation in procurement" and Annex No. 3 "Confirmation".

- 1.5.2. The offer shall be developed and drawn up in accordance with the requirements of the laws and regulations of the Republic of Latvia, including the requirements of the Law on legal force of documents, the Law on electronic documents (if applicable) and Cabinet of Ministers Regulation No. 558 of September 4, 2018 "Procedures for the Development and Drawing up of documents".
- 1.5.3. Where an offer is submitted in printed/paper format, the following shall be observed:
- 1.5.3.1. the offer shall be submitted bound in one document, with successive numbered pages, the ends of threads shall be glued on the back of the last page, the sticker shall bear an indication of the number of pages numbered and wired in the document, a certification regarding the correctness of copies of the documents, the name of the applicant, the date of preparation of the offer, the name of the author of the document, the place where the document was drawn up and the signature of the official of the applicant or his or her authorised person (appending the authorisation);
- 1.5.3.2. 2 (two) copies of the offer must be submitted: 1 (one) original and 1 (one) copy. The first page of the original shall bear the word "ORIGINAL" and the first page of the copy shall bear the word "COPY". The original and copy of the offer shall be placed in one envelope, on which the following shall be indicated: the name and address of the customer; the name and address of the applicant; a check mark: "Acquisition of the regulatory information Management (RIM) system";
- 1.5.3.3. the documents contained in the offer must be clearly legible, without correction. If corrections have been made, they shall be subject to explanation and approved by the signature of the authorised person.
- 1.5.4. When preparing the offer for submission by e-mail, the tenderer shall observe that:
- 1.5.4.1. offer documents must be prepared in separate electronic documents with standard office software tools in a readable format (such as Microsoft Office format or PDF format);
- 1.5.4.2. the offer documents of the applicant shall be signed with a secure electronic signature and the signature shall contain a time stamp;
- 1.5.4.3. email name: "Acquisition of regulatory information Management (RIM) system".
- 1.5.5. The offer documents shall be signed by the representative of the applicant with the right of signature established in the Enterprise Register of the Republic of Latvia or in an appropriate register abroad or by a person authorised by such person, attaching a duly drawn up authorisation and a document certifying the right of signature (representation) of the issuer of the authorisation. The mandate must specify precisely the extent of the rights and obligations conferred on the authorised person.
- 1.5.6. Offers submitted to the commissioning party shall not be returned to the applicants.

2. INFORMATION ON THE SUBJECT MATTER OF THE PROCUREMENT

2.1. Price

- 2.1.1. The total price of the RIM system in euro without value added tax (hereinafter - VAT) shall be indicated in the offer, dividing in following positions:
- 2.1.1.1. costs of implementation, validation, integration and migration;
- 2.1.1.2. the purchase price of the RIM system license;
- 2.1.1.3. subscription costs for 5 years on the basis of offered price.
- 2.1.2. the price shall include costs of installation and start-up, validation work and staff instruction/training in accordance with the requirements specified in the Annex No. 1.

2.2. Delivery deadlines and payment conditions

- 2.2.1. The supply, installation, validation and staff training of the system shall be carried out in accordance with the technical and functional requirements of the procurement subject in accordance with the conditions of the contract/contracting party as soon as possible, but no later than by March 31st 2025. Due to objective circumstances, the

time period may be extended by agreement between tenderer and commissioning party.

2.2.2. The terms of payment will be laid down in the contract.

3. SELECTION CRITERIA FOR THE APPLICANT

- 3.1. The selection requirements of the tenderer shall be mandatory for all tenderers wishing to obtain the contract.
- 3.2. The tenderer may be any legal person, as well as an association of such suppliers in any combination thereof, which offers to supply and install the necessary RIM system and has submitted an offer for procurement in accordance with the requirements of these rules.
- 3.3. The applicant is a supplier or an association of suppliers registered in accordance with the procedures laid down in laws and regulations (if such registration is necessary in accordance with the laws and regulations in force).
- 3.4. The applicant may not be registered in any of the States and territories referred to in Cabinet of Ministers Regulation No. 333 of June 27, 2023 "List of low tax or duty free States and territories".
- 3.5. The applicant may not have insolvency proceedings declared, may not have suspended economic activities, or may not have commenced liquidation or litigation regarding bankruptcy proceeding/legal protection proceeding.
- 3.6. The applicant may not be in a conflict of interest with the commissioning party in accordance with the provisions of regulatory enactments. No participant, Member, Member of the Council or board of directors, procurator, commercial trustee or employee of the applicant is a participant (shareholder) of the commissioning party, Member, Member of the Council or board of directors, relative of any of the referred to persons up to the second degree of kinship, spouse or brother-in-law up to the first degree of affinity, or procurator or commercial trustee of the commissioning party, etc.
- 3.7. The tenderer must be able to ensure the supply of the procurement object in accordance with the technical and functional requirements of the procurement subject.
- 3.8. Where an offer is submitted by an association of suppliers, the package of documents to be submitted must be accompanied by a cooperation agreement which stipulates that all members of the association of suppliers are jointly and individually responsible for carrying out the work specified in the procurement contract, and an authorisation for the main participant to represent the association of suppliers in the procurement and to sign the tender documents on behalf of the participants. The co-operation agreement must necessarily stipulate which legal persons have merged in the supplier association, the amount of work to be performed by each Member of the supplier association, a certification that, if the supplier association is determined to be the winner of the procurement, the supplier association will register the partnership or enter into a partnership agreement in accordance with the procedures laid down in the laws and regulations of the Republic of Latvia, in both cases agreeing that at least the members of the association on whose economic and financial capacity the supplier is based and who will be financially responsible for the performance of the contract shall assume joint and several liability.
- 3.9. The tenderer must submit together with the offer:
 - 3.9.1. supporting documentation to represent the manufacturer, if applicable;
 - 3.9.2. documents certifying the training of the employees of the applicant, which certify the ability of the employee to perform installation, validation and staff instruction/training of the system;
 - 3.9.3. other necessary documents indicated in Annex No. 1 - certificates, copies of attestations, etc.

4. PROCUREMENT CONTRACT

- 4.1. The commissioning party shall enter into a procurement contract with the selected tenderer on the basis of the offer of the tenderer. The contract shall be concluded on the basis of the technical specification, prices and other conditions specified in the offer.

5. RIGHTS AND OBLIGATIONS OF THE APPLICANT

5.1. The applicant has the right to:

- 5.1.1. request additional information within the framework of procurement;
- 5.1.2. amend or withdraw the offer submitted by the deadline for submission of offers.

5.2. Obligations of the applicant:

- 5.2.1. prepare an offer in accordance with the requirements of these rules;
- 5.2.2. to provide true information;
- 5.2.3. when submitting personal data to the commissioning party, the applicant shall ensure that the submission of such personal data complies with the requirements arising from Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 “On the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General data Protection Regulation) (text with EEA relevance)”;
- 5.2.4. cover all costs related to the preparation and submission of the offer, irrespective of the procurement results.

6. OTHER INFORMATION

- 6.1. The following annexes have been added to the procurement rules:
- 6.1.1. Annex 1 — “User requirements specification”;
 - 6.1.2. Annex 2 — “Application for participation in procurement”;
 - 6.1.3. Annex 3 — “Confirmation”.

“Acquisition of the Regulatory information management (RIM) system” rules

Technical specification - Regulatory Information Management (RIM) system requirements

1. Purpose

The purpose of is to describe and maintain user requirements for the RIM system. The user requirements described in this document will provide documented evidence that the chosen solution works for the intended use with a sufficient level of testing to support this fact.

Employees of JSC “Olainfarm” **Regulatory Affair department** will use the computerized system described in this document.

When describing computerized system requirements, JSC “Olainfarm” employees should follow Latvian state regulations, EMA Article 57, FDA 21 CFR Part 11, EudraLex vol 4 Annex 11 and GAMP 5 (Good Automated Manufacturing Practices) guidelines.

2. Business scope and objectives

- a) Ensure compliance with the requirements of the IDMP standard.
- b) To get a centralized software platform that simplifies Regulatory industry's product application and registration lifecycle tracking.
- c) Enabling end-to-end tracking of Regulatory activities related to different kinds of products.
- d) Organize the work throughout the lifespan of the product development and medicine marketing.
- e) Improvement Regulatory business planning and organizes the Product Registration process to track and manage all Regulatory activities and life cycle.
- f) Avoidance of duplicated effort and streamlines product applications and submission operations.

3. The anticipated business benefits derived from implementing Regulatory information Management system in terms of cost, productivity, time to market, harmonization and compliance are:

- a) Reduces effort and timelines to obtain Regulatory compliance concerning products and Regulatory organizations.
- b) Delivers clear oversight of lifecycle compliances.
- c) Effectively manages the post-submission queries raised by Health Authorities.
- d) Helps manage commitments, variations, and obligations easily.
- e) Tracks marketing authorization and lifecycle applications.
- f) Tracks dossiers for variation in products and Regulatory organizations.
- g) Tracks variations, reviews of records, and product information.
- h) Accomplishes Regulatory mandates of electronic systems, such as FDA 21 CFR Part 11.
- i) Improves efficiency and collaboration with increased speed and quality of the submission.

4. Compliance

- EMA Article 57 & IDMP compliance (Q2 2025 - EMA set deadlines for DCP/NP registered products).



5. Glossary

GMP	Good Manufacturing Practices
FDA 21 CFR 11	Code for US Food and Drug Administration Federal Regulations: Electronic Records/Electronic Signature Rule
EMA Article 57	European Medicines Agency data basis - Data submission on authorised medicines
EudraLex vol 4 Annex 11	The rules governing medicinal products in the European Union
URS	User Requirement Specification
PDF	Portable Document Format
RIM system	Regulatory information management system
IDMP	Identification of Medicinal Products
XML	Extensible Markup Language
EAEU	Eurasian Economic Union
GAMP	Good automated manufacturing practice
Validation	The process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in testing and then production maintains the desired level of compliance at all stages.
SoW	Statement of Work
SLA	Service Level Agreement
IT	Information Technology
DCP/NP	Decentralized procedure / National procedure

6. Main requirements of RIM system:

- must allow to use at least 30 JSC “Olainfarm” employees (scalable up to 50);
- should have cloud and/or on-premise implementation scenario with web and local application;
- should meet GMP, FDA 21 CFR Part 11, EudraLex vol 4 Annex 11, EMA Article 57 & IDMP requirements;
- should have Product data management;
- should have Product registration management;
- should have Product registration lifecycle management;



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- g) should have submission compilation tool or must allow make integration with EDMS myProcess;
- h) should have submission publishing tool or must allow make integration with EDMS myProcess;
- i) should have submission management tool or must allow make integration with EDMS myProcess;
- j) should have easy configurable dashboard & reporting solution.
- k) supplier should provide SoW for optimal implementation approach.
- l) supplier should organize project management activities for project implementation (e.g. planning, monitoring, tracking, communication).
- m) supplier should be capable to plan and execute system validation activities (IQ, OQ), provide supporting documentation for core modules, additional modules and change control process;
- n) supplier should organize data transformation of approximately 280 submissions (1330 sequences) into XEVMPD/IDMP standard.
- o) supplier should be able to organize courses and training about product and modules;
- p) supplier should have 24/7 support team and allow future systems updates compatibility with existing version;
- q) supplier should made integration between RIM system and JSC "Olainfarm" current EDMS myProcess for data transfer and publication activities.
- r) supplier should have to migrate 100 + up to 200 EU and 300+ up to non-EU products from current Olainfarm EDMS to RIM system.
- s) supplier should to perform migration workshop to define the best migration approach and provide a more exact estimate for a full migration.
- t) supplier should provide migration verification and supporting documentation.
- u) supplier should provide at least two environments – production and validation. If migration is necessary, so migration environment as well.
- v) supplier should to perform a GAP analysis in order to identify the differences between JSC "Olainfarm" current processes and its desired future state. Supplier will also define the best configuration approach and provide a more exact estimate for a configuration.
- w) supplier should have incident management tool and provide SLA agreement after Go_Live.

THE APPLICATION
on participation in procurement
“ _____ ”

Applicant _____, unified
registrations
(name)
No. _____,

_____ (given name and surname of authorised person)

If the tenderer is an association of suppliers:

1.1. persons forming an association of suppliers (name, Reg. No., legal address):

_____;

1.2. the level of responsibility of each person _____.

with the submission of this application:

1. Apply to participate in the procurement “Acquisition of the Regulatory information management (RIM) system” (hereinafter - procurement).
2. Proposes to perform the execution of the procurement object in accordance with the specified time schedule, the procurement regulations and the annexes thereto.
3. Undertakes to comply with the procurement requirements, agrees to comply with all the parameters specified in the procurement technical specification in conformity with all the requirements specified in the procurement regulations, as well as in conformity with the requirements of the laws and regulations in force in the Republic of Latvia.
4. Certify that there is the necessary professional, technical and organisational capacity, financial resources, facilities, personnel and other physical infrastructure necessary for the execution of the procurement object.
5. Agrees with the provisions of the Procurement Regulation and the appendices attached thereto and undertakes to enter into a procurement contract and fulfil all the conditions of the procurement contract, if the commissioning party chooses this offer.
6. Certify that all the information provided is true, including the exact contact details provided.
7. Contact:

Applicant's registered office:

Actual address of the applicant:

Contact:

Phone No.:

Email:

Bank name:

Bank address:

Bank Code:

Account number:

(position of manager or authorised person) (signature) (transcript of signature)

_____ seal
(date)

CONFIRMATION¹

Hereby certify that _____ (name of the undertaking), unified registration No.
_____:

has not been declared insolvent, its economic activities have not been suspended or suspended,
no bankruptcy/insolvency proceedings have been initiated.

(position of manager or authorised person) (signature) (transcript of signature)

_____ seal
(date)

¹If necessary, the Confirmation shall be prepared and signed by the subcontractors affiliated by the tenderer.