

Tender Specifications RWA23002-10008

Public service contract for:

**“Technical Assistance for Capacity Building and
On-site Training of Good Storage and
Distribution Practices (GSDP) Inspectors”**

Negotiated Procedure without Prior Publication

Country: RWANDA

LOMESU Project - RWA2300211

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1 General provisions

1.1 Derogations from the General Implementing Rules

Section 4, '*Specific contractual and administrative conditions*' of these Tender Specifications (CSC/Cahier Spécial des Charges) holds the specific administrative and contractual provisions that apply to this public procurement contract as a derogation of the Royal Decree of 14.01.2013 (GIR) or as a complement or an elaboration thereof.

These tender specifications do not derogate from the "GIR".

1.2 Contracting authority

The contracting authority of this public procurement contract is Enabel, the Belgian Agency for international cooperation, public-law company with social purposes, with its registered office at Rue Haute 147, 1000 Brussels in Belgium (enterprise number 0264.814.354, RPM/RPR Brussels).

This tender is organised by Enabel in Rwanda, acting under a mandate from the European Union to implement projects in health, agriculture, agroforestry, and urbanisation, thereby contributing to Rwanda's socio-economic development. All activities and commitments described in this document are undertaken within the framework of that mandate.

For the purpose of this procurement contract, Enabel shall be represented by Ms. Virginie HALLET, Country Director of Enabel in Rwanda and in Tanzania, or, where applicable, by any other person(s), duly mandated in accordance with Enabel's mandate structure, to represent Enabel vis-à-vis third parties and to award public procurement contracts.

1.3 Institutional setting of Enabel

The general framework of reference in which Enabel operates is:

- The Belgian Law on Development Cooperation of 19 March 2013¹;
- The Belgian Law of 21 December 1998 establishing the Belgian Technical Cooperation as a public-law company²;
- The Belgian Law of 23 December 2017 changing the name of the Belgian Technical Cooperation and defining the missions and functioning of Enabel, the Belgian development agency, published in the Belgian Official Gazette on 11 December 2017.

The following initiatives are also guiding Enabel in its operations: We mention as main examples:

- In the field of international cooperation: the United Nations Sustainable Development Goals and the Paris Declaration on the harmonisation and alignment of aid;
- In the field of the fight against corruption: the Law of 8 May 2007 approving the United Nations Convention against Corruption, adopted in New York on 31 October 2003³, as well as the Law of 10 February 1999 on the Suppression of Corruption transposing the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions;
- In the field of Human Rights: the United Nations' Universal Declaration of Human Rights (1948) as well as the 8 basic conventions of the International

¹ Belgian Official Gazette of 30 December 1998, of 17 November 2001, of 6 July 2012, of 15 January 2013 and of 26 March 2013.

² Belgian Official Gazette of 1 July 1999.

³ Belgian Official Gazette of 18 November 2008.

Labour Organisation⁴ on Freedom of Association (C. n°87), on the Right to Organise and Collective Bargaining (C. n°98), on Forced Labour (C. n°29 and 105), on Equal Remuneration and on Discrimination in Respect of Employment (C. n°100 and 111), on Minimum Age for Admission to Employment (C. n°138), on the Prohibition of the Worst Forms of Child Labour (C. n°182);

- In the field of environmental protection: The Climate Change Framework Convention in Paris, 12 December 2015;
- The first Management Contract concluded between Enabel and the Belgian federal State (approved by the Royal Decree of 17.12.2017, Belgian Official Gazette 22.12.2017) that sets out the rules and the special conditions for the execution of public service tasks by Enabel on behalf of the Belgian State.
- Enabel's Code of Conduct of January 2019, Enabel's Policy regarding sexual exploitation and abuse of June 2019 and Enabel's Policy regarding fraud and corruption risk management of June 2019;

1.4 Rules governing the procurement contract

- The following, among other things, applies to this public procurement contract:
- The Law of 17 June 2016 on public procurement contracts⁵;
- The Law of 17 June 2013 on justifications, notification and legal remedies for public procurement contracts and certain procurement contracts for works, supplies and services⁶;
- The Royal Decree of 18 April 2017 on the award of public procurement contracts in the classic sectors⁷;
- Royal Decree of 14 January 2013 establishing the General Implementing Rules for public procurement contracts and for concessions for public works⁸;
- Circulars of the Prime Minister with regards to public procurement contracts.
- Enabel's Policy regarding sexual exploitation and abuse – June 2019;
- Enabel's Policy regarding fraud and corruption risk management – June 2019;
- Legislation with regards to sexual harassment at the workplace or equivalent;
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation – 'GDPR'), and repealing Directive 95/46/EC;
- Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

All Belgian regulations on public contracts can be consulted on www.publicprocurement.be; Enabel's Code of Conduct and the policies mentioned above can be consulted on Enabel's website via <https://www.enabel.be/content/integrity-desk>.

1.5 Definitions

The following definitions apply to this procurement contract:

⁴ <http://www.ilo.org/ilolex/french/convdisp1.htm>.

⁵ Belgian Official Gazette 14 July 2016.

⁶ Belgian Official Gazette of 21 June 2013.

⁷ Belgian Official Gazette 9 May 2017.

⁸ Belgian Official Gazette 27 June 2017.

The tenderer/bidder: An economic operator submitting a tender;

The contractor/ service provider/consultant: The tenderer to whom the procurement contract is awarded;

The contracting authority: Enabel, represented by the Country Director of Enabel in Rwanda and/or any other person(s) duly mandated in accordance with Enabel's mandate structure to represent Enabel vis-à-vis third parties;

The tender/bid: Commitment of the tenderer to perform the procurement contract under the conditions that he has submitted;

Days: In the absence of any indication in this regard in the Tender Specifications and the applicable regulations, all days should be interpreted as calendar days;

Procurement documents: Tender Specifications including the annexes and the documents they refer to;

Technical specifications: A specification in a document defining the characteristics of a product or a service, such as the quality levels, the environmental and climate performance levels, the design for all needs, including accessibility for people with disabilities, and the evaluation of conformity, of product performance, of the use of the product, safety or dimensions, as well as requirements applicable to the product as regards the name by which it is sold, terminology, symbols, testing and test methods, packaging, marking or labelling, instructions for use, the production processes and methods at every stage in the life cycle of the supply or service, as well as the evaluation and conformity procedures;

Variant: An alternative method for the design or the performance that is introduced either at the demand of the contracting authority, or at the initiative of the tenderer;

Option: A minor and not strictly necessary element for the performance of the procurement contract, which is introduced either at the demand of the contracting authority, or at the initiative of the tenderer;

Inventory: The procurement document which splits up the performance in different items and specifies the quantity or the method to determine the price for each of them;

General Implementing Rules (GIR): Rules laid down in the Royal Decree of 14.01.2013 establishing the General Implementing Rules for public procurement contracts and for concessions for public work;

The Tender Specifications (Cahier spécial des charges/CSC): This document and its annexes and the documents it refers to;

Corrupt practices: The offer of a bribe, gift, gratuity or commission to any person as an inducement or reward for performing or refraining from any act relating to the award of a procurement contract or performance of a procurement contract already concluded with the contracting authority;

Litigation: Court action;

Subcontractor in the meaning of public procurement regulations: The economic operator proposed by a tenderer or contractor to perform part of the contract. The subcontractor is understood as the economic operator with the capacity which the applicant or tenderer relies upon or to whom he entrusts all or part of his engagements;

Controller in the meaning of the GDPR: the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data;

Sub-contractor or processor in the meaning of the GDPR: a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;

Recipient in the meaning of the GDPR: a natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not;

Personal data: any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

1.6 Processing of personal data by the contracting authority and confidentiality

1.6.1 Processing of personal data by the contracting authority

The contracting authority undertakes to process the personal data that are communicated to it in response to the Call for Tenders with the greatest care, in accordance with legislation on the protection of personal data (General Data Protection Regulation, GDPR). Where the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data contains stricter provisions, the contracting authority will act in accordance with said law.

1.6.2 Confidentiality

The tenderer or contractor and Enabel are bound to secrecy vis-à-vis third parties with regards to any confidential information obtained within the framework of this public contract and will only divulge such information to third parties after receiving the prior written consent of the other party. They will disclose this confidential information only among appointed parties involved in the assignment. They guarantee that said appointed parties will be adequately informed of their obligations in respect of the confidential nature of the information and that they shall comply therewith.

PRIVACY NOTICE OF ENABEL: Enabel takes your privacy serious. We undertake to protect and process your personal data with due care, transparently and in strict compliance with privacy protection legislation.

See also: <https://www.enabel.be/content/privacy-notice-enabel>

1.7 Deontological obligations

Any failure to comply with one or more of the deontological clauses may lead to the exclusion of the candidate, tenderer or contractor from other public procurement contracts for Enabel.

For the duration of the procurement contract, the contractor and his staff respect human rights and undertake not to go against political, cultural or religious customs of the beneficiary country. The tenderer or contractor is bound to respect fundamental labour standards, which are internationally agreed upon by the International Labour Organisation (ILO), namely the conventions on union freedom and collective bargaining, on the elimination of forced and obligatory labour, on the elimination of employment and professional discrimination and on the abolition of child labour.

In accordance with Enabel's Policy regarding sexual exploitation and abuse, the contractor and his staff have the duty to behave in an irreproachable manner towards the beneficiaries of the projects and towards the local population in general. They must abstain from any acts that could be considered a form of sexual exploitation or abuse and they must abide by the basic principles and guidelines laid down in this policy.

Any attempt of a candidate or a tenderer to obtain confidential information, to proceed to illicit arrangements with competitors or to influence the evaluation committee or the contracting authority during the investigation, clarification, evaluation and comparison of tenders and candidates procedure will lead to the rejection of the application or the tender.

Moreover, in order to avoid any impression of risk of partiality or connivance in the follow-up and control of the performance of the procurement contract, it is strictly forbidden to the contractor to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to agents of the contracting authority who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the procurement contract, regardless of their hierarchical rank.

The contractor of the procurement contract commits to supply, upon the demand of the contracting authority, any supporting documents related to the performance conditions of the contract. The contracting authority will be allowed to proceed to any control, on paperwork or on site, which it considers necessary to collect evidence to support the presumption of unusual commercial expenditure. Depending on the gravity of the facts observed, the contractor having paid unusual commercial expenditure is liable to have its contract cancelled or to be permanently excluded from receiving funds.

In accordance with Enabel's Policy regarding sexual exploitation and abuse of June 2019 and Enabel's Policy regarding fraud and corruption risk management complaints relating to issues of integrity (fraud, corruption, etc.) must be sent to the Integrity desk through the <https://www.enabelintegrity.be> website.

1.8 Applicable law and competent courts

The procurement contract must be performed and interpreted according to Belgian law.

The parties commit to sincerely perform their engagements to ensure the good performance of this procurement contract.

In case of litigation or divergence of opinion between the contracting authority and the contractor, the parties will consult each other to find a solution.

If agreement is lacking, the Brussels courts are the only courts competent to resolve the matter.

2 Subject-matter and scope of the procurement contract

2.1 Type of procurement contract

This procurement contract is a services procurement contract.

2.2 Subject-matter of the procurement contract

This services procurement contract concerns the “**Technical Assistance for Capacity Building and On-site Training of Good Storage and Distribution Practices (GSDP) Inspectors**”, in accordance with the conditions set out in these Tender Specifications.

2.3 Lots

The procurement contract consists of a single, indivisible lot, since the services and components are interdependent and require seamless integration, consistent technical and quality standards, and a single point of accountability to ensure efficiency, quality, and cost-effectiveness.

A tender for part of a lot is inadmissible.

2.4 Items

The procurement contract consists of one single item with the tasks described in the technical specifications (See also below **section 5 of the tender documents**).

These tasks are pooled and form one single procurement contract.

2.5 Term of the procurement contract⁹

The contract shall enter into force upon notification of the award decision and shall have a **total duration of two (2) months**.

2.6 Variants

Variants are not permitted.

2.7 Option

Options are not permitted.

2.8 Quantity

Quantities (person days) are determined in the technical specifications (**See section 5 of the tender specifications**).

⁹ Please note: term of the procurement contract not to be confused with performance period.

3 Subject-matter and scope of the procurement contract

3.1 Award procedure

Negotiated Procedure without Prior Publication in application of Article 42 of the Law of 17 June 2016.

3.2 Publication

3.2.1 Official publication

This procurement contract is published on the Enabel website (www.enabel.be).

3.3 Information

The awarding of this procurement contract is coordinated by **Mr. Evariste SIBOMANA**, evariste.sibomana@enabel.be.

Throughout this procedure all contacts between the contracting authority and the (prospective) tenderers about this procurement contract will exclusively pass through this service / this person. (Prospective) tenderers are prohibited to contact the contracting authority in any other way with regards to this contract, unless otherwise stipulated in these Tender Specifications.

Until 10 calendar days before the final date for receipt of the tenders, candidate-tenderers may ask questions about these Tender Specifications and the procurement contract.

Questions will be in writing to:

Mr. Evariste SIBOMANA

(evariste.sibomana@enabel.be)

with copy to

Mr. Antoine GATERA

(antoine.gatera@enabel.be)

and

Mr. Réal NIMPAGARITSE

(real.nimpagaritse@enabel.be)

and they will be answered in the order received. The complete overview of questions asked will be available at the address mentioned above at the latest 7 days before the deadline for submission of bids

Until the notification of the award decision no information will be given about the evolution of the procedure.

The procurement documents can be consulted free of charge at the following internet address: www.enabel.be. To be able to submit a tender in full knowledge of the facts, the tenderer may visit the website.

The tenderer is supposed to submit his tender after reading and taking into account any corrections made to the contract notice or the Tender Specifications that are published in the Belgian Public Tender bulletin or that are sent to him by e-mail. To do so, when the tenderer has downloaded the Tender Specifications, it is strongly advised that he gives his coordinates to the public procurement administrator mentioned above and requests information on any modifications or additional information.

In accordance with Article 81 of the Royal Decree of 18 April 2017, the tenderer is required to report immediately any gap, error or omission in the procurement documents that precludes him from establishing his price or compare tenders, within ten days at the latest before the deadline for receipt of tenders.

3.4 Tender

3.4.1 Data to be included in the tender

The tenderer must use the tender form in annexe. In case he does not use this form, he is fully responsible for the perfect concordance between the documents he has used and the form.

The tender and the annexes to the tender form are drawn up in English.

By submitting a tender, the tenderer automatically renounces to his own general or specific sales conditions, even if these are mentioned in any of the annexes to his tender.

The tenderer clearly designates in his tender which information is confidential and/or relates to technical or business secrets and may therefore not be divulged by the contracting authority.

3.4.2 Period the tender is valid

The tenderers are bound by their tender for a period of **120 days** from the deadline for the receipt date.

The validity of the tender will be negotiated, if the deadline stated above is overrun.

3.4.3 Determination of prices

All prices given in the tender form must obligatorily be quoted in EUROS (**see also below art. 6.3– Price Form**).

This procurement contract is a price-schedule contract, i.e. a contract in which only the unit prices are lump-sum prices. The price to be paid will be obtained by applying the unit prices mentioned in the inventory to the quantities actually performed.

In accordance with Article 37 of the Royal Decree of 18 April 2017, the contracting authority may for the purpose of verifying the prices carry out an audit of any and all accounting documents and an on-site audit to check the correctness of the indications supplied.

3.4.3.1 Elements included in the price

The service provider is deemed to have included in his unit and global prices any charges and taxes generally applied to services.

The following are in particular included in the prices (non-exhaustive list):

- Expert cost including: fees, the per diems, accommodation costs, local transport costs, insurance costs, security costs, communication costs (including the internet), administrative and secretariat costs, photocopy and printing costs, costs for documentation of the services that can be required by the contracting authority, the production and delivery of documents or records linked to the performance of the services, the customs and excise duties for materials and products used, the packaging costs, the acceptance costs, all costs, staff and material and logistics expenses needed to perform the present contract, where applicable, the measures imposed by occupational safety and worker health legislation, the intellectual property right fees, the purchase or leasing of third party services needed for the performance of the contract, and the applicable Withholding taxes.
- Reimbursable Costs: (paid based upon presentation of justification documents, up to the maximum budget set and accepted in financial proposal): only international travel costs and visa costs (if any) are accepted as reimbursable costs.
- International travel days are not reimbursed by Enabel.

3.4.4 How to submit tenders?

The tenderer may only submit one tender as follows:

- **The tender will be drawn up in 3 copies, one of them being the original and two copies.**
- **Soft Copy (Exactly identical to the hard copy) must be submitted in one or more PDF files on a USB stick. Bidders who do not submit the required copies (hard and the soft copies), might be rejected.**

The tender and all accompanying documents have to be numbered and signed by the tenderer or his/her representative. The same applies to any alteration, deletion or note made to this document.

The representative of the bidder must clearly state that he/she is authorised to commit the tenderer. If the tenderer is a company / association without legal body status, formed by separate natural or legal persons (temporary group or temporary partnership), the tender must be signed by each of these persons.

The signed and dated original (including the soft copy on the key) will be sent in a sealed enveloped mentioning:

“TENDER RWA23002-10008”

The tender must be **received before 02/09/2026 at 04:00 PM Kigali time.**

It must be sent to:

Mr. Réal NIMPAGARITSE
ECA - Enabel in Rwanda
Belgian agency for international cooperation
KN 67 Street, plot N° 10 SORAS Towers,
Wing A, 6th Floor Opposite St Michel Catholic Church
B.P. 6089 KIYOVU

Any request for participation or tender must arrive before the final submission date and time. Requests for participation or tenders that arrive late will not be accepted¹⁰.

Attention points:

- *the bids sent by email will be rejected!*
- *Kindly refer also to the **Section. 7 – Document to be included in the proposal/Offer.***

3.4.5 Change or withdrawal of a tender that has already been submitted

When a tenderer wants to change or withdraw a tender already sent or submitted this must be done in accordance with the provisions of Articles 43 and 85 of the Royal Decree of 18 April 2017.

To change or withdraw a tender already sent or submitted, a written statement is required, which will be correctly signed by the tenderer or his representative. The subject-matter and the scope of the changes must be indicated in detail. Any withdrawal must be pure and simple.

The withdrawal may also be communicated by electronic means, provided that it is confirmed by registered letter deposited at the post office or against acknowledgement of receipt at the latest the day before the tender acceptance deadline.

When the submission report drawn up following the modifications or withdrawal set out in clause 1 does not bear the signature referred to in paragraph 1, the modification or withdrawal

¹⁰ Article 83 of the Royal Decree Award
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is automatically deemed null and void. This nullity applies only to the modifications or withdrawal, not to the tender itself.

3.4.6 Opening of Tenders

The tenders will be opened behind closed doors.

3.4.7 Selection of tenderers

3.4.7.1 Exclusion grounds

The mandatory and optional exclusion grounds are given in the Declaration on honour enclosed to these Tender Specifications.

By submitting this tender, the tenderer certifies that he is not in any of the cases of exclusion listed in the Articles 67 to 70 of the Law of 17 June 2016 and the Articles 61 to 64 of the Royal Decree of 18 April 2017.

The contracting authority will verify the accuracy of this Declaration on honour for the tenderer with the best tender.

For that purpose, the contracting authority will ask the tenderer concerned to provide information or documents allowing the contracting authority to verify the tenderer's personal situation by the fastest means and within the term set by the contracting authority.

The contracting authority will itself ask for information or documents that it can obtain free of charge by digital means from the instances that manage the information or documents.

3.4.7.2 Selection criteria

Moreover, by means of the documents requested in the 'Selection file (**see section 5.10**)', the tenderer must prove that he is sufficiently capable, from an economic and financial as well as from a technical point of view, to successfully perform this public procurement contract.

The minimum required profile for the consulting firm and keys experts will be analysed at the selection stage.

The bidders who will not meet the minimum technical requirements will not be selected for the award stage.

3.4.7.3 Overview of the procedure

In a first phase, the tenders submitted by the selected tenderers will be evaluated as to formal and material regularity. Irregular tenders will be rejected.

The contracting authority reserves the right to have the irregularities in the tenderers' tender regularised during the negotiations.

In a second phase, the formally and materially regular tenders will be evaluated as to content by an evaluation commission.

This evaluation will be conducted on the basis of the award criteria given in these Tender Specifications and aims to setting a shortlist of tenderers with whom negotiations will be conducted. The contracting authority may decide to include a maximum of three tenderers in the shortlist.

Then, the negotiation phase follows. In view of improving the contents of the tenders, the contracting authority may negotiate with tenderers the initial tenders and all subsequent tenders that they have submitted, except final tenders. The minimum requirements and the award criteria are not negotiable. However, the contracting authority may also decide not to negotiate. In this case, the initial tender is the final tender.

When the contracting authority intends to conclude the negotiations, it will so advise the remaining tenderers and will set a common deadline for the submission of any BAFOs. Once negotiations have closed, the BAFO will be compared with the exclusion, selection and award criteria. The tenderer whose BAFO shows the best value for money (obtaining the best score

based on the award criteria given below) will be designated the contractor for this procurement contract.

3.4.7.4 Award criteria

The contracting authority will choose the regular BAFO that it finds to be most advantageous, taking account of the following criteria:

Technical proposal 70%

Technical proposal will be evaluated based on the following criterion and scoring:

Criteria N°	Criteria for methodology evaluation	Maximum score
1	Comprehensive and detailed methodology outlining implementation of all activities and sub-activities	30
2	Clear understanding of the Terms of Reference (ToRs) and appropriateness of the proposed overall strategy	20
3	Quality, Relevance, and logical sequencing of the proposed work plan & timetable of activities/ sub-activities	20
	TOTAL	70

Price: 30%

With regards to the 'price' criterion, the following formula will be used:

$$\text{Score of Bid A} = \frac{\text{amount of lowest bid price} \times 30}{\text{Bid price A}}$$

The lowest price will get the maximum point.

3.4.7.5 Final score

The scores for the award criteria will be added up. The procurement contract will be awarded to the tenderer with the highest final score, after the contracting authority has verified the accuracy of the Declaration on honour of this tenderer and provided the control shows that the Declaration on honour corresponds with reality.

3.4.7.6 Awarding the procurement contract

the procurement contract will be awarded to the tenderer who has submitted the most economically advantageous tender.

Notice though that in accordance with Art. 85 of the Law of 17 June 2016, there is no obligation for the contracting authority to award the procurement contract.

The contracting authority may either decide not to award the procurement contract; either redo the procedure, if necessary, through another award procedure.

3.4.8 Concluding the procurement contract

In accordance with Art. 88 of the Royal Decree of 18 April 2017, the procurement contract occurs through the notification to the selected tenderer of the approval of his tender.

Notification is via digital platforms, e-mail or fax.

So, the full contract agreement consists of a procurement contract awarded by Enabel to the chosen tenderer in accordance with:

- These Tender Specifications and its annexes;
- The approved BAFO of the contractor and all of its annexes;
- The notification of the award decision;

- Any later documents that are accepted and signed by both parties, as appropriate.

In an objective of transparency, Enabel undertakes to publish each year a list of recipients of its contracts. By introducing his tender, the successful tenderer declares that he agrees with the publication of the title of the contract, the nature and object of the contract, its name and location, and the amount of the contract.

4 Specific contractual conditions

This chapter of these Tender Specifications holds the specific provisions that apply to this public procurement contract as a derogation of the 'General Implementing Rules for public procurement contracts and for public works concessions' of the Royal Decree of 14 January 2013, hereinafter referred to as 'GIR', or as a complement or an elaboration thereof. The numbering of the articles below (between brackets) follows the numbering of the GIR articles. Unless indicated, the relevant provisions of the General Implementing Rules (GIR) apply in full.

These Tender Specifications derogate from Art.25-33 of the General Implementing Rules.

4.1 Managing official (Art. 11)

The managing official is **Mr. Antoine GATERA, Strategy Expert/Project Manager, e-mail: antoine.gatera@enabel.be**

Once the procurement contract is concluded, the managing official is the main contact point for the service provider. Any correspondence or any questions with regards to the performance of the procurement contract will be addressed to her, unless explicitly mentioned otherwise in these Tender Specifications.

The managing official is responsible for the follow-up of the performance of the contract.

The managing official is fully competent for the follow-up of the satisfactory performance of the procurement contract, including issuing service orders, drawing up reports and states of affairs, approving the services, progress reports and reviews. She may order any modifications to the procurement contract with regards to its subject-matter provided that they remain within its scope.

However, the signing of amendments or any other decision or agreement implying derogation from the essential terms and conditions of the procurement contract are not part of the competence of the managing official. For such decisions the contracting authority is represented as stipulated under 'The contracting authority'.

Under no circumstances is the managing official allowed to modify the terms and conditions (e.g. performance deadline) of the contract, even if the financial impact is nil or negative. Any commitment, change or agreement that deviates from the conditions in the Tender Specifications and that has not been notified by the contracting authority, will be considered null and void.

4.2 Subcontractors (Art. 12 to 15)

The fact that the contractor entrusts all or part of his commitments to subcontractors does not relieve him of liability to the contracting authority. The latter does not recognise any contractual relation with third parties.

The contractor remains, in any case, solely liable to the contracting authority.

The service provider commits to having the procurement contract performed by the key experts/persons indicated in the tender, except for force majeure. The persons mentioned or their replacements are all deemed to effectively be involved in the performance of the procurement contract. Any replacements must be approved by the contracting authority.

When the contractor uses a subcontractor to carry out specific processing activities on behalf of the contracting authority, the same data protection obligations as those of the contractor are imposed on that subcontractor by contract or any other legal act.

In the same way, the contractor will respect and enforce to his subcontractors, the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation, GDPR). The

contracting authority may conduct an audit of the processing carried out in order to validate compliance with this legislation.

4.3 Confidentiality (art. 18)

The knowledge and information gathered by the tenderer under the framework of this public contract is strictly confidential.

Under no circumstances can the information collected, regardless of its origin and nature, be transferred to third parties in any form.

The tenderer is therefore bound by the duty of discretion.

In accordance with Article 18 of the Royal Decree of 14 January 2013 establishing the general rules for public procurement, the tenderer undertakes to consider and process in a strictly confidential manner any information, all facts, any documents and/or any data, whatever their nature and support, which have been communicated to him, in any form and by any means, or to which he has access, directly or indirectly, in the context or on the occasion of this public contract. Confidential information covers, in particular, the very existence of this public contract, without this list being limited.

Therefore, he undertakes to:

- Respect and enforce the strict confidentiality of these elements and to take all necessary precautions in order to preserve their secrecy (these precautions cannot in any case be inferior to those taken by the tenderer for the protection of his own confidential information);
- Consult, use and/or exploit, directly or indirectly, all of the above elements only to the extent strictly necessary to prepare and, if necessary, to carry out this public contract (particularly in accordance with the privacy legislation with respect to personal data processing);
- Not reproduce, distribute, disclose, transmit or otherwise make available to third parties the above elements, in whole or in part, and in any form, unless having obtained prior and written consent of the contracting authority;
- Return, at the first request of the contracting authority, the above elements;
- In general, not disclose directly or indirectly to third parties, whether for advertising or any other reason, the content of this public contract.

4.4 Protection of personal data

4.4.1 Processing of personal data by the contracting authority

The contracting authority undertakes to process the personal data that are communicated to it in response to the call for tenders with the greatest care, in accordance with legislation on the protection of personal data (General Data Protection Regulation, GDPR). Where the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data contains stricter provisions, the contracting authority will act in accordance with said law.

4.4.2 PROCESSING OF PERSONAL DATA

During contract performance, the contractor may process personal data of the contracting authority exclusively in the name and on behalf of the contracting authority, for the sole purpose of performing the services in accordance with the provisions of the Tender Specifications or in execution of a legal obligation.

For any processing of personal data carried out in connection with this public contract, the contractor is required to comply with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR) and the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

By simply participating in the contracting process, the tenderer certifies that he will strictly comply with the obligations of the GDPR for any processing of personal data conducted in connection with that public contract.

Given the public contract, it is to be considered that the contracting authority and the contractor will each be responsible, individually, for the processing.

4.5 Intellectual property (Art. 19 to 23)

The contracting authority acquires the intellectual property rights created, developed or used during performance of the contract.

Without prejudice to clause 1 and unless otherwise stipulated in the procurement documents, when the subject-matter of the procurement contract consists of the creation, manufacture or the development of designs or of logos, the contracting authority acquires the intellectual property thereof, as well as the right to trademark them, to have them registered and to have them protected.

For domain names created under the procurement contract, the contracting authority also acquires the right to register and protect them, unless otherwise stipulated in the procurement documents.

4.6 Performance bond (Art. 25 to 33)

The performance bond is not applicable to this tender.

4.7 Conformity of performance (Art. 34)

The services must comply in all respects with the procurement documents. Even in the absence of technical specifications in the procurement documents, the services must comply in all aspects with good practice.

4.8 Changes to the procurement contract (Art. 37 to 38/19)

4.8.1 Replacement of the contractor (Art. 38/3)

Provided that he meets the selection and exclusion criteria set out in this document, a new contractor may replace the contractor with whom the initial procurement contract was agreed in cases other than those provided for in Art. 38/3 of the General Implementing Rules (GIR).

The contractor submits his request as quickly as possible by registered post, stating the reasons for this replacement and providing a detailed inventory of the state of supplies and services already performed, the new contractor's contact details and the documents and certificates which the contracting authority cannot access free of charge.

The replacement will be recorded in an amendment dated and signed by all three parties. The initial contractor remains liable to the contracting authority for the performance of the remainder of the procurement contract.

4.8.2 Adjusting the prices (Art. 38/7)

For this procurement contract, price reviews are not permitted.

4.8.3 Indemnities following the suspensions ordered by the contracting authority during performance (Art. 38/12)

The contracting authority reserves the right to suspend the performance of the procurement contract for a given period, mainly when it considers that the procurement contract cannot be performed without inconvenience at that time.

The performance period is extended by the period of delay caused by this suspension, provided that the contractual performance period has not expired. If it has expired, the return of fines for late performance will be agreed.

When activities are suspended, based on this clause, the contractor is required to take all necessary precautions, at his expense, to protect the services already performed and the materials from potential damage caused by unfavourable weather conditions, theft or other malicious acts.

The contractor has a right to damages for suspensions ordered by the contracting authority when:

- The suspension lasts in total longer than one twentieth of the performance time and at least ten working days or two calendar weeks, depending on whether the performance time is expressed in working days or calendar days;
- The suspension is not due to unfavourable weather conditions;
- The suspension occurred during the contract performance period.

Within thirty days of their occurrence or the date on which the contractor or the contracting authority would normally have become aware of them, the contractor reports the facts or circumstances succinctly to the contracting authority and describes precisely their impact on the progress and cost of the procurement contract.

4.8.4 Unforeseen circumstances

As a rule, the contractor is not entitled to any modification of the contractual terms due to circumstances of which the contracting authority was unaware.

A decision of the Belgian State to suspend cooperation with a partner country is deemed to be unforeseeable circumstances within the meaning of this article. Should the Belgian State break off or cease activities which implies therefore the financing of this procurement contract, Enabel will do everything reasonable to agree a maximum compensation figure.

4.9 Preliminary technical acceptance (Art. 42)

The contracting authority reserves the right to demand an activity report at any time of the assignment to the service provider (meetings held, persons met, institutions visited, summary of results, problems encountered and unresolved issues, deviations from the planning and deviations from the ToR...).

4.10 Performance modalities (Art. 146 et seq.)

4.10.1 Deadlines and terms (Art. 147)

See art. 2.5 above.

4.10.2 Place where the services must be performed and formalities (Art. 149)

Implementation activities will be conducted primarily **at the Rwanda FDA Headquarters in Nyarutarama, 32 KG 9 Ave, Kigali, as outlined in section 5 below.**

4.11 Inspection of the services (Art. 150)

If during contract performance irregularities are found, the contractor will be notified about this immediately by fax or e-mail, which will be confirmed consequently by official letter. The contractor is bound to perform the non-complying services again.

The service provider advises the managing official by registered post or e-mail showing the exact date of dispatch, at which date the services can be controlled.

4.12 Liability of the service provider (Art. 152-153)

The service provider takes the full responsibility for mistakes and deficiencies in the services provided.

Moreover, the service provider indemnifies the contracting authority against damages for which it is liable towards third parties due to late performance of the services or due to failure of the service provider.

4.13 Zero tolerance Sexual exploitation and abuse

In application of Enabel's Policy regarding sexual exploitation and abuse of June 2019 there will be zero tolerance towards any misconduct that could impact the professional credibility of the tenderer.

4.14 Means of action of the contracting authority (Art. 44-51 and 154-155)

The service provider's default is not solely related to services as such but also to the whole of the service provider's obligations.

In order to avoid any impression of risk of partiality or connivance in the follow-up and control of the performance of the procurement contract, it is strictly forbidden to the service provider to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to the employees of the contracting authority who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the procurement contract, regardless of their hierarchical rank.

In case of violation, the contracting authority may impose a lump-sum fine to the service provider for each violation, which can be to up to three times the amount obtained by adding up the (estimated) values of the advantage offered to the employee and of the advantage that the contractor hoped to obtain by offering the advantage to the employee. The contracting authority will decide independently about the application and the amount of this fine.

This clause is without prejudice to the possible application of other measures as of right provided in the GIR, namely the unilateral termination of the procurement contract and/or the exclusion of procurement contracts of the contracting authority for a determined duration.

4.14.1 Failure of performance (Art. 44)

§1 The contractor is considered to be in failure of performance under the procurement contract:

1° when the delivery is not carried out in accordance with the conditions specified in the procurement documents;

2° at any time, when the delivery has not progressed in such a way that it can be fully completed on the due dates;

3° when he does not observe written orders, which are given in due form by the contracting authority.

§2 Any failure to comply with the provisions of the procurement contract, including the non-observance of orders of the contracting authority, is recorded in a report ('process verbal'), a copy of which will be sent immediately to the contractor.

The contractor must repair the defects without any delay. He may assert his right of defence by letter addressed to the contracting authority within fifteen days from the date of dispatch of the report (process verbal). Silence on his part after this period shall be deemed as acknowledgement of the reported facts.

Any defects detected that can be attributed to the contractor render him liable to one or more of the measures provided for in Articles 45 to 49, 154 and 155.

4.14.2 Fines for delay (Art. 46 and 154)

The fines for delay differ from the penalties referred to in Article 45. They are due, without the need for notice, by the mere lapse of the performance term without the issuing of a report and they are automatically applied for the total number of days of delay.

Without prejudice to the application of fines for delay, the contractor continues to guarantee the contracting authority against any damages for which it may be liable to third parties due to late performance of the procurement contract.

4.14.3 Measures as of right (Art. 47 and 155)

§1 When, upon expiry of the term given in Article 44, §2, the contractor has not taken action or has presented means deemed unjustified by the contracting authority, the contracting authority may apply the measures as of right described in paragraph 2.

However, the contracting authority may apply measures as of right without waiting for the expiry of the term given in Article 44, §2, when the contractor has explicitly recognised the defects found.

§2 The measures as of right are:

1° Unilateral termination of the procurement contract. In this case the entire performance bond, or if no bond has been posted an equivalent amount, is acquired as of right by the contracting authority as lump sum damages. This measure excludes the application of any fine for delay in performance in respect of the terminated part;

2° Performance under regie of all or part of the non-performed procurement contract;

3° Conclusion of one or more replacement procurement contracts with one or more third parties for all or part of the procurement contract remaining to be performed.

The measures referred to in 1°, 2° and 3° will be taken at the expense and risk of the defaulting contractor. However, any fines or penalties imposed during the performance of a replacement procurement contract will be borne by the new contractor.

4.15 End of the procurement contract

4.15.1 Acceptance of the services performed (Art. 64-65 and 156)

The managing official will closely follow up the services during performance.

The services will not be accepted until after fulfilling audit verifications, technical acceptance and prescribed tests.

The contracting authority disposes of a verification term of thirty days starting on the final or partial end date of the services, set in conformity with the modalities in the procurement documents, to carry out the acceptance formalities and to notify the result to the service provider. This term commences provided that the contracting authority possesses, at the same time, the list of services delivered or the invoice. Upon expiry of the thirty-day term following the date

stipulated for completion of the entirety of the services, depending on the case, an acceptance report or a refusal of acceptance report will be drawn up.

Where the services are completed before or after this date, it is the responsibility of the service provider to notify the managing official by registered letter, and at the same time to ask for the acceptance procedure to be carried out. Within thirty days after the date of receipt of the service provider's request, an acceptance or a refusal of acceptance report will be drawn up, depending on the case.

The acceptance specified above is final.

4.15.2 Invoicing and payment of services (Art. 66 to 72 – 160)

The service provider sends (one copy only of) the invoices and the contract acceptance report (original copy) to the following:

Mr. Antoine GATERA – antoine.gatera@enabel.be – **Strategy Expert/Project Manager – Health Care & Pharmaceutical Regulation with copy to rwa.invoices@enabel.be**

Only services that have been performed and approved correctly may be invoiced.

The contracting authority disposes of a verification term of thirty days starting on the end date for the services, set in conformity with the modalities in the procurement documents, to carry out the technical acceptance and provisional acceptance formalities and to notify the result to the service provider.

The amount owed to the service provider must be paid within thirty days with effect from the expiry of the verification term or with effect from the day after the last day of the verification term, if this is less than thirty days. And provided that the contracting authority possesses, at the same time, the duly established invoice and any other documents that may be required.

When the procurement documents do not provide for any separate debt claim, the invoice will constitute the debt claim.

No advance may be asked by the contractor.

Payments may be made in instalments (progress payments) as follow:

S/N	Deliverable	Payment Modalities	
D1	Upon Approval of the inception report (D1)	1 st Instalment	10% of the contract amount
D2	Training Materials and Inspection Tools Report (D2)	2 nd Instalment	20% of the contract amount
D3 - D4	Upon completion and approval of reports presenting: a. GSDP Training Delivery Report (D3) b. On-site Mentorship and Coaching Report (D4)	3 rd Instalment	40% of the contract amount
D5 – D6 & D7	Upon completion and approval of reports presenting: a. Inspection Portfolio report (D5) b. Competency Assessment Report(D6) c. Final Technical Report and Sustainability Package (D7)	4 th Instalment	30% of the contract amount

4.16 Litigation (Art. 73)

The competent courts of Brussels have exclusive jurisdiction over any dispute arising from the performance of this procurement contract. French or Dutch are the languages of proceedings.

The contracting authority will in no case be held liable for any damage caused to persons or property as a direct or indirect consequence of the activities required for the performance of this procurement contract. The contractor indemnifies the contracting authority against any claims for compensation by third parties in this respect.

In case of 'litigation', i.e. court action, correspondence must (also) be sent to the following address:

Enabel, public-law company

Legal unit of the Logistics and Acquisitions service (L&A)

To the attention of Mrs Laura Jacobs

rue Haute 147

1000 Brussels

Belgium

5 Terms of Reference

5.1 BACKGROUND

The Rwanda Food and Drug Authority (Rwanda FDA), established under Law No. 003/2018, is mandated to regulate the quality, safety, and efficacy of health products, including oversight of pharmaceutical distribution systems. As part of its regulatory functions, Rwanda FDA enforces compliance with Good Storage and Distribution Practices (GSDP) to ensure the quality, integrity, traceability, and proper handling of medical products throughout the supply chain.

In line with its strategic objectives to strengthen regulatory systems and enhance post-market surveillance, Rwanda FDA is reinforcing its capacity to conduct GSDP inspections.

Building on the existing inspection capacity within Rwanda FDA, there remains a need to further strengthen practical competencies through structured, hands-on exposure to real inspection environments

Rwanda FDA currently has a limited number of qualified Lead GSDP inspectors and seeks to strengthen the practical competencies and qualification of additional inspectors through structured training, mentorship, competency assessment, and practical inspection experience.

The assignment therefore aims to strengthen the operational and regulatory capacity of Rwanda FDA GSDP inspectors through practical training, on-site mentorship, and qualification support delivered in line with the Annual GSDP Inspection Plan and internationally recognized best practices.

This assignment will be implemented under the LOMESU Project, which supports Rwanda FDA regulatory systems strengthening through targeted technical assistance and institutional capacity-building initiatives (see also art. 1.2).

The assignment is expected to contribute to the development of a pool of competent inspectors capable of independently conducting GSDP inspections and progressively qualifying as lead inspectors.

5.2 OBJECTIVES OF THE ASSIGNMENT

5.2.1. Overall Objectives

The overall objective of this assignment is to strengthen the practical competencies and support the qualification of Rwanda FDA GSDP inspectors to independently plan, conduct, document, report, and follow up on GSDP inspections in line with national requirements, WHO standards, and internationally recognized good practices.

The assignment will support the progression of participating inspectors toward qualifications as lead GSDP inspectors through practical training, mentorship, competency assessment, and structured knowledge transfer.

5.2.2. Specific Objectives

The assignment has the following specific objectives:

1. To provide practical training and on-site mentorship to Rwanda FDA GSDP inspectors, strengthening competencies across the full GSDP inspection cycle, including inspection planning, inspection conduct, documentation review, report writing, classification of deficiencies, CAPA assessment, and follow-up of regulatory actions.
2. To support the practical qualification of GSDP inspectors through hands-on participation in real and/or mock inspections conducted in line with the Annual GSDP Inspection Plan, including documented assessment of competencies and identification of development needs.
3. To improve the quality, consistency, and standardization of GSDP inspection practices, including harmonization of inspection procedures, reporting formats, and classification of deficiencies in line with internationally recognized good practices.
4. To strengthen inspectors' competencies in regulatory decision-making and appropriate follow-up of inspection findings and corrective actions.
5. To support knowledge transfer and adoption of internationally recognized best practices in GSDP inspections and inspector qualification.
6. To strengthen the use of inspection tools, reporting templates, and practical inspection methodologies within Rwanda FDA to support sustainable inspector qualification and continuous improvement of inspection activities.
7. To assess and document inspector competencies using a structured competency assessment framework and provide recommendations for progression toward qualification as lead GSDP inspectors.

5.3 SCOPE OF THE WORK

The consultant shall design and implement a practical capacity-building programme combining classroom-based learning, practical exercises, mentorship, and inspection-based learning.

The assignment shall include, but not necessarily be limited to, the following activities:

5.3.1. Capacity building Through Training

- a) Develop and deliver practical training sessions on GSDP inspections, with particular focus on newly recruited inspectors.
- b) Incorporate theoretical sessions and practical exercises, including case studies, mock inspections, report-writing exercises, and CAPA assessment exercises, in line with Rwanda FDA training needs.

Conduct pre-training and post-training assessments to measure knowledge acquisition and identify areas requiring additional mentoring support.

5.3.2. Support to Inspector Qualification

The Consultant shall

- a) Provide hands-on mentorship and coaching during real and/or mock GSDP inspections.

- b) Guide inspectors through the practical application of inspection procedures, including inspection preparation, inspection conduct, documentation review, classification of deficiencies, CAPA assessment, and inspection reporting.
- c) Assess inspectors' competencies and provide practical feedback to support qualification as lead inspectors.
- d) Document assessment results and provide individual feedback and recommendations for progression toward qualification as lead inspectors

The consultant shall develop and apply a practical competency assessment framework to evaluate participating inspectors during training and inspection activities.

The framework shall define competency areas, assessment criteria, performance ratings, and recommendations for further development.

The framework shall serve as a tool for Rwanda FDA to support future inspector qualification activities.

Competency assessment shall be based on direct observation during inspections, review of inspection documentation, participation in inspection discussions, and assessment against predefined competency criteria.

5.3.3. Harmonization of Inspection Practices and Tools

The consultant shall:

- a) Support the refinement and harmonization of inspection tools and templates, including inspection checklists, reporting formats, deficiency classification approaches, and CAPA assessment tools.
- b) Promote consistent application of inspection procedures and reporting practices in line with internationally recognized good practices.
- c) Review existing inspection tools and recommend improvements where necessary to align with WHO guidance and internationally recognized good practices.

5.3.4. Knowledge Transfer and Best Practices

- a) Share practical experiences and lessons learned from. from regulatory authorities, inspectorates, consulting assignments, and internationally recognized inspection systems relevant to GSDP implementation.
- b) Facilitate knowledge transfer to support continuous improvement and sustainability of GSDP inspection activities within Rwanda FDA.

5.4 Contract management and reporting arrangement

The Technical Assistance Provider shall operate under the overall oversight of the Director General of Rwanda FDA. Day-to-day coordination and technical supervision will be ensured by the Pharmaceutical Inspection and Licensing Division of Rwanda FDA, in collaboration with the LOMESU Project team.

The Technical Assistance Provider shall:

- a) Provide periodic progress updates during implementation of the assignment;
- b) Submit a final technical report summarizing activities conducted, training delivered, mentorship activities undertaken, competency assessment outcomes, key observations, lessons

learned, and recommendations for continued inspector qualification and improvement of GSDP inspection practices.

5.5 Services necessary to carry out the assignment and expected outcomes

Upon completion of the training and mentorship programme, the expected outcomes shall include, but not be limited to, the following:

1. Strengthened practical competencies and qualification of participating Rwanda FDA GSDP inspectors, including documented competency assessment results and recommendations for progression toward qualification as lead inspectors;
2. Improved quality, consistency, and harmonization of GSDP inspection practices, including inspection planning, conduct, reporting, classification of deficiencies, CAPA assessment, and follow-up of regulatory actions;
3. Strengthened application of inspection tools, reporting templates, documentation practices, and regulatory decision-making in line with internationally recognized good practices;
4. Enhanced capacity of inspectors to identify, document, classify, and follow up inspection deficiencies effectively and consistently;
5. Strengthened institutional capacity of Rwanda FDA to sustain inspector qualification and mentorship programmes through standardized inspection and competency assessment tools, knowledge transfer, and mentorship approaches; and
6. Enhanced implementation of Good Storage and Distribution Practices across the pharmaceutical supply chain through more effective and consistent regulatory oversight.

5.6 Place of the assignment

The assignment shall be implemented **primarily** in Kigali, Rwanda - Nyarutarama, 32 KG 9 Ave, Kigali **at Rwanda FDA premises**.

Training activities shall be conducted at Rwanda FDA premises or at another venue agreed upon by Rwanda FDA and the contracting authority.

Practical mentorship activities shall be conducted at selected inspection sites identified by Rwanda FDA in accordance with the approved Annual GSDP Inspection Plan.

Inspection sites may include pharmaceutical wholesalers, distributors, warehouses, transport operators, importers, exporters, and other establishments subject to GSDP inspections.

5.7 PARTICIPANTS AND DURATION

5.7.1. Duration of the Assignment

The assignment shall be implemented over a maximum period of two (2) months from the date of contract signature, with a total level of effort of twenty-one (21) person-days for the consultant.

The level of effort shall cover all activities related to the assignment, including preparation, development of training materials and inspection tools, delivery of training sessions, on-site mentorship during inspections, competency assessment of participating inspectors, report writing, and submission of deliverables.

The assignment shall combine classroom-based learning, practical exercises, and field-based mentorship activities conducted in line with the Rwanda FDA Annual GSDP Inspection Plan.

5.7.2. Participants

Approximately 13 to 15 Rwanda FDA inspectors involved in GSDP inspection activities within the Pharmaceutical Inspection and Licensing Division (PIL) are expected to participate in the assignment.

5.8 REGULATORY REFERENCES

The assignment shall take into consideration applicable Rwanda FDA requirements and relevant international standards, including:

- Rwanda FDA Good Storage and Distribution Practices Guidelines;
- Rwanda FDA inspection procedures and standard operating procedures;
- WHO Good Distribution Practices guidance;
- WHO Global Benchmarking Tool (GBT);
- Applicable national regulatory requirements;
- Relevant international guidance and best practices related to pharmaceutical storage and distribution systems.

5.9 DELIVERABLES

The consultant shall provide the following deliverables

S/N	Deliverable	Description	Indicative Timeline (Calendar Days)	Indicative Level of Effort (Person-Days)
D1	Inception Report	A comprehensive inception report outlining the consultant's understanding of the assignment, detailed methodology, implementation schedule, risk mitigation measures, and competency assessment approach	Within max 2 week after contract award notification	2
D2	Training Materials and Inspection Tools Report	A comprehensive report presenting all developed training materials, training plan and agenda and inspection tools, including training presentations, facilitator guides, case studies, inspection checklists, reporting templates, deficiency classification tools, benchmarking against WHO requirements and CAPA principles, CAPA assessment tools, and supporting reference materials. All materials should be editable and adapted to Rwanda FDA regulated supply chain		3
D3	GSDP Training Delivery Report	A report documenting the delivery of practical and theoretical GSDP training sessions for participating inspectors.	Within max 3 week after approval of D2	5

D4	On-site Mentorship and Coaching Report	A comprehensive report documenting mentorship and coaching activities conducted during on-site GSDP inspections, including areas covered, participants mentored, observations made, practical guidance provided, challenges encountered, lessons learned, progress achieved, and recommendations for strengthening inspection competencies and continuous performance improvement		6
D5	Inspection Portfolio report	A compiled portfolio documenting the practical GSDP inspection activities undertaken during the assignment, including inspection plans, completed inspection checklists, sample inspection reports, deficiency classification of non-compliances identified during the inspections, CAPA assessment, and other practical assignments completed by participants.		2
D6	Competency Assessment Report	A report detailing Competency assessment methodology, individual competency assessment results, identified strengths and development needs, recommendations for progression toward qualification as Lead GSDP Inspectors, proposed individual development plans, and a completed competency matrix in accordance to Rwanda FDA guidelines for Qualification of GxP inspectors.	Within max 1 week after approval of D4	1
D7	Final Technical Report and Sustainability Package	Final report summarizing all activities conducted, training delivered, mentorship outcomes, competency assessment results, lessons learned, recommendations, and sustainability measures.		2
Total			Maximum implementation period: 2 months	21 Person-Days

5.10 Minimum Required profile (to be analysed at selection stage).

5.10.1. The minimum required profile

The bidder may be:

- **an individual consultant who is currently working, or has previously worked, with (or for) a National regulatory operating at WHO GBT maturity level 3 or 4 and who will perform the assignment directly.**

In all cases, the bidder shall be **duly registered/authorised to provide the services** in accordance with the legislation applicable in its country of establishment or residence and shall hold a valid registration number and/or Tax Identification Number (TIN), or an equivalent tax registration number, as applicable.

Documentary evidence of legal registration or establishment and of the valid tax registration number shall be provided.

The bidder shall also provide:

- **documentary evidence of the proposed expert's current or previous employment or engagement with a relevant national regulatory authority.** Such evidence may include an employment certificate, certificate of service, employment or service contract, certificate of satisfactory completion, reference letter, or any other relevant supporting documentation.

5.10.2. Essential Qualifications and Experience for the key expert

- At least a **bachelor's degree in pharmacy**, Pharmaceutical Sciences, Public Health, Supply Chain Management, Quality Management, or another relevant field;
- At least **five (5) years of previous experience in leading GSDP inspections and overseeing the full inspection lifecycle**, including inspection planning, execution, report writing, classification of deficiencies, CAPA assessment, and follow-up of regulatory or enforcement actions;
- Excellent written and spoken **English**.

Copies of the CV, degrees and certifications, together with any other relevant supporting documents required to demonstrate compliance with the above requirements, shall be provided.

The contracting authority reserves the right to request any additional documents or clarifications deemed necessary to verify compliance with the above requirements. It may also, at its own discretion, contact the references indicated in the submitted documents to verify the quality of the services delivered.

6 Forms

6.1 Identification forms

6.1.1 Legal person entity private/public legal body

OFFICIAL NAME ②			
ABBREVIATION			
MAIN REGISTRATION NUMBER③			
SECONDARY REGISTRATION NUMBER (if applicable)			
PLACE OF MAIN REGISTRATION	CITY	COUNTRY	
DATE OF MAIN REGISTRATION	DD	MM	YYYY
VAT NUMBER			
OFFICIAL ADDRESS			
POSTCODE	P.O. BOX	CITY	
COUNTRY	PHONE		
E-MAIL			
DATE		STAMP	
SIGNATURE OF AUTHORISED REPRESENTATIVE			

-
- ① **Public law body WITH LEGAL PERSONALITY**, meaning a public entity being able to represent itself and act in its own name, i.e. being capable of suing or being sued, acquiring and disposing of property, entering into contracts. This legal status is confirmed by the official legal act establishing the entity (a law, a decree, etc.).
- ② **National denomination and its translation in EN or FR if existing.**
- ③ **Registration number in the national register of the entity.**

6.1.2 Public law entity

OFFICIAL NAME^① BUSINESS NAME (if different) ABREVIATION LEGAL FORM			
ORGANISATION TYPE		FOR PROFIT NOT FOR PROFIT	
		NGO^②	YES NO
MAIN REGISTRATION NUMBER^③ SECONDARY REGISTRATION NUMBER (if applicable)			
PLACE OF MAIN REGISTRATION		CITY	COUNTRY
DATE OF MAIN REGISTRATION		DD MM YYYY	
VAT NUMBER ADDRESS OF HEAD OFFICE			
POSTCODE	P.O. BOX	CITY	
COUNTRY		PHONE	
E-MAIL			
DATE		STAMP	
SIGNATURE OF AUTHORISED REPRESENTATIVE			

^① National denomination and its translation in EN or FR if existing.

^② NGO = Non Governmental Organisation, to be completed if NFPO is indicated.

^③ Registration number in the national register of companies. See table with corresponding field denomination by country.

6.1.3 Subcontractors (if applicable)

Name and legal form	Address / Registered office	Object

6.2 Financial identification

ACCOUNT NAME (1)			
ADDRESS			
TOWN/CITY		POST CODE	
COUNTRY			
CONTACT			
TELEPHONE		TELEFAX	
E - MAIL			

<u>BANK (2)</u>			
NAME OF BANK			
ADDRESS (OF BRANCH)			
TOWN/CITY		POST CODE	
COUNTRY			
ACCOUNT NUMBER			
IBAN (3)			
NAME OF SIGNATORIES	NAME & FORENAME	FUNCTION	

<u>STAMP of BANK + SIGNATURE of BANK'S REPRESENTATIVE (both are obligatory)</u> 	<u>DATE + SIGNATURE OF ACCOUNT HOLDER(Obligatory)</u>
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(1) The name or title under which the account was opened and not the name of the authorised representative.

(2) It is preferable to attach a copy of a recent bank statement. Please note that the bank statement must provide all the information indicated above under "ACCOUNT NAME" and "BANK". In this case, the bank's stamp and the signature of its representative are not required. The signature of the account holder is obligatory in all cases.

(3) If the IBAN code (international bank account number) is applicable in the country where your bank is situated.

6.3 Tender Forms – prices

By submitting this tender the tenderer commits to performing this public contract in conformity with the provisions of the Tender Specifications/ – and explicitly declares accepting all conditions listed in the Tender Specifications and renounces any derogatory provisions such as his own general sales conditions.

The unit prices and the global prices for each item in the inventory are established relative to the value of these items in relation to the total value of the tender. All general and financial costs as well as the profits are distributed between the various items in proportion to their weight.

The value-added tax is a special item of the inventory, to be added to the tender value. The tenderer commits to performing the public contract in accordance with the provisions of the Tender Specifications for the following prices, given in euros and inclusive of VAT:

	Unit	Unit price incl. WHT excl. VAT ^{11, 12}	Quantity (max 21 person days)	Total incl. WHT excl. VAT
Expert Fees	Person-days	€		€
SUB-TOTAL: incl. WHT and excl. VAT (A)				€
WHT¹² to be retained at source: 15% of (A) for international bidders or DTA rates. (B)				€
NET to be paid to the bidder (C) = (A-B)				€
VAT of 18% to be added on (A); for international bidders¹³ refer to the footnote (D)				€
SUB-TOTAL: incl. WHT and VAT (E) = (A+D)				€
Reimbursable Fees (if applicable)				
International travel costs		€		€
Visa costs		€		€
SUB-TOTAL (F)				€
GRAND TOTAL (G) = (E+F)				€

Should the bidder be registered in Rwanda, EBM invoice will be required for payments. Should this tender be approved, the performance bond will be constituted under the conditions and deadlines stipulated in the Tender Specifications.

The confidential information and/or the information relating to technical or business secrets is indicated clearly in the tender.

The tenderer declares on honour that the information given is accurate and correct and that it has been established while fully aware of the consequences of misrepresentation.

Certified true and sincere,

Name and signature (s):

Done at, on

¹¹ Refer to the Rwanda Revenue Authority (RRA) link, publishing the double taxation agreements (DTA) for international bidders: https://www.rra.gov.rw/en/publications?tx_news_pi1%5Baction%5D=detail&tx_news_pi1%5Bcontroller%5D=News&tx_news_pi1%5Bnews%5D=1105&cHash=f71e9bc7ede752e64679f8c39e73871c

¹² Refer to article 63 of the law N° 027/2022 of 20/10/2022, establishing taxes on income in Rwanda. A tax of 15% shall be withheld on public tenders if the recipient is not registered with the Tax Administration or is registered but does not have his/her previous income tax declaration.

¹³ Refer to article 14 of the law N° 049/2023 of 05/09/2023, For international bidders a reverse VAT of 18% to international bidders which will be retained and paid by Enabel will be applied.

6.4 Declaration on honour – exclusion criteria

Hereby, I / we, acting as legal representative(s) of above-mentioned tenderer, declare that the tenderer does not find himself in one of the following situations :

- 1) The tenderer or one of its 'directors[1]' was found guilty following a conviction by final judgement for one of the following offences:
 - 1° involvement in a criminal organisation
 - 2° corruption
 - 3° fraud
 - 4° terrorist offences, offences linked related to terrorist activities or incitement to commit such offence, collusion or attempt to commit such an offence
 - 5° money laundering or terrorist financing
 - 6° child labour and other trafficking in human beings
 - 7° employment of foreign citizens under illegal status
 - 8° creating a shell company.
- 2) The counterparty which fails to fulfil his obligations relating to the payment of taxes or social security contributions for an amount in excess of EUR 3 000, except if the counterparty can demonstrate that a contracting authority owes him one or more unquestionable and due debts which are free of all foreseeable liabilities. These debts are at least of an amount equal to the one for which he is late in paying outstanding tax or social charges.
- 3) The counterparty who is in a state of bankruptcy, liquidation, cessation of activities, judicial reorganisation or has admitted bankruptcy or is the subject of a liquidation procedure or judicial reorganisation, or in any similar situation resulting from a procedure of the same kind existing under other national regulations;
- 4) When Enabel can demonstrate by any appropriate means that the counterparty or any of its directors has committed serious professional misconduct which calls into question his integrity.

Are also considered such serious professional misconduct:

 - a. A breach of Enabel's Policy regarding sexual exploitation and abuse – June 2019
 - b. A breach of Enabel's Policy regarding fraud and corruption risk management – June 2019
 - c. A breach of a regulatory provision in applicable local legislation regarding sexual harassment in the workplace
 - d. The counterparty was seriously guilty of misrepresentation or false documents when providing the information required for verification of the absence of grounds for exclusion or the satisfaction of the selection criteria, or concealed this information
 - e. Where Enabel has sufficient plausible evidence to conclude that the counterparty has committed acts, entered into agreements or entered into arrangements to distort competition

The presence of this counterparty on one of Enabel's exclusion lists as a result of such an act/agreement/arrangement is considered to be sufficiently plausible an element.
- 5) When a conflict of interest cannot be remedied by other, less intrusive measures;
- 6) When significant or persistent failures by the counterparty were detected during the execution of an essential obligation incumbent on him in the framework of a previous contract, a previous contract placed with another contracting authority, when these failures have given rise to measures as of right, damages or another comparable sanction.

Also failures to respect applicable obligations regarding environmental, social and labour rights, national law, labour agreements or international provisions on environmental, social and labour rights are considered 'significant'.

The presence of the counterparty on the exclusion list of Enabel because of such a failure serves as evidence.

- 7) Restrictive measures have been taken vis-à-vis the counterparty with a view of ending violations of international peace and security such as terrorism, human-rights violations, the destabilisation of sovereign states and de proliferation of weapons of mass destruction.

The counterparty or one of its directors are on the lists of persons, groups or entities submitted by the United Nations, the European Union and Belgium for financial sanctions:

For the United Nations, the lists can be consulted at the following address:

<https://finances.belgium.be/fr/tresorerie/sanctions-financieres/sanctions-internationales-nations-unies>

For the European Union, the lists can be consulted at the following address:

<https://finances.belgium.be/fr/tresorerie/sanctions-financieres/sanctions-europ%C3%A9ennes-ue>

https://eeas.europa.eu/headquarters/headquarters-homepage/8442/consolidated-list-sanctions_en

https://eeas.europa.eu/sites/eeas/files/restrictive_measures-2017-01-17-clean.pdf

For Belgium:

https://finances.belgium.be/fr/sur_le_spf/structure_et_services/administrations_generales/tr%C3%A9sorerie/contr%C3%B4le-des-instruments-1-2

- 8) << If Enabel executes a project for another funder or donor, other grounds for exclusion may be added.

The tenderer formally declares being able, when asked and without delay, to provide the relevant certificates and other kinds of supporting documents, except if:

a. Enabel can directly obtain the supporting documents concerned by consulting a national database in a Member State that is accessible for free, provided the tenderer has given the required information (website address, responsible authority for providing the information, specific reference of the documents) so Enabel can obtain these, with concomitant permission to access them;

b. Enabel already has said documents.

The tenderer formally agrees with Enabel accessing the supporting documents substantiating the information provided in this document.

Date

Location

Signature

6.5 Integrity statement for the tenderers

Hereby, I / we, acting as legal representative(s) of above-mentioned tenderer, declare the following:

3. Neither members of administration or employees, or any person or legal person with whom the tenderer has concluded an agreement in view of performing the public contract, may obtain or accept from a third party, for themselves or for any other person or legal person, an advantage appreciable in cash (for instance, gifts, bonuses or any other kind of benefits), directly or indirectly related to the activities of the person concerned for the account of Enabel.
4. The board members, staff members or their partners have no financial or other interests in the businesses, organisations, etc. that have a direct or indirect link with Enabel (which could, for instance, bring about a conflict of interests).
5. I have / we have read and understood the articles about deontology and anti-corruption included in the Tender Documents (see 1.7.), as well as *Enabel's Policy regarding sexual exploitation and abuse* of June 2019 and *Enabel's Policy regarding fraud and corruption risk management* of June 2019 and I / we declare fully endorsing and respecting these articles.

If above-mentioned public contract is awarded to the tenderer, I/we declare, moreover, agreeing with the following provisions:

4. In order to avoid any impression of risk of partiality or connivance in the follow-up and control of the performance of the public contract, it is strictly forbidden to the public contractor (i.e. members of the administration and workers) to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to the employees of Enabel who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the public contract, regardless of their hierarchical rank.
5. Any (public) contract will be terminated, once it appears that contract awarding or contract performance would have involved the obtaining or the offering of the above-mentioned advantages appreciable in cash.
6. Any failure to comply with one or more of the deontological clauses will be considered as a serious professional misconduct which will lead to the exclusion of the contractor from this and other public contracts for Enabel.
7. The public contractor commits to supply, upon the demand of the contracting authority, any supporting documents related to the performance conditions of the contract. The contracting authority will be allowed to proceed to any control, on paperwork or on site, which it considers necessary to collect evidence to support the presumption of unusual commercial expenditure.

Finally, the tenderer takes cognisance of the fact that Enabel reserves the right to lodge a complaint with the competent legal instances for all facts going against this statement and that all administrative and other costs resulting are borne by the tenderer.

Signature preceded by 'read and approved', in writing, and indication of name and function of the person signing:

.....

Place, date

7 DOCUMENT TO BE INCLUDED IN THE PROPOSAL/OFFER

1. LEGAL IDENTIFICATION FORMS – ART. 6.1
2. FINANCIAL IDENTIFICATION FORM – ART. 6.2
3. PROFILE REQUIREMENTS AND SUPPORTING DOCUMENTS – ART. 5.10
4. TECHNICAL OFFER – ART. 3.4.7.4 AND ART. 5
5. TENDER FORM -PRICES – ART. 6.3
6. DECLARATION ON HONOUR – EXCLUSION CRITERIA – ART. 6.4
7. INTEGRITY STATEMENT– ART. 6.5
8. CRIMINAL RECORD CERTIFICATE FOR THE PERSON MANDATED TO COMMIT FOR THE FIRM
9. TAX CLEARANCE CERTIFICATE

At the latest before award, the Tenderer must provide a valid **recent certification** (up to 6 months) from the competent authority stating that the Tenderer is **in order with the payment of applicable taxes** that apply by law in the country of establishment.