



## **Tender Specifications**

**RWA21001-10040 of May 2023**

**Services procurement contract for**

**“Individual consultant to conduct Good  
Manufacturing Practices (GMP) and  
Capacity development in India”.**

**Negotiated Procedure without Prior Publication**

**Country: RWANDA**

**Navision code: RWA2100111**

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# 1 General provisions

## 1.1 Derogations from the General Implementing Rules

Chapter ‘*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 or as a complement or an elaboration thereof.

These tender documents derogate from Art. 25-33 of the General Implementing Rules (see point 4.8 “Performance guarantee”).

## 1.2 Contracting authority

The contracting authority of this public procurement contract is Enabel, the Belgian development agency, 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).

Enabel has the exclusive competence for the execution, in Belgium and abroad, of public service tasks of direct bilateral cooperation with the partner countries. Moreover, it may also perform other development cooperation tasks at the request of public interest organisations, and it can develop its own activities to contribute towards realisation of its objectives.

For this procurement contract, Enabel is represented by **Mr. Dirk DEPREZ, Resident Representative of Enabel RWANDA** who will sign the award letter and mandated to represent the company towards third parties.

## 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 2013<sup>1</sup>;
- The Belgian Law of 21 December 1998 establishing the Belgian Technical Cooperation as a public-law company<sup>2</sup>;
- The Belgian Law of 23 November 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 2003<sup>3</sup>, 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;

<sup>1</sup> Belgian Official Gazette of 30 December 1998, of 17 November 2001, of 6 July 2012, of 15 January 2013 and of 26 March 2013.  
Belgian Official Gazette of 1 July 1999.

<sup>3</sup> Belgian Official Gazette of 18 November 2008.

- 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 Labour Organisation<sup>4</sup> 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 contracts<sup>5</sup>;
- The Law of 17 June 2013 on justifications, notification and legal remedies for public procurement contracts and certain procurement contracts for works, supplies and services<sup>6</sup>;
- The Royal Decree of 18 April 2017 on the award of public procurement contracts in the classic sectors<sup>7</sup>;
- Royal Decree of 14 January 2013 establishing the General Implementing Rules for public procurement contracts and for concessions for public works<sup>8</sup>;
- 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;

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

<sup>5</sup> Belgian Official Gazette 14 July 2016.

<sup>6</sup> Belgian Official Gazette of 21 June 2013.

<sup>7</sup> Belgian Official Gazette 9 May 2017.

<sup>8</sup> Belgian Official Gazette 27 June 2017.

All Belgian regulations on public contracts can be consulted on [www.publicprocurement.be](http://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:

The tenderer: An economic operator submitting a tender;

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

The contracting authority: Enabel, represented by the Resident Representative of Enabel in RWANDA;

The tender: 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 works;

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**

1.7.1. 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.



1.7.2. 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.

1.7.3. 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.

1.7.4. 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.

1.7.5. 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.

1.7.6. 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.

1.7.7. 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 consists in the performance of “**Good Manufacturing Practices (GMP) and Capacity development in India**”, in conformity with the conditions of these Tender Specifications.

### 2.3 Lots<sup>9</sup>

*(Articles 2, 52° and 58 of the Law and Articles 49 and 50 of the Royal Decree Award)*

The procurement contract has 3 Lots, each of them being indivisible. A tender for part of a lot is inadmissible. The 3 Lots are described below:

- **Lot 1:** Good Manufacturing Practices (GMP) inspection development in **Ahmedabad (1 site) and Telangana (1 site), India**
- **Lot 2:** Good Manufacturing Practices (GMP) inspection in **Boisar-Thane 401506 (1 site) and Dombivali (E) (1 site)**
- **Lot 3:** Good Manufacturing Practices (GMP) inspection in **Mumbai (1 site) and Vasai (E) -Thane 401208 (1 site)**

When tendering for several lots, the tenderer may not offer discounts or better conditions in his tender in case these lots were to be awarded to him.

**The tenderer indicates in his tenders for several lots his order of preference for the awarding of these lots.**

**The contracting authority limits the number of lots that may be awarded to a single tenderer to only one single Lot per tenderer.**

### 2.4 Items

Each Lot of this procurement contract consists of the one item (1) with tasks described in ToRs below (See also point 5 of the tender specification)

These tasks are pooled and form one single Lot -.

### 2.5 Term of the procurement contract<sup>10</sup>

The contract begins upon award notification and has an overall duration of maximum of 4 months (120 calendar days) starting from the date of the reception of the award notification letter. Variants are not permitted.

Each tenderer may submit only one tender.

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<sup>9</sup> For contracts of an amount equal to or greater than € 135 000 excl. VAT, the contracting authority is obliged to consider dividing the contract into lots unless a valid reason is given in the procurement documents.

<sup>10</sup> Please note: term of the procurement contract not to be confused with performance period.

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## **2.6 Option**

Options are not permitted.

## **2.7 Quantity**

*(Art. 57 of the Law)*

Quantities are determined in the ToRs (See point 5 of the tender specifications)

## 3 Procedures for 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 Semi-official notification

#### 3.2.1 Enabel publication

This procurement contract is published on the Enabel website ([www.enabel.be](http://www.enabel.be)) **up to 31<sup>st</sup> May 2023**.

### 3.3 Information

The awarding of this procurement contract is coordinated by **Mrs. Françoise MUSHIMIYIMANA, National Expert in Contractualization and Administration at Enabel Rwanda** – [francoise.mushimiyimana@enabel.be](mailto:francoise.mushimiyimana@enabel.be)

Throughout this procedure all contacts between the contracting authority and the (prospective) tenderers about this procurement contract will exclusively pass through 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 **21/05/2023** inclusive (10 days before the deadline for submission of bids), candidate-tenderers may ask questions about these Tender Specifications and the procurement contract.

Questions will be in writing to Françoise MUSHIMIYIMANA,  
([francoise.mushimiyimana@enabel.be](mailto:francoise.mushimiyimana@enabel.be)),

with copy to

Lyse UWINGABIRE ([lyse.uwingabire@enabel.be](mailto:lyse.uwingabire@enabel.be))

and

Evariste SIBOMANA, ([evariste.sibomana@enabel.be](mailto:evariste.sibomana@enabel.be))

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](http://www.enabel.be)

To be able to submit a tender in full knowledge of the facts, the tenderer may visit the website [www.enabel.be](http://www.enabel.be)

The tenderer is supposed to submit his tender after reading and taking into account any corrections made to the Tender Specifications that are published on the Enabel website 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.

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 (**see point 6 “Forms”**). In case he does not use these forms, 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 calendar days from the reception deadline 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, **all taxes included (including VAT<sup>11</sup> and the applicable WHT)**.

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

*(Art. 32 §3 Royal Decree 18.04.2017)*

The service provider is deemed to have included in his unit and global prices any charges and taxes generally applied to services, including value-added tax.

The following are in particular included in the prices:

- **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 expenses needed to perform the present contract, the copyright fees, the purchase or leasing of third party services needed for the performance of the contract, Transport outside Kigali and the applicable **Withholding taxes**.
- Reimbursable (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.

<sup>11</sup> For international bidders, the reverse VAT of 18% will be applicable (art.12 of the law 37/2012 of 09/11/2012)

### 3.4.4 How to submit tenders?

Without prejudice to any variants, the tenderer may only submit one tender only per procurement contract.

The tenderer submits his tender as follows:

**The tender will be drawn up in 3 copies, one of them being the original and two copies.**

**Soft Copies (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 (original hand-written signature) by the tenderer or his/her representative. The same applies to any alteration, deletion or note made to this document.

The representative 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", the tender documents number **RWA21001-10040** and the Navision code **RWA2100111**.

The tender must be received **before Wednesday 31<sup>st</sup> May 2023 at 4:00 AM Kigali time**. It must be sent to:

**The Attention of Françoise MUSHIMIYIMANA  
National ECA - Enabel Rwanda  
Belgian development agency  
KN 67 Street, plot N° 10  
SORAS Towers, Wing A, 6<sup>th</sup> Floor  
Opposite St Michel Catholic Church  
B.P. 6089 KIYOVU**

It may be submitted:

- a) Either By post mail (standard mail or registered mail)

In this case, the sealed envelope is put in a second closed envelope. The delivery record makes proof of compliance with the time-limit for receipt.

- b) Delivered by hand directly to the contracting authority against a signed and dated receipt: In this case, acknowledgement of receipt makes proof of compliance with the time-limit for receipt.

The service can be reached on working days during office hours: from 8 am to 12:30 pm and from 1:30 pm to 5 pm (Rwanda time). 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 accepted<sup>12</sup>.

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Art. 83 of the Royal Decree Award

### 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 unconditional.

The withdrawal may also be communicated by fax or 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 tender is submitted via e-tendering, the tender is modified or withdrawn in accordance with Article 43, §2 of the Royal Decree of 18 April 2017.

Thus, a tender that is modified or withdrawn after the signing of the submission report means that a new submission report, signed in accordance with paragraph 1, must be sent.

The subject-matter and the scope of the changes must be indicated in detail.

The withdrawal must be pure and simple.

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 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 tender must be in the possession of the contracting authority before the final submission date and time specified in point 3.5 “Submission of tenders”. The tenders shall be opened behind closed doors.

### 3.4.7 Selection of tenderers

*Articles 66 – 80 of the Law; Articles 59 to 74 Royal Decree Award*

#### 3.4.7.1 Exclusion grounds

*Articles 52 and 69 of the Law; Article 51 of the Royal Decree of 18.04.2017*

The mandatory and optional exclusion grounds are given in attachment to these Tender Specifications.

By submitting this tender and signing the included **Declaration on honour – exclusion criteria** form, 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 exactitude 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

*Article 71 of the Law and Articles 65 to 74 of the Royal Decree of 18.04.2017*

Moreover, by means of the documents requested in the ‘**Selection file**’, the tenderer must prove that he is sufficiently capable, from a **technical** point of view, to successfully perform this public procurement contract.

**The minimum required profile (qualifications and experience) for the key experts** will be analysed at the selection stage.

#### **Minimum Qualifications and Skills**

Each interested consultant must have:

- At least an advanced University degree in BSc (Hons) Molecular or Cell Biology, B. Pharmacy (Hons), Chemistry, Biochemistry, Medicine, Microbiology, Biotechnology, Bioengineering or related science.
- Must have professional qualification (proven by a document) or certified as a GMP lead inspector/auditor by a National Medicines Regulatory Authority (**with related proof such as a confirmation letter from NRA that one is qualified lead GMP Inspector or certification as a Lead GMP Inspector or list of GMP inspections carried out as lead GMP inspector**)

#### **Minimum required Professional experience.**

- Must have a minimum of 5 years’ professional work experience in the regulation of medicines related to Production/Control/Quality assurance acquired by working with a manufacturer or National Regulatory Authority
- With At least 2 similar assignments as a GMP Inspector/auditor (proven by certificate of good completion or any other related document proving this experience).
- Experience at the international level would be an asset. (either as a WHO GMP observer, or other similar assignments)

***The bidder who will not meet the minimum requirements on the required profile, will not be selected for the award stage.***

### 3.4.7.3 Overview of the procedure

*Text valid in case **several award criteria** are given in the Tender Specifications.*

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. The contracting authority will restrict the number of tenders to be negotiated by applying the award criteria stated in the procurement documents. 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. **Maximum 3 tenderers** may be included 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:

#### a) Technical proposal 60%

The tenderer presents the detailed methodology to perform the requested services showing the suitability with Terms of Reference and comments made on it, activity schedule, staff schedule and work organization between team members based on the instructions given in the Terms of Reference. They are subject to evaluation according to the following sub-criteria:

1.	<ul style="list-style-type: none"> <li>Detailed Methodology including the details on how all activities and sub-activities will be performed, max 15 points</li> <li>understanding of ToRs and overall strategy to be used, max 15 points</li> <li>risk assessment and mitigation measures max 10 points</li> </ul>	40 points
2.	Detailed work plan & timetable of activities and sub- activities and clear distribution of man-days by activities	20 points

For the technical award criteria, the average score has to be at least 70% (42/60) to qualify for the Negotiation stage.

#### b) Financial proposal (40%)

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

$$\text{Points tender A} = \frac{\text{amount of lowest tender} * 40}{\text{Amount of tender A}}$$

#### 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

##### **Articles 41 and 81 of the Law**

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.

The contracting authority maintains the right to award only a certain lot or certain lots.

#### **3.4.8 Concluding the procurement contract**

##### ***Art. 88 of the Royal Decree Award***

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 and, on the same day, by registered post.

**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;
- If any, minutes of the information session and/or clarifications and/or the addendum,
- The approved BAFO of the contractor and all of its annexes;
- The registered letter of 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 Special contractual provisions

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 documents derogate from Art.25-33 of the General Implementing Rules.

### 4.1 Definitions (Art. 2)

- Contract manager: The official or any other person who manages and controls the performance of the contract;
- Performance bond: Financial guarantee given by the successful tenderer to cover its obligations until final and good performance of the contract;
- Acceptance: Observation by the contracting authority that the performance of all or part of the works, supplies or services is in compliance with good practice and with the terms and conditions of the contract;
- Progress payment: Payment of an instalment under the contract after service delivery is accepted;
- Advance: Payment of part of the contract before service delivery (if accepted);
- Amendment: Agreement established between the contracting parties during contract performance in view of changing documents applicable to the contract.

### 4.2 Correspondence with the service provider (Art. 10)

Notifications by the contracting authority are addressed to the domicile or to the registered office mentioned in the tender, except if the tender documents require the service provider to elect domicile elsewhere after conclusion of the contract.

### 4.3 Managing official (Art. 11)

The managing official is **Mr. Washington T. Samukange**, Tel: (+250) 788 332 212,

E-mail : [washington.samukange@enabel.be](mailto:washington.samukange@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 him/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. (S)he 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.

#### **4.4 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 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.

*Art. 12/3 § 2 of the Royal Decree of 14 January 2013:*

*3° when this involves a service contract in a sector susceptible to fraud, the subcontracting chain may only have two levels at most, namely the contractor's direct subcontractor and the second level subcontractor.*

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.

#### **4.5 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.

## **4.6 Protection of personal data**

### **4.6.1 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.

### **4.6.2 PROCESSING OF PERSONAL DATA BY A SUBCONTRACTOR**

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.

The personal data that will be processed are confidential. The contractor will therefore limit access to data to the strictly necessary personnel for the performance, management and monitoring of the public contract.

For the performance of the public contract, the contracting authority will determine the purposes and means of processing personal data. In this case, the contracting authority will be responsible for the processing and the contractor will be its processor, within the meaning of Article 28 of the GDPR.

Processing carried out on behalf of a controller must be governed by a contract or other legal act that is binding on the processor with regard to the personal data controller and that sets out that the subcontractor acts only on the instruction of the person in charge of the processing and

that the confidentiality and security obligations regarding the processing of personal data are also the responsibility of the subcontractor Article 28 §3 of the GDPR).

To this end, the tenderer must fill out, sign and submit to the contracting authority the subcontracting agreement given in Annex 6.18.

#### **4.7 Intellectual property (Art. 19 to 23)**

§1 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.

When the contracting authority does not acquire the intellectual property rights, it obtains a patent licence of the results protected by intellectual property law for the exploitation modes that are mentioned in the procurement documents.

The contracting authority lists the exploitation modes for which it intends to obtain a licence in the procurement documents.

#### **4.8 Performance bond (Art. 25 to 33)**

No performance bond is required

#### **4.9 Conformity of performance (Art. 34)**

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

#### **4.10 Changes to the procurement contract (Art. 37 to 38/19)**

##### **4.10.1 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.

#### 4.10.2 Adjusting the prices (Art. 38/7)

For this procurement contract, price reviews are not permitted.

#### 4.10.3 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.

#### 4.10.4 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.

### 4.11 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...).

### 4.12 Performance modalities (Art. 146 et seq.)

#### 4.12.1 Deadlines and terms (Art. 147)

The services must be performed within 4 months (overall contract duration) as from the day after the date on which the service provider received the contract conclusion notification letter, with maximum 60-man days. **The closure of the service provider's business for annual holidays is included in this calculation.**



#### **4.12.2 Place where the services must be performed and formalities (Art. 149)**

The services will be performed in Rwanda

#### **4.12.3 Evaluation of the services performed.**

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

When the services have been performed, the quality and conformity of the services shall be evaluated. A report of this evaluation shall be drawn up. The original copy of this report will be sent to the contractor. Any services that have not been performed correctly or in conformity shall be started again.

#### **4.13 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 registered 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.

#### **4.14 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.

#### **4.15 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.

#### **4.16 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.

#### **4.16.1 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 by registered mail.

The contractor must repair the defects without any delay. He may assert his right of defence by registered 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.

#### **4.16.2 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.

#### **4.16.3 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

Tender Specifications RWA21001-10040 "GMP and Capacity development in India"

contractor. However, any fines or penalties imposed during the performance of a replacement procurement contract will be borne by the new contractor.

## **4.17 End of the procurement contract**

### **4.17.1 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.

## **4.18 Invoicing and payment of services (Art. 66 - 72 and 160)**

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

**To the attention of SAMUKANGE, Washington**  
**Intervention Manager – KWIGIRA Project**  
**Belgian development agency**  
**KN 67 Street, plot N° 10**  
**SORAS Towers, Wing A, 6th Floor**  
**Opposite St Michel Catholic Church**  
**B.P. 6089 KIYOVU**  
**KIGALI- RWANDA**

Only services that have been performed 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 contractor must be paid within 30 calendar days with effect from the expiry of the verification period, and provided that the contracting authority possesses, at the same time, the duly established invoice.

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

The invoice will be mention:

- **“Enabel, 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)”;**
- the name of the contract: **“Good Manufacturing Practices (GMP) and Capacity development in India”.**
- the reference of the tender documents: **« RWA21001-10040 »**
- the Navision code and the lot number: **“RWA2100111”.**
- the name of the Managing Official: **“SAMUKANGE, Washington”.**

The invoice shall be in EUROS.

No advance may be asked by the contractor.

**100% of the contract amount will be paid upon completion and approval of the services to be implemented.**

#### **4.19 Modifications to the contract (Art. 37-38 and 151)**

The contracting authority has the right to change the initial tender unilaterally, if the following conditions are respected:

1° the scope of the contract remains unaltered;

2° the modification is limited to 10 % of the initial awarded amount.

The essential terms and conditions can only be modified with reasons, to be mentioned in an amendment.

#### **4.20 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 Inge Janssens

rue Haute 147

1000 Brussels

Belgium

## 5 Terms of Reference

### INDIVIDUAL CONSULTANT TO CONDUCT GOOD MANUFACTURING PRACTICES (GMP) AND CAPACITY DEVELOPMENT IN INDIA.

#### 5.1. GENERAL INFORMATION

##### **Rwanda FDA**

The Rwanda Food and Drugs Authority was established by the Law N° 003/2018 of 09/02/2018 determining its mission, organization and functioning. The mandate of Rwanda FDA is to protect public health from substandard and falsified products through regulating the manufacture, importation and exportation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco & tobacco products.

Within Rwanda FDA, the Food and Drugs Inspection and Compliance Division (FDIC) is responsible for conducting Good Manufacturing Practice (GMP) inspections of premises used to manufacture regulated products. In order to fully operationalise this Division, Rwanda FDA is seeking to engage the services of a consultant to provide capacity building and technical support for inspectors conducting GMP inspections of medicines in local and foreign facilities.

##### **Access to quality vaccines, medicines and health technology in Rwanda – KWIGIRA project**

Enabel, the Belgian development agency signed an agreement with European Union to support Rwanda FDA (Rwanda Food and Drugs Authority) for 4 years (2022-2026) to implement its strategic plan. Rwanda Food and Drugs Authority (Rwanda FDA) Strategic Plan was developed to ensure proper implementation of the Authority's mission provided under the Law N° 003/2018 of 09/02/2018. The specific objective of the agreement is:

‘To assist Rwanda FDA to adequately perform its mission to protect public health and to reach and maintain maturity level 3 of WHO Global Benchmarking Tool (GBT) to fully regulate pharmaceutical products including vaccines manufactured in Rwanda’.

##### **Rwanda FDA requirements**

One of the Rwanda FDA priorities is to build expertise and skills of their inspectors in the areas of regulatory licensing and Good Manufacturing Practices (GMP) Inspections.

In light of this, Enabel seeks to hire a qualified GMP lead inspector to perform coached GMP inspections of Rwanda FDA GMP inspectors in GMP inspections of manufacturing facilities in India.

#### 5.2. OBJECTIVE OF THE ASSIGNMENT

The objective of the consultancy is to develop the capacity, competencies and skills of Rwanda FDA GMP inspectors in GMP inspections of manufacturing facilities of human medicinal products through Coached GMP Inspections

### 5.3. SCOPE OF THE ASSIGNMENT

The major component of the consultancy is to provide Coached GMP Inspections of Rwanda FDA inspectors in GMP Inspections of manufacturing facilities in India.

The tender is made of 3 Lots as follows:

- **Lot 1:** Good Manufacturing Practices (GMP) inspection development in **Ahmedabad (1 site) and Telangana (1 site), India**
- **Lot 2:** Good Manufacturing Practices (GMP) inspection in **Boisar-Thane 401506 (1 site) and Dombivali (E) (1 site)**
- **Lot 3:** Good Manufacturing Practices (GMP) inspection in **Mumbai (1 site) and Vasai (E) -Thane 401208 (1 site)**

#### Key activities/ tasks (per Lot)

- To accompany Rwanda FDA inspectors to conduct coached GMP inspections to facilitate product registration across different product types (oral dosage forms, sterile products, biologicals, vaccines etc.) in India.

#### Duration of the contract

The contract will have an overall duration of four (4) months (120 calendar days).

### 5.4. DELIVERABLES AND ESTIMATED duration

#### 5.4.1. DELIVERABLES

By the end of the consultancy mission, the consultant will be expected to deliver the following:

- Report on coached inspections
- Reviewed GMP inspection reports for inspected sites in the approved Rwanda FDA format.

Note also that all deliverables and reports have to be approved by Enabel's designated Contract Manager and RFDA representatives.

#### 5.4.2. ESTIMATED DURATION ( timeline)

Deliverables	Estimated man-days per deliverables per Lot
<b>Lot 1 – Ahmedabad (1 site) and Telangana (1 site), India</b>	
Training and training report on coached inspection	1 person day
Reviewed GMP inspection reports for inspected sites	12 person days
<b>Lot 2 – Thane (1 site) and Dombivali (E) (1 site), India</b>	
Training and training report on coached inspection	1 person day
Reviewed GMP inspection report for inspected sites	11 person days
<b>Lot 3 - Mumbai (1 site) and Thane (1 site), India</b>	
Training and training report on coached inspections	1 person day

Reviewed GMP inspection reports for inspected sites	11 person days
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## 5.5. MANDATORY REQUIRED TECHNICAL PROFILE OF THE INDIVIDUAL CONSULTANT

**The minimum required individual Consultant profile (to be considered in selection stage, please refer to point 3.4.7.2 Selection criteria & 6.6 technical Selection file ) Other required skills**

- Excellent facilitation and interpersonal communication skills
- Fluent in English
- Good knowledge of recognized international guidelines such as WHO, PIC/S and other international guidance documents relevant to pharmaceutical GMP inspections.
- Ability to identify key issues associated with the task, anticipate risks and propose recommendations to mitigate the anticipated risks.

## 5.6. Reporting arrangements:

.....

# 6 Forms

## 6.1. Identification forms

### 6.1.1. Natural person

To fill the form, please click here : <https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:e15a7f59-9a3c-4072-89ac-deb89f513e1c>

<b>I. PERSONAL DATA</b>			
FAMILY NAME(S)①			
FIRST NAME(S)①			
DATE OF BIRTH			
JJ	MM	YYYY	
PLACE OF BIRTH (CITY, VILLAGE)		COUNTRY OF BIRTH	
TYPE OF IDENTITY DOCUMENT			
IDENTITY CARD	PASSPORT	DRIVING LICENCE②	OTHER③
ISSUING COUNTRY			
IDENTITY DOCUMENT NUMBER			
PERSONAL IDENTIFICATION NUMBER④			
PERMANENT PRIVATE ADDRESS			
POSTCODE	P.O. BOX	CITY	

<b>REGION ⑤</b>  <b>PRIVATE PHONE</b>  <b>PRIVATE E-MAIL</b>		<b>COUNTRY</b>	
<b>II. BUSINESS DATA</b>		If YES, please provide business data and attach copies of official supporting documents	
Do you run your own business without a separate legal personality (e.g. sole traders, self-employed etc.) and you provide as such services to the Commission, other Institutions, Agencies and EU-Bodies ?  <div style="display: flex; justify-content: space-around;"> <span><b>YES</b></span> <span><b>NO</b></span> </div>		<b>BUSINESS NAME (if applicable)</b>  <b>VAT NUMBER</b>  <b>REGISTRATION NUMBER</b>  <b>PLACE OF REGISTRATION</b>  <div style="display: flex; justify-content: space-between;"> <span></span> <span><b>CITY</b></span> </div> <div style="display: flex; justify-content: space-between;"> <span></span> <span><b>COUNTRY</b></span> </div>	
<b>DATE</b>		<b>SIGNATURE</b>	

- 
- ① As indicated on the official document.
  - ② Accepted only for Great Britain, Ireland, Denmark, Sweden, Finland, Norway, Iceland, Canada, United States and Australia.
  - ③ Failing other identity documents: residence permit or diplomatic passport.
  - ④ See table with corresponding denominations by country.
  - ⑤ To be completed with Region, State or Province by non EU countries only, excluding EFTA and candidate countries.

### 6.1.2. Legal person entity private/public legal body

To fill the form, please click here :

<https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:fcf7423f-7287-4cbb-9c7b-645ab60734a3>

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

- 
- 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.



### 6.1.3. Public law entity

To fill the form, please click here :

<https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:fcf7423f-7287-4cbb-9c7b-645ab60734a3>

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

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.

#### 6.1.4. Subcontractors

Name and legal form	Address / Registered office	Object

## 6.2. Financial identification Form

<b><u>BANKING DETAILS</u></b>	
ACCOUNT NAME <sup>13</sup>	
IBAN/ACCOUNT NUMBER <sup>14</sup>	
CURRENCY	
BIC/SWIFT CODE	
BANK NAME	

<b>ADDRESS OF BANK BRANCH</b>		
STREET & NUMBER		
TOWN/CITY	POST CODE	
COUNTRY		

<b><u>ACCOUNT HOLDER'S DATA</u></b> AS DECLARED TO THE BANK		
ACCOUNT HOLDER		
STREET & NUMBER		
TOWN/CITY	POST CODE	
COUNTRY		

SIGNATURE OF ACCOUNT HOLDER (Obligatory)	DATE (Obligatory)

<sup>13</sup> This does not refer to the type of account. The account name is usually the one of the account holder. However, the account holder may have chosen a different name to its bank account.

<sup>14</sup> Fill in the IBAN Code (International Bank Account Number) if it exists in the country where your bank is established.

### 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 tenderer commits to performing the public contract in accordance with the provisions of the Tender Specifications for the following prices, in EUR and inclusive of VAT and other applicable taxes (written in figures):

<b>1. Expert Fees</b>				
	<b>Unit</b>	<b>Unit price* incl. VAT &amp; WHT</b>	<b>Quantity</b>	<b>Total incl. VAT &amp; WHT<sup>15</sup></b>
<b>Expert 1</b> (Consultant)	Man-day	€		€
<b>VAT<sup>16</sup></b>			<b>18%</b>	
<b>Sub-total</b>				<b>€</b>
<b>2. Reimbursable Fees (if applicable)</b>				
International travel costs		€		€
Visa costs		€		€
<b>GRAND TOTAL</b>				<b>€</b>

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.

**Note:**

- **EXPERT COST** including: fees, the per diems, accommodation costs, local travel 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 expenses needed to perform the present contract, the copyright fees, the purchase or leasing of third party services needed for the performance of the contract, Transport outside Kigali, Accommodation, and the applicable **Withholding taxes (WHT)**.
- **REIMBURSABLE COST:** Only International travel costs & Visa costs.
- Enabel does not reimburse international travel days (if any).

Certified true and sincere,

Handwritten original signature (s): .....

<sup>15</sup> Mind double taxation for international bidders- see RRA website

<sup>16</sup> Reverse VAT for international bidders (art. 12 of the LAW N° 37/2012 OF 09/11/2012)

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## 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.

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- 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/headquarters/headquarters-homepage/8442/consolidated-list-sanctions_en)

[https://eeas.europa.eu/sites/eeas/files/restrictive\\_measures-2017-01-17-clean.pdf](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%A9sorier/contr%C3%B4le-des-instruments-1-2](https://finances.belgium.be/fr/sur_le_spf/structure_et_services/administrations_generales/tr%C3%A9sorier/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.

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

.....

Place, date

## 6.5. Integrity statement for the tenderers

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

- 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.
- 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).
- 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:

- 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.
- 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.
- 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.
- 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

## 6.6. Selection file – technical aptitude

<b>Technical aptitude: See Art. 68 of the Royal Decree of 18.04.2017</b>	
<p>To perform this assignment, the consultant is required to meet the following minimum requirements:</p> <p><b>Minimum Qualifications and Skills</b></p> <p>Each interested consultant must have:</p> <ul style="list-style-type: none"> <li>➤ At least an advanced University degree in BSc (Hons) Molecular or Cell Biology, B. Pharmacy (Hons), Chemistry, Biochemistry, Medicine, Microbiology, Biotechnology, Bioengineering or related science.</li> <li>➤ Must have professional qualification (proven by a document) or certified as a GMP lead inspector/auditor by a National Medicines Regulatory Authority (<b>with related proof such as a confirmation letter from NRA that one is qualified lead GMP Inspector or certification as a Lead GMP Inspector or list of GMP inspections carried out as lead GMP inspector</b>)</li> </ul> <p><b>Minimum required Professional experience.</b></p> <ul style="list-style-type: none"> <li>➤ Must have a minimum of 5 years' professional work experience in the regulation of medicines related to Production/Control/Quality assurance acquired by working with a manufacturer or National Regulatory Authority</li> <li>➤ With At least 2 similar assignments as a GMP Inspector/auditor (proven by certificate of good completion or any other related document proving this experience).</li> <li>➤ Experience at the international level would be an asset. (either as a WHO GMP observer, or other similar assignments)</li> </ul> <p>The tenderer includes in his tender a list with the main services that have been delivered over the past three years including the amount and date as well as the public or private recipients. Service delivery is demonstrated by certificates drawn up or approved by the competent authority or, where the client was a private purchaser, by certification of the private purchaser, or by default, by a simple statement of the service provider.</p>	<p><b>PROVIDE THE PROOF OF THE MINIMUM REQUIRED PROFILE for the consultant as described here.</b></p>



## Other documents to be provided

### 6.7. List of the similar assignments

Bidder must provide in his bid the list of the **main project (min.2) performed any/or/and of the following areas: GMP Inspector/audito**, Regulation of medicines related to Production/Control/Quality assurance acquired by working with a manufacturer or National Regulatory Authority

fund established, including the amount involved and the relevant dates, and the public or private bodies on behalf of which they were carried out showing that the Bidder has experience in delivering those supplies.

Description of the main similar service deliveries	Delivery places	Amount involved	Relevant dates in the last 5 years	Name of the Client

## 6.8. Key expert

The tenderer must complete the summarized table hereunder. He/she must provide in his/her offer a signed CV and degree certificate.

Name of expert	Proposed position	Years of relevant experience	Education background	Special area of knowledge

## 6.9. Annexes

### 6.9.1. GDPR clauses (in case of CONTRACTOR who will process personal data)

*This annex is to be used if the tenderer is a sub-contractor in the sens of GDPR regulations, a natural or legal entity that processes personal data on behalf of Enabel.*

*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.*

AGREEMENT on the Processing of personal data (GDPR)

**BETWEEN:**

**The contracting authority: Enabel, the Belgian development agency**, public-law company with social purposes, with its registered office at Rue Haute 147, 1000 Brussels, Belgium (enterprise number 0264.814.354, RPM/RPR Brussels).

Represented by: [.....],

Hereinafter referred to as 'the contracting authority' or 'personal data controller'.

**AND:**

**The contractor:** [.....], with its registered office at [.....], and which is registered with the Crossroad Bank for Enterprises under number [.....],

Represented by: [.....],

in accordance with Article [.....] of the statutes of the company,

Hereinafter referred to as 'the contractor' or 'processor'.

The contracting authority and the contractor are referred to separately as a 'Party' and are jointly referred to as the 'Parties'.

## **Preamble**

By decision of the [.....], the contractor was awarded a public contract in accordance with Tender Specifications no. [.....].

The needs of this public contract involve the processing of personal data within the meaning of the Belgian law on the protection of natural persons with regard to the processing of personal data and of European Regulation 2016/679 (GDPR).

The purpose of this amendment is to comply with the requirements of Article 28 of the GDPR.

The public contract conditions are not otherwise derogated, particularly in terms of the time frame and value of the public contract awarded.

## **Article 1: Definitions**

- 1.1. Terms such as 'process'/'processing', 'personal data', 'personal data controller', 'processor' and 'personal data breach' must be interpreted in light of data protection legislation. 'Data protection legislation' refers to any regulation of the European Union and/or its Member States, including, without being limited to laws, directives and regulations for the protection of personal data, in particular European Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and 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.

## **Article 2: Subject-matter of the Agreement**

- 2.1. During performance of the public contract, the contracting authority entrusts the contractor with the processing of personal data. The contractor undertakes to process personal data in the name of and on behalf of the contracting authority.
- 2.2. The contractor performs the public contract in accordance with the provisions of this Agreement.

- 2.3. Both Parties explicitly undertake to comply with the provisions of applicable data protection laws and to do nothing or fail to cause the other Party to violate relevant and applicable data protection laws.
- 2.4. The elements included in the processing are further included and clarified in Annex 1 of this Agreement. The following are particularly included in said Annex:
- a) Personal data processing activities;
  - b) The categories of personal data processed;
  - c) The categories of stakeholders to which the personal data of the contracting authority's relate;
  - d) The purpose of the processing.
- 2.5. Only the personal data mentioned in Annex 1 of this Agreement may and must be processed by the contractor. In addition, personal data will only be processed in light of the purposes set out by the Parties in Annex 1 of this Agreement.
- 2.6. Both Parties undertake to take appropriate measures to ensure that personal data are not misused or acquired by an unauthorized third party.
- 2.7. In the event of a conflict between the provisions of this Agreement and those of the Tender Specifications, the provisions of this Agreement will prevail.

### **Article 3: Instructions of the contracting authority**

- 3.1. The contractor undertakes to process personal data only on the documented instructions of the contracting authority and in accordance with agreed processing activities as defined in Annex 1 of this Agreement. The contractor will not process the personal data subject to this Agreement in a manner inconsistent with the instructions and provisions of this Agreement.
- 3.2. The contractor undertakes to process personal data in accordance with the documented instructions of the personal data controller, including for transfers of personal data to third countries or to international organisations, unless it is required under EU or Member State law. In this case, the processor informs the personal data controller of this legal obligation prior to processing unless the relevant law prohibits such information for important public interest reasons.
- 3.3. The contracting authority may unilaterally make limited changes to the instructions. The contracting authority undertakes to consult with the contractor before making significant changes to the instructions. Changes affecting the content of this Agreement must be agreed by the Parties.

- 3.4. The contractor undertakes to immediately notify the contracting authority if it considers that the instructions received (in whole or in part) constitute a violation of the Regulations or other provisions of EU law or Member State data protection law.

#### **Article 4: Assistance to the contracting authority**

- 4.1. **Legal conformity** The contractor assists the contracting authority in accordance with its obligations under the Regulation, taking into account the nature of the processing and the information available to the contractor.
- 4.2. **Personal data breach** In the case of a personal data breach in relation to processing under this Agreement, the contractor must without undue delay after having become aware of it notify the personal data breach to the contracting authority.

At the very least, this notification should include the following information:

- (a) Nature of the personal data breach;
- (b) The categories of personal data;
- (c) The categories and approximate number of data subjects concerned;
- (d) The categories and approximate number of personal data records concerned;
- (e) The likely consequences of the personal data breach;
- (f) The measures taken or proposed to be taken by the contractor to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.

The contractor is required to remedy the negative consequences of a data breach as quickly as possible or to minimise other potential consequences. The contractor will immediately implement all remedies requested by the contracting authority or the relevant authorities to remedy any data breach or other non-compliance and/or mitigate the risks associated with these events. The contractor will have to cooperate at all times with the contracting authority and observe its instructions in order to enable it to carry out an appropriate investigation into the data breach, formulate a correct response and then take appropriate action.

- 4.3. **Data protection impact assessment** Where applicable and where requested by the contracting authority, the contractor assists the contracting authority in carrying out the data protection impact assessment in accordance with Article 35 of the Regulation.

#### **Article 5: Obligations of the contractor/processor**

- 5.1. The contractor will deal with all reasonable requests from the contracting authority for the processing of personal data related to this Agreement, immediately or within

Tender Specifications RWA21001-10040 "GMP and Capacity development in India"

a reasonable period of time (based on the legal obligations set out in the Regulation) and in an appropriate manner.

- 5.2. The contractor guarantees that there is no obligation arising from any applicable legislation that makes it impossible to comply with the obligations of this Agreement.
- 5.3. The contractor maintains complete documentation, in accordance with the law or regulations applicable to the processing of personal data carried out for the contracting authority. In particular, the contractor must keep a record of all categories of processing activities carried out on behalf of the contracting authority in accordance with Article 30 of the GDPR.
- 5.4. The contractor undertakes not to process personal data for any purpose other than the performance of the public contract and the fulfilment of the responsibilities of this Agreement in accordance with the documented instructions of the contracting authority; if the contractor, for whatever reason, cannot comply with this requirement, he will notify the contracting authority without delay.
- 5.5. The contractor will immediately inform the contracting authority, if he believes that an instruction by the contracting authority violates applicable data protection legislation.
- 5.6. The contractor will ensure that personal data are disclosed only to those who need it to perform the public contract in accordance with the principle of proportionality and the principle of "need to know" (i.e. data are provided only to persons who need personal data to perform the public contract as determined in the relevant Tender Specifications and this Agreement).
- 5.7. The contractor undertakes not to disclose personal data to persons other than contracting authority personnel who require personal data to comply with the obligations of this Agreement and ensures that identified staff have accepted appropriate legal and contractual confidentiality obligations.
- 5.8. If the contractor is in breach of this public contract and the GDPR by determining the purposes and means of processing, he should be considered a personal data controller in the context of such processing.

## **Article 6: Obligations of the contracting authority/controller**

- 6.1. The contracting authority will provide all necessary assistance and cooperate in good faith with the contractor to ensure that any processing of personal data is in accordance with the requirements of the Regulation, including the principles relating to the processing of personal data.
- 6.2. The contracting authority will agree with the contractor on the appropriate channels of communication to ensure that instructions, guidance and other communications regarding personal data that are processed by the contractor on behalf of the contracting authority are well received between the Parties. The contracting authority notifies the contractor of the identity of the single point of contact of the awarding authority that the contractor is required to contact under this Agreement. Unwritten instructions (e.g. oral instructions by telephone or in person) must always be confirmed in writing.

The point of contact of the contracting authority is: [dpo@enabel.be](mailto:dpo@enabel.be)

- 6.3. The contracting authority guarantees that it will not issue any instructions, guidance or requests to the contractor who does not comply with the provisions of the Regulation.
- 6.4. The contracting authority provides the necessary assistance to the contractor and/or his or her subsequent subcontractors to comply with a request, order, investigation or subpoena addressed to the contractor or his subsequent subcontractor(s) by a competent government or judicial authority.
- 6.5. The contracting authority guarantees that it will not instruct, guide or ask the contractor to compel the contractor and/or his subsequent subcontractor(s) to violate any obligation imposed by the applicable mandatory national legislation to which the contractor and/or his subcontractor(s) are subject.
- 6.6. The contracting authority ensures that it will cooperate in good faith with the contractor in order to mitigate the negative effects of a security incident affecting the personal data processed by the contractor and/or his subsequent contractor(s) on behalf of the contracting authority.

#### **Article 7: Use of subsequent subcontractors/processors**

- 7.1. In accordance with the Tender Specifications, the contractor may use the capacity of a third party to tender for the public contract, which constitutes further subcontracting within the meaning of Article 28 of the GDPR<sup>17</sup>.

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<sup>17</sup> To be adapted in accordance with Tender Specifications.

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- 7.2. The contractor may engage another subcontractor (hereinafter, the ‘subsequent subcontractor’) for carrying out specific processing activities. In this case, he informs the contracting authority in advance and in writing of any change considered with regards to adding or replacing other subcontractors. This information must clearly indicate the processing activities that are subcontracted, the identity and contact details of the subcontractor and the dates of the subcontracting contract. The contracting authority disposes of a minimum period of [...] from the date of reception of said information to voice any objections. Such subsequent subcontracting may only be carried out if the contracting authority has not voiced any objection during said period.
- 7.3. The contractor will use only subsequent subcontractors who provide sufficient guarantees to implement appropriate technical and organisational measures in such a manner that the processing will meet the requirements of this public contract, of Belgian legislation and of the GPDR and assures the rights of the data subject concerned.
- 7.4. When the contractor uses another subcontractor to carry out specific processing activities in the name of the contracting authority, obligations in any respect identical to those provided for in this Agreement will have to be imposed on this subsequent subcontractor; the latter in particular must provide the same sufficient guarantees to implement appropriate technical and organisational measures in such a manner that the processing will meet the requirements of the Regulation.
- Agreements with the subsequent subcontractor are written down. Upon request, the contractor will be required to provide the contracting authority with a copy of this contract or these contracts.
- 7.5. Where the subsequent subcontractor fails to fulfil his data protection obligations, the contractor shall remain fully liable to the contracting authority for the performance of the subsequent subcontractor's obligations.
- 7.6. The contractor must pass on the specific objectives and instructions issued by the contracting authority in a precise and timely manner to the subsequent subcontractor(s) when and where these objectives and instructions relate to the part of the processing in which the subsequent subcontractor(s) is or are involved.

## **Article 8: Rights of the data subject concerned**

- 8.1. Where possible, taking into account the nature of the processing and through appropriate technical and organisational measures, the contractor undertakes to assist the contracting authority in fulfilling its obligation to respond to requests of exercise of data subject rights in accordance with Chapter III of the Regulation.
- 8.2. With respect to any request from the data subjects concerned in connection with their rights regarding the processing of personal data concerning them by the

contracting authority and/or his subsequent subcontractor(s), the following conditions apply:

- The contractor will immediately inform the contracting authority of any request made by a data subject concerned relating to personal data that the contractor and/or his subsequent subcontractor(s) are processing on behalf of the contracting authority;
- The contractor will comply promptly and require his subsequent subcontractor(s) to promptly comply with any request from the contracting authority to comply with a request by the data subject concerned to exercise one of their rights;
- The contractor will ensure that he and his subsequent subcontractor(s) have the technical and organisational capabilities to block access to personal data and to physically destroy the data without the possibility of recovery if and when such a request is made by the contracting authority. Without prejudice to the above, the contractor retains the opportunity to consider whether the request of the contracting authority does not constitute a violation of the Regulation.

- 8.3. The contractor must, at the request of the contracting authority, provide all necessary assistance and provide all necessary information for the contracting authority to defend its interests in any proceeding - judicial, arbitral or otherwise - brought against the contracting authority or its staff for any violation of the fundamental rights to privacy and the protection of the personal data of the data subjects concerned.

#### **Article 9: Security measures**

- 9.1. Throughout the duration of this Agreement, the contractor must have appropriate technical and organisational measures in place to ensure that the processing meets the requirements of the Regulation and ensures the protection of the rights of the data subject concerned.
- 9.2. The contractor undertakes to implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk, in accordance with Article 32 of the Regulation.
- 9.3. In assessing the appropriate level of security account shall be taken in particular of the risks that are presented by processing, in particular from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data transmitted, stored or otherwise processed.

- 9.4. The parties recognise that security requirements are continually evolving and that effective security requires frequent assessment and regular improvement of outdated security measures. The contractor will therefore have to continually assess and strengthen, complete or improve the measures implemented with a view to the continued compliance of his obligations.
- 9.5. The contractor provides the contracting authority with a complete and clear description, in a transparent and understandable manner, of how he handles its personal data (Annex 3).
- 9.6. In the event that the contractor changes the security measures applied, the contractor undertakes to notify so immediately to the contracting authority.
- 9.7. The contracting authority reserves the right to suspend and/or terminate the public contract, where the contractor can no longer provide appropriate technical and organisational measures regarding processing risks.

#### **Article 10: Audit**

- 10.1. The contractor acknowledges that the contracting authority is under the supervision of one Supervisory Authority or several Supervisory Authorities. The contractor acknowledges that the contracting authority and any Supervisory Authority concerned will have the right to conduct an audit at any time, and at least during the contracting authority's regular office hours, during the term of this Agreement in order to assess whether the contractor complies with the Regulation and the provisions of this Agreement. The contractor provides the necessary cooperation.
- 10.2. This auditing right may not be used more than once in a calendar year, unless the contracting authority and/or the Supervisory Authority has reasonable grounds to assume that the contractor is acting in conflict with this Agreement and/or the provisions of the Regulation. The restriction of the right of control does not apply to the Supervisory Authority.
- 10.3. At the written request of the contracting authority, the contractor will provide the contracting authority or the relevant Supervisory Authority with access to the relevant parts of the contractor's administration and to all places and information of interest to the contractor (as well as, applicable to those of its agents, subsidiaries and subsequent subcontractors) to determine whether the contractor complies with the Regulation and provisions of this Agreement. At the request of the contractor, the parties concerned agree to a confidentiality agreement.
- 10.4. The contracting authority must take all appropriate measures to minimise any obstruction caused by the audit on the day-to-day functioning of the contractor or the services performed by the contractor.

- 10.5. If there is agreement between the contractor and the contracting authority on a significant breach in compliance with the Regulation and/or the Agreement, as reported in the audit, the contractor will remedy this breach as soon as possible. Parties may agree to put in place a plan, including a timetable for implementing the plan, to address the gaps revealed by the audit.
- 10.6. The contracting authority will cover the costs of any audit carried out within the meaning of this article. Without prejudice to the above, the contractor will bear the costs of his employees. However, where the audit has revealed that the contractor is clearly not in compliance with the Regulation and/or provisions of this Agreement, the contractor bears the costs of said audit. The costs of re-compliance with the Regulation and/or the provisions of this Agreement are borne by the contractor.

#### **Article 11: Transfers to third parties**

- 11.1. The transmission of personal data to third parties in any way is in principle prohibited, unless required by law or if the contractor has obtained explicit authorisation from the contracting authority to do so.
- 11.2. In the event that a legal obligation applies to the transfer of personal data, which is the subject of this Agreement, to third parties, the contractor shall inform the contracting authority before the transfer.

#### **Article 12: Transfer outside the EEA**

- 12.1. The contractor will process personal data from the contracting authority only in a location in the EEA.
- 12.2. The contractor shall not process or transfer the personal data of the contracting authority, or process them himself or through third parties, outside the European Union, unless after express and explicit prior authorisation from the contracting authority.

The contractor will have to ensure that no access to the personal data of the contracting authority by a third party in any way leads to the transfer of these data outside the European Union.

#### **Article 13: Behaviour towards national government and judicial authorities**

- 13.1. The contractor will immediately notify the contracting authority of any request, injunction, investigation or subpoena of a competent national government or judicial authority addressed to the contractor or its subsequent subcontractor(s) that involves the disclosure of personal data processed by the contractor or a subsequent subcontractor for and on behalf of the contracting authority or any data and/or information relating to that processing.

#### **Article 14: Intellectual property rights**

14.1. All intellectual property rights relating to personal data and databases containing such personal data are reserved for the contracting authority, unless otherwise agreed between the Parties.

#### **Article 15: Confidentiality**

15.1. The contractor undertakes to guarantee the confidentiality and processing of personal data.

15.2. The contractor ensures that employees or subsequent subcontractors authorised to process personal data have committed to conducting the processing confidentially and are also bound by a contractual obligation of confidentiality.

#### **Article 16: Liability**

16.1. Without prejudice to the public contract, the contractor is only liable for the damage caused by the processing if he has not complied with the obligations of the Regulation specifically for subcontractors or if he acted outside or contrary to the legal instructions of the contracting authority.

16.2. The contractor is liable for the payment of administrative fines resulting from a violation of the Regulation.

16.3. The contractor will be exempt from liability only if he can prove that he is not responsible for the event that caused a violation of the Regulation.

16.4. If it appears that the contracting authority and the contractor are responsible for the damage caused by the processing of personal data, both Parties will be liable and will pay damages, in accordance with their individual share of liability for the damage caused by the processing.

#### **Article 17: End of contract**

17.1. This Agreement applies as long as the contractor processes personal data in the name and on behalf of the contracting authority under this public contract. If the public contract ends, this Agreement will also end.

17.2. In the event of a serious breach of this Agreement or the applicable provisions of the Regulation, the contracting authority may order the contractor to terminate the processing of personal data with immediate effect.

17.3. In the event of termination of the Agreement, or if the personal data are no longer relevant to the provision of services, the contractor will, by decision of the contracting authority, remove all personal data or return them to the contracting

authority and delete personal data and other copies. The contractor will provide proof in writing, unless applicable legislation requires the storage of personal data. Personal data will be returned to the contracting authority free of charge, unless otherwise agreed upon.

### **Article 18: Mediation and competence**

18.1. The contractor agrees that if the data subject concerned alleges claims for damages under this Agreement, the contractor will accept the decision of the data subject concerned:

- To refer the dispute to mediation with an independent person
- To refer the dispute to the courts of the place of establishment of the contracting authority
- 

18.2. The Parties agree that the choice made by the data subject concerned will not infringe on the substantial or procedural rights of the data subject concerned to seek redress in accordance with other provisions of applicable national or international law.

19.1. Any dispute between the Parties over the terms of this Agreement must be brought before the appropriate courts, as determined in the main agreement.

Thus, agreed on the [.....] and established in two copies of which each Party acknowledges having received a signed copy.

FOR THE CONTRACTING AUTHORITY

FOR THE CONTRACTOR

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Name: [.....]

Name: [.....]

Function: [.....]

Function: [.....]

### **Annex 1: Description of personal data processing activities by the contractor<sup>18</sup>**

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<sup>18</sup> To be filled out by the contracting authority and the contractor.

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**1. Processing activities carried out by the subcontractor**

Subject matter of processing:

Nature of processing: *[For instance, organisation, consultation, storage and collection, etc.]*

Duration of the processing:

Purpose of the processing:

**2. The categories of personal data that the subcontractor will process on behalf of the controller (where applicable (\* indicate as appropriate)).**

- ☐ Personal identification data (e.g. name, address and telephone, etc.)
- ☐ Electronic identification data (e.g. e-mail address, ID Facebook, ID Twitter, user names, passwords or other connection data, etc.)
- ☐ Electronic location data (e.g. IP addresses, mobile phone, GPS, connection points, etc.)
- ☐ Biometric identification data (e.g. fingerprints, iris scan, etc.)
- ☐ Copies of identity documents
- ☐ Financial identification data (e.g. account numbers (bank), credit card numbers, salary and payment information, etc.)
- ☐ Personal characteristics (e.g. gender, age, date of birth, marital status, nationality, etc.)
- ☐ Physical data (e.g. height, weight, etc.)
- ☐ Habits of life
- ☐ Psychological data (e.g. personality, character, etc.)
- ☐ Family composition
- ☐ Leisure and interests
- ☐ Memberships
- ☐ Consumption habits
- ☐ Education and training
- ☐ Career and occupation (e.g. function, title, etc.)

- ☐ Images/photos
- ☐ Sound recordings
- ☐ National Social Security Register Number/Identification Number
- ☐ Details of the contract (e.g. contractual relationship, order history, order numbers, invoicing and payment, etc.)
- ☐ Other categories of data, <Describe>

**3. The special categories of personal data that the subcontractor will process on behalf of the controller (where applicable) (indicate as appropriate)**

- ☐ Special categories of personal data (Art. 9 GDPR)
  - Data revealing racial or ethnic origin
  - Data concerning sexual orientation
  - Political opinions
  - Trade union membership
  - Religious or philosophical beliefs
- ☐ Data concerning health (Art. 9 DGPR)
  - Physical health
  - Mental health
  - Risk situations and risk behaviours
  - Genetic data
  - Healthcare data
- ☐ Judicial data (Article 10 of the general data protection law)
  - Suspicions and indictments
  - Convictions and sentences
  - Judicial measures
  - Administrative sanctions
  - DNA data

**4. The categories of data subjects concerned (\*indicate as appropriate)**



- ☐ (Potential)/(former) clients

If yes, <describe>

- ☐ Applicants and (former) employees, interns, etc.

If yes, <describe>

- ☐ (Potential)/(former) suppliers

If yes, <describe>

- ☐ (Potential)/(former) (business) partners

If yes, <describe>

- ☐ Other category

If yes, <describe>

**5. Extent of processing (number of records/number of data subject concerned)**

<Describe>

**6. Period of use and period for which the (various categories of) personal data are stored:**

<Describe>

**7. Processing place**

<Describe>

If processing is outside the EEA, please specify the appropriate guarantees that are put in place

<Describe>

**8. Use of subsequent subcontractors/processors:**

<Describe>

**9. Contact details of the responsible contact person at the controller's**

Name:	
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Title:	
Telephone number:	
E-mail:	
Name: <sup>19</sup>	
Title:	
Telephone number:	
E-mail:	

#### 10. Contact details of the responsible contact person at the processor's:

Name:	
Title:	
Telephone number:	
E-mail:	
Name:	
Title:	
Telephone number:	
E-mail:	

#### Annexe 2: Security of processing<sup>20</sup>

The controller should use only processors providing sufficient guarantees, in particular in terms of expert knowledge, reliability and resources, to implement technical and organisational measures which will meet the requirements of this Regulation (in particular Article 32 of the GDPR), including for the security of processing.<sup>21</sup>

In order to ensure a level of security adapted to the risk, given the state of knowledge and the nature, scope, context and purposes of the processing, as well as the risks, of varying

<sup>19</sup> Identify the person responsible of the project/department/other as appropriate

<sup>20</sup> To be filled out by contractor

<sup>21</sup> Consideration 81 of the GDPR

degree of probability and severity, of processing for the rights and freedoms of natural persons, the contractor implements appropriate technical and organisational measures.

These security measures comprise the following, among others:

- [Describe]