

## 1. Premises

These General Terms and Conditions of purchase concern the purchase of goods or services by GlaxoSmithKline Manufacturing SpA, based in 2, Alexander Fleming Street, 37135 Verona, Italy, an Italian private entity with sole shareholder which is a member of the GlaxoSmithKline group of companies and is subject to the activity of direction and coordination of GlaxoSmithKline Plc, Verona Register of Companies, TAX id and VAT code n. 00212840235, paid up capital Euro 65.250.000

## 2. Definitions

**"Agreement"** or **"Agreements"** means the specific agreements entered - from time to time - by GSKM and Supplier with the acceptance of the Purchase Order by Supplier, according to section 3 of these General Terms and Conditions. The Agreement will consist of: the Purchase Order, these General Terms and Conditions, and any other document, such as the Specification, economic attachment and any other documents (or parts thereof) specified in the Purchase Order or attached to the above-mentioned documents.

**"Commercial Secrets"** means all business information, technical-industrial experiences, including those commercial, subject to legitimate GSKM control, in any form provided or made available, directly or indirectly, identified as secret, confidential, reserved or similar specifications.

**"General Terms and Conditions"** means the general terms and conditions of purchase of goods or services set out in this document.

**"Goods"** means tangible and intangible assets sold by Supplier to Purchaser and specified in the Purchase Order.

**"GSKM"** or **"Purchaser"** means GlaxoSmithKline Manufacturing SpA.

**"Parties"** means GSKM and Supplier.

**"Purchase Order"** means the purchase order sent by Purchaser.

**"Services"** means work and intellectual services specified in the Purchase Order.

**"Specification"** means the technical and quality specifications, including packaging and delivery of the Goods, as requested by Purchaser which can be sent in written form to Supplier. These Specification will form an integral part of the Agreement and will be deemed to be accepted unless objections by Supplier within 3 (three) days from the receipt of the Specification.

**"Supplier"** means the person, firm or company to whom the Purchase Order is addressed.

## 3. Issue, variation and suspension of the Purchase Order

3.1 These General Terms and Conditions will apply between the Parties except in the case of express exceptions specified in the Purchase Order or in other documents which are part of the Agreement; however, the terms and conditions in any separately negotiated document (including, confirmation of delivery or of the purchase order, the invoice or any other commercial document) will not have effect and will be considered null and void if they are not in written form, signed by the Parties and if date is not later than the date of the Purchase Order.

3.2 These General Terms and Conditions do not bind Purchaser to purchase any Goods or Services from Supplier, but provide the general terms and conditions which will apply to the purchase of goods or services when Purchaser sends a Purchase Order to Supplier.

3.3 Purchaser will not be liable in respect of any Purchase Order other than those sent in the format agreed by the Parties (email or facsimile).

3.4 Purchase Orders will be deemed to be accepted by Supplier on the earlier of: a) Supplier issuing a written acceptance of the Purchase Order within the term fixed for the acceptance or, failing that, within the term of three days from receipt of the Purchase Order; b) Supplier not issuing to the Purchaser a written communication of refusal within the term fixed for the acceptance or, failing that, within the term of three days from receipt of the Purchase Order.

3.5 Before the delivery of the Goods or the performance of the Services, Purchaser is entitled to change or cancel, entirely or in part, in writing the Purchase Order. The Supplier can claim only documented cost actually incurred for the execution of the Purchase Order until the reception of the change or cancel notice; no further cost or liability will accrue on its account. The amount of the said credit will be notified within 15 (fifteen) days from the receipt of the above-mentioned notification. If, consequently to this variation, the price previously agreed changes, this change will be agreed in a written form by the Parties.

3.6 If the Purchase Order regards the purchase of Goods, provisions of these General Terms and Conditions concerning Service will not apply. Vice versa, if the Purchase Order regards the purchase of Services, provisions of these General Terms and Conditions concerning Goods will not apply.

## 4. Delivery of Goods

4.1 Unless otherwise instructed in writing by Purchaser's nominated representative, all Goods must be delivered and all Services must be performed at Verona site based in Via A. Fleming 2 or S. Polo di Torriale (PR), Strada Provinciale Asolana n. 90 or other place specified in the Purchase Order and at the time specified in the Purchase Order.

4.2 Supplier will arrange the transport of the Goods until the delivery in the place specified in the Purchase Order, also providing proper insurance.

4.3 Title of the Goods will pass on Purchaser from the acceptance of the Goods in the above-mentioned place of delivery.

4.4 Risk in the Goods will pass on Purchaser on completion of delivery in the place specified in the Purchase Order, including unloading and storage.

4.5 Time will be of the essence in relation to the performance of any and all of Supplier's obligations pursuant to the Agreement.

4.6 Where it is impossible the delivery of the Goods within the time agreed, the Supplier will have to notify immediately the delay and the expected duration of the delay.

4.7 Goods delivered in advance may not be accepted by Purchaser and, regarding the payment of the price, the delivery term agreed by the Parties will apply.

4.8 Damage or breakage due to imperfect or unsuitable packaging, even if occurred in normal conditions of transport, will be borne by Supplier.

## 5. Quality and fitness for purpose

5.1 Supplier guarantees that:

- Goods comply with all national and international applicable laws. Where Goods consist of machine, plan or equipment, Supplier guarantees the compliance with safety and accident prevention regulations and, where applicable, with ISPEL, CEI, VVFF provisions; with this regard, Supplier will provide the related documentation. Where the purchase concerns dangerous substances, Supplier will provide the Purchaser with the safety data sheet, as provided by the current laws;
- Goods and Services comply with the Agreement;
- Goods are free from defects in design, material and workmanship;
- Goods are consistent with parts which could be assembled to the Goods, according to the Specification or other information provided to Supplier;
- Goods are fit for purposes for which they are intended, or notified to Supplier;

- Goods are in strict compliance with any samples, patterns, drawings provided to Supplier.
- 5.2 Supplier will also guarantee the good functioning of the Goods for a period of 12 (twelve) months from the date of delivery unless otherwise agreed by the Parties or from Testing (if provided).
- 5.3 Subject to art. 1495, second paragraph, Italian Civil Code, the Parties agree that the term for complaint - as provided for by articles 1495, 1497, 1512 Italian Civil Code - is 30 (thirty) days from discovery of defect, lack of quality or defect of functioning.
- 5.4 In case of defect or nonconformity of the Goods, Purchaser will be entitled in its sole discretion to the following remedies:
  - require Supplier to correct the defect or nonconformity or replace the Goods, at Supplier's cost, within 15 (fifteen) days, if no different term is provided, from Purchaser's notice of defect or nonconformity;
  - ask a reasonable reduction of the price of defective or nonconforming Goods;
  - terminate the Agreement by giving notice in writing to Supplier regarding defective or nonconforming Goods, refuse the payment of the price and recover sums already paid.
- 5.5 If Services do not conform with the Agreement, Supplier will make all necessary changes, at Supplier's cost, to ensure the conformity of the Services with the Agreement.

#### **6. Testing**

Goods are subject to a final standard test ("Testing") before the delivery, if requested by Purchaser and specified in the Purchase Order. Testing will be carry out in the presence of the Parties and will be recorded in writing and relevant document signed by the parties. The positive result of Testing and/or Purchaser's approval do not relieve Supplier from obligations provided in section 5 (Quality and fitness for purpose).

#### **7. Intellectual property rights**

- 7.1 Supplier declares and warrants that:
  - a) Goods do not infringe any third party's intellectual property rights; Supplier will hold Purchaser harmless against any third party's claim;
  - b) is entitled to transfer to Purchaser the right to use, incorporate and market the Goods; and
  - c) Purchaser will have the right to use the Goods or the results obtained with the Goods, in consideration of the price paid.
- 7.2 Purchaser retains intellectual property rights and ownership of all materials, plans, drawings, tools, data, the Specification, patterns and/or designs provided by Purchaser to Supplier, and they will all returned at any time in good condition at Purchaser's request.

#### **8. Compensation**

Supplier will indemnify Purchaser, on demand from and against all losses incurred or suffered as a result of or in connection with:

- breach of guaranties provided by section 5 (Quality and fitness for purpose) of these General Terms and Conditions;
- any claim that the Goods or the provision of the Services by Supplier, the use by or on behalf of Purchaser of the Goods or of any asset used or provided by Supplier in connection with the performance of the Services, infringes the intellectual property rights or any other rights of any third party;
- any other breach of the Agreement, Specifications and these General Terms and Conditions.

#### **9. Supplier's employees**

Supplier will comply with any and all obligations towards its employees, as provided for by any applicable laws, including, by way of exemplification, the provisions on safety and health at the work place, the provisions related to the payment of the social contributions and of the emoluments.

Supplier will guarantee the observance by its employees who has access to Purchaser site of all the safety conditions, provided by health and safety regulations, fire prevention, hygiene at work, health surveillance and environmental protection, and rules provided by Purchaser procedures for the access and behaviour at Purchaser site.

Purchaser may prohibit the access and ask the immediate removal of personnel that does not observe all the above-mentioned rules, or does not meet the above-mentioned criteria.

#### **10. Termination**

##### **10.1 Express termination clause**

Purchaser is entitled to terminate the Agreement, according to art. 1456 Italian Civil Code, as follows:

- Supplier's breach of the Agreement which consists of: delay in the delivery, also if delay concerns only part of Goods/Services or nonconformity with Specifications;
- breach of section 13 (Assignment) of these General Terms and Conditions;
- breach of section 19 (Confidentiality) of these General Terms and Conditions;
- breach of section 20 (Ethical standards and human rights) of these General Terms and Conditions;
- breach of section 22 (Sanctions and Exports) of these General Terms and Conditions
- breach of section 23 (Data Integrity) of these General Terms and Conditions;
- breach of section 24 (GSK anti bribery and corruption requirements) of these General Terms and Conditions.

In such case the Purchase Order, in all or in part, will be cancelled, save for Purchaser's right to damages. When Purchaser has the right to compensation for damages or penalty, the Parties can proceed with compensation between mutual debts and credits. In case of credit resulting from damages, Purchaser will evaluate the damage in *bona fide* and offset the sum according to art. 1252 Italian Civil Code.

##### **10.2 Invitation to perform**

Subject to clause 10.1, if Supplier is in breach of the Agreement and does not remedy the breach within 15 (fifteen) days of Purchaser notice so to do (if capable of remedy) Purchaser may terminate the Agreement immediately by notice to Supplier, according to art. 1454 Italian Civil Code.

##### **10.3 Termination**

The Agreement may be terminated at any time by Purchaser for any reason whatsoever by giving Supplier a 30 (thirty) day notice of termination in writing.

#### **11. Price and payment terms**

- 11.1 Provided the Goods and Services have been delivered to GSKM, payment will be made, by bank transfer, by GSKM to Supplier for Goods and Services which comply with the Agreement, as follows.

Derogation to Legislative Decree n. 231/2002, as modified by Legislative Decree n. 192/2012

The Parties agree to derogate from payment term and late payment interest provisions, as follows:

- payment will be made 60 (sixty) days from the date of receipt of invoice at beginning of next month;
- in case of late payments, legal interest rate, as provided for by art. 1284 Italian Civil code, will apply and interest will be calculated from the receipt of written request of Supplier.

Supplier declares and recognizes that the said derogations are not grossly unfair and in particular the definition of the date on which the interest for late payments are due helps a proper accounting management .

- 11.2 Invoices will be issued to **GlaxoSmithKline Manufacturing Spa** and submitted electronically via *Sistema di Interscambio* (“SDI”) specifying the “**Identification Code**” notified by GSKM.  
Purchase Order number and IBAN code/SWIFT code must be quoted on all invoices. Should the Supplier fail to specify the Purchase Order number, the Supplier will be required to issue a credit note and a new invoice with the above-mentioned information.  
**The obligation of electronic invoicing does not apply in specific cases**  
Individuals and entities that don’t have an obligation to issue the electronic invoices, according to article 1, Legislative Decree August, 5<sup>th</sup>, 2015, n. 127, as amended by article 15, Law Decree October, 23<sup>rd</sup>, 2018, n. 119 and those that will be identified with subsequent laws, will issue the invoices:
- via regular mail, the original invoice in paper format to RECALL Information Management, Rif. 15, PO BOX 24085, Madrid 28080, Spain; or
  - electronically, via GSK’s electronic global trading platform, Tungsten, without prejudice to the paper form.
- Purchase Order number and IBAN code/SWIFT code must be quoted on all invoices. Should the Supplier fail to specify these information, Purchaser will return the invoice to Supplier and the payment will become due 60 (sixty) days date of invoice, after providing such information.
- 11.4 For information concerning payment status please call 045-9219273-on Tuesday and Thursday, from 9 to 11, or write [GMS-Richieste-fornitori@gsk.com](mailto:GMS-Richieste-fornitori@gsk.com)
- 11.5 Payments will be made, on behalf of GSKM, by GlaxoSmithKline IHC Limited, which is a member of the GlaxoSmithKline group of companies and is subject to the activity of direction and coordination of GlaxoSmithKline Plc, based in 980 Great West Road, Brentford, Middlesex TW8 9GS.

#### **12. Penalty for delay**

If Supplier is behind schedule in the delivery of Goods or Services, Purchaser is entitled to apply a penalty of 1% of the Purchase Order price for each day of delay up to a maximum of 10% of the Purchase Order price. The amount of penalty will be communicated to Supplier after delivery of Goods/Services and it will be set off with Purchaser’s debts relevant to price for Goods/Services.

#### **13. Assignment**

Supplier’s rights, obligations and credits under the Agreement may not be assigned in whole or in part without the prior written consent of Purchaser (acting in its sole discretion) and any such consent will not be deemed to relieve Supplier of any of its obligations and liability to Purchaser pursuant to the Agreement.

#### **14. GSKM trademarks**

Supplier will not, without the prior written consent of Purchaser, use Purchaser trademarks or other images relevant to Purchaser trademark and in any case in compliance with “GSKM Visual Identity guidelines” which will be provided by Purchaser. Supplier will not use the name GSK Manufacturing Spa or the description of the activities carried out for GSKM without prior written consent of GSKM.

#### **15. Privacy**

The data that will be subject to processing and related to this Agreement must be considered out of scope of the Reg. EU 679/16, Leg. Decree 16/03 and eventual Decrees that implement at a national level the existing Data Privacy laws (hereinafter referred to as “Reg. EU 679/16 GDPR”) if regarding the respective companies (es. name, main seat, head office address, VAT code, fiscal code etc.) and not the processing of natural person’s personal data.

With regards to Reg. EU 679/16 GDPR, the data that will be subject to processing and related to this Agreement, could also regard natural persons:

- that Supplier owns as Data Controller and that GSKM might need to collect and store in its own databanks. In this case, GSKM shall procure to provide such natural persons with an appropriate Notice Letter.
- that GSKM owns as a Data Controller and that Supplier might need to process in order to carry out the activities foreseen in the Contract. In this case, GSKM will appoint Supplier as External Data Processor, in compliance with the provisions set forth in specific Appendix.

#### **16. Liability and insurance**

Supplier will indemnify and hold Purchaser harmless against any direct liabilities, damages, claims, costs, losses and expenses incurred or paid by Purchaser howsoever arising from any defect in the Goods or Services or any breach by Supplier of its obligations hereunder or of any statutory duty or from any act or omission of Supplier’s employees, agents or sub-contractors.

Supplier will insure with a reputable insurance company its liabilities under the Agreement as follows:

- a General Liability Policy with a leading Insurance Company for one maximum coverage, without franchise, of a value not lower than € 2.500.000,00 (twomillionfivehundredsthousandeuros) each damage/year. The policy is to provide also for a maximum coverage of a value not lower than € 150.000,00 (onehundredfiftythousandeuros) for indirect damages such as interruptions or total or partial suspension of the industrial or commercial activities or services and so on, upon presentation of suitable documentation by Purchaser proving the sustained damage;
- a Product Liability Policy with a leading Insurance Company for one maximum coverage, without franchise, of a value not lower than € 2.500.000 (twomillionfivehundredsthousandeuros) each damage/year.

Supplier, on demand, will have to produce the relevant appropriate certifications duly issued by the Insurance Company regarding the above insurance covers.

Any limitation, monetary or otherwise in such policy will not be construed as a limitation on Supplier’s liability and Supplier will, notwithstanding such limitation, remain liable in full for any matters and to any extent not covered by the policy.

#### **17. Inspection**

Purchaser, and any third party it appoints on its behalf, will have the right upon prior notice to inspect Supplier at Supplier’s premises in order to check that the Goods or Services to monitor compliance with the Agreement, laws and GSKM provisions provided by section 21 (Compliance with laws and GSKM provisions), as well as check the suitability of Supplier to perform the Agreement. Supplier will cooperate fully with such inspection and provide the documentation requested in order to check the compliance with contractual obligations, including the compliance with anticorruption laws.

#### **18. Governing law and jurisdiction**

The construction, validity and performance of the Agreement will be governed by the laws of Italy.

For any dispute arising out or connected with the Agreement the parties hereby submit to the exclusive jurisdiction of the Court of Verona.

#### **19. Confidentiality**

- 19.1 Supplier will, and will procure that its employees and sub-contractors will, keep confidential all information of a commercial or technical nature disclosed to Supplier by Purchaser for the purpose of the Agreement, and will not use or disclose such information to any third

party without Purchaser's prior written consent. Supplier will not without Purchaser's prior written consent disclose, copy, publicise or publish, the existence of the Agreement or any information related to the Agreement including the name of Purchaser, any Purchaser Affiliate.

- 19.2 If Supplier doesn't comply with its obligation of confidentiality, such conduct will be considered as an act of unfair competition according to article 2598 Italian Civil Code, as well as an unlawful act, not only according to the Contract but also according to articles 98 and 99 of Legislative Decree n. 30/2005 (as amended by Legislative Decree n. 63/2018), with all consequent responsibilities provided by current laws.
- 19.2 Supplier will retain Purchaser Commercial Secrets only for as long as specified in the Agreement or as otherwise necessary to satisfy the purposes for which it was provided to Supplier, except only to the extent longer retention is required by applicable law.
- 19.3 Supplier will (at its sole cost) return, delete or destroy all Purchaser Commercial Secrets then in its possession or under its control, including without limitation all originals and copies of such Purchaser Commercial Secrets, upon Purchaser's request for any reason. Supplier will certify compliance with this requirement by written notice to Purchaser received no later than thirty (30) days following such return, deletion or destruction of all Purchaser Commercial Secrets.
- 19.4 When transferring Purchaser Commercial Secrets, and in communications between Purchaser and Supplier, Supplier will use encryption based on guidance provided by Purchaser.
- 19.5 Upon discovering any suspected or actual unauthorized disclosure, loss or theft of GSKM Commercial Secrets (a "Data Security Breach"), Supplier will send an e-mail to csir@gsk.com notifying GSKM. Supplier will work with GSKM in good faith to identify a root cause and remediate a Data Security Breach.
- 19.6 GSKM and its agents, auditors (internal and external), regulators and other representatives as GSKM may designate may inspect, examine and review the systems, records, data, practices and procedures of Supplier (and any subcontractors it may use) that are used in rendering the services under the Agreement to verify the integrity of GSKM Commercial Secrets and compliance with the data privacy, confidentiality and security requirements of the Agreement.

## **20. Ethical standards and human rights**

- 20.1 Supplier represents and warrants, to the best of its knowledge, that in connection with this Agreement, it respects the human rights of its staff and does not employ child labor, forced labor, unsafe working conditions, or cruel or abusive disciplinary practices in the workplace and that it does not discriminate against any workers on any ground (including race, religion, disability, gender, sexual orientation or gender identity); and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the laws on working hours and employment rights in the countries in which it operates. Supplier will be respectful of its employees right to freedom of association and Supplier will encourage compliance with these standards by any supplier of goods or services that it uses in performing its obligations under this Agreement.
- 20.2 Unless otherwise required or prohibited by law, Supplier warrants that in relation to its performance of this Agreement:
  - a) it does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child
  - b) it does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge original identification papers or monetary deposits on starting work;
  - c) it provides a safe and healthy workplace, presenting no immediate hazards to its workers. Any housing provided by Supplier to its workers is safe for habitation. Supplier provides access to clean water, food, and emergency healthcare to its in the event of accidents or incidents at Supplier's workplace;
  - d) it does not discriminate against any workers on any ground (including race, religion, disability, gender, sexual orientation or gender identity);
  - e) it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;
  - f) it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, (whichever is the higher) and provides each employee with all legally mandated benefits;
  - g) it complies with the laws on working hours and employment rights in the countries in which it operates;
  - h) it is respectful of its employees right to join and form independent trade unions and freedom of association.
- 20.3 Supplier is responsible for controlling its own supply chain and shall encourage compliance with ethical standards and human rights by any subsequent supplier of goods and services that are used by Supplier when performing its obligations under this Agreement.
- 20.4 Supplier shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies. In the case of any complaints, Supplier shall report the alleged complaint and proposed remedy to GSKM.
- 20.5 GSKM reserves the right upon reasonable notice (unless inspection is for cause, in which case no notice shall be necessary) to enter upon Supplier's premises to monitor compliance with the provisions of this Clause 19, and Supplier shall, subject to compliance with applicable laws, provide to GSKM any relevant documents requested by GSKM in relation thereto.

## **21. Environment**

Supplier will maintain compliance with all applicable laws, regulations, licenses, permits, information registrations and restrictions. Supplier has implemented an EHS policy and risk-based management system with a commitment to provide a safe and healthy workplace and protect the environment. Supplier provides relevant information, education and training to workers on the hazards, risks and controls associated with their job. Supplier provides the physical infrastructure and engineering controls necessary to ensure safe storage, handling and processing of materials and waste in order to protect people, the environment and local communities from harm.

## **22. Sanctions and Exports**

- 22.1 Supplier represents and warrants that it is aware of and, in carrying out its obligations under this Agreement, will comply at all times with and not become exposed to penalties under Sanctions & Trade Controls (i.e., all sanctions, export control, and anti-boycott laws, regulations, orders, directives, designations, licenses, and decisions of the European Union, the United Kingdom, the United States of America, and of any other country with jurisdiction over activities undertaken in connection with this Agreement). Supplier represents and warrants that at all times, in the performance of its obligations under this Agreement, it will not take any action that causes GSKM to violate or otherwise become exposed to penalties under any Sanctions & Trade Controls. GSKM will not be required to take or refrain from taking any action, nor shall it be required to furnish any information, that would be prohibited or penalizable under any Sanctions & Trade Controls.

GSKM may terminate this Agreement with immediate effect if, in GSKM's sole discretion, Supplier breaches any the foregoing clauses or, in GSKM's sole discretion, GSKM's performance of its obligations pursuant to this Agreement may breach or be penalizable under Sanctions & Trade Controls (whether or not in existence at the date of this Agreement and whether or not there have been any other changes in circumstance from those that existed at the date of this Agreement). If GSK terminates this Agreement pursuant to this clause, it will not be obliged to make any payments, indemnify, or otherwise provide compensation to Supplier subsequent to the termination of this Agreement.

22.2 Supplier will disclose to GSKM any relevant export control classification codes applicable to the goods, software, technology, and/or services supplied under this Agreement in advance of, or simultaneously with, their supply.

Supplier will not supply, directly or indirectly, to GSKM any goods, software, technology, or services sourced from a Sanctions Target or, without prior disclosure to and consent from the GSKM, an EO 13599 List Party, an SSI Party, or a Sanctioned Country or Territory (i.e., any country or territory against which comprehensive sanctions or an import ban are imposed by the United States, the European Union, or the United Kingdom).

Supplier will, upon request, provide GSKM with assistance, including but not limited to providing any relevant transaction documentation, in order to enable GSKM to comply with all applicable export control laws and regulations, including the export control laws and regulations of the United States of America, the European Union, the United Kingdom, and any other country with jurisdiction over the export of the contracted goods, software, technology, or services.

### 23. Data Integrity

GSKM considers data integrity a fundamental requirement to guarantee safety of patients, quality of products, reputation of the company and achievement of company objectives.

GSKM must also comply with guidelines on good manufacturing practices of medicinal products (GMP) and with Legislative Decree n. 219/2006. Data means information, in both paper and electronic format, used for recording accurately and completely all activities performed.

GSKM requires that data have the following features summarized in the acronym ALCOA:

A – Attributable: data are traceable to the originator (person and/or a computerized system, a device, an instrument), including any changes made to data, i.e. who performed an action;

L – Legible: data are readable and understandable;

C – Contemporaneous: data are recorded at the time they are generated;

O – Original: data as the file or format in which it was first generated;

A – Accurate: data are correct, truthful and to the appropriate precision.

Supplier will ensure:

- use of data in an appropriate manner and in accordance with "ALCOA";
- integrity of data for the data lifecycle;
- accuracy and consistency of acquired and managed data;
- data retention as provided for by laws and GSKM;
- compliance with requirements of CFR 21 Part 11;
- no alteration and/or manipulation.

Supplier acknowledges the importance to GSKM of ensuring that the Services are undertaken in accordance with the following data integrity practices ("Data Integrity Practices"):

(b) data are being generated using sound scientific techniques and processes;

(c) data are being accurately recorded in accordance with Data Integrity Practices by persons performing the Services hereunder;

(d) data are being analysed appropriately without bias in accordance with Data Integrity Practices;

(e) data and results are being stored securely and can be easily retrieved;

(f) data trails exist to easily demonstrate and/or reconstruct key decisions made during the performance of the Services, presentations made about the Services and conclusions reached with respect to the Services.

Parties may amend, where appropriate, Data Integrity Practices enclosing a specific Appendix (Additional data integrity practices).

At any time during the Contract, GSKM may require changes to the requirements of this clause, where GSK reasonably believes such changes are required to ensure that the Services are undertaken in compliance with Data Integrity Practices.

GSKM shall be permitted, in its sole discretion, to undertake on-site compliance audits of Supplier's Data Integrity Practices in respect of the Services

GSKM shall hold Supplier responsible in case of failure to comply with the provisions of this clause.

Supplier shall indemnify and hold GSKM harmless from any claim, responsibilities and cost.

### 24. GSKM anti bribery and corruption requirements

Supplier agrees that it shall comply fully at all times with all applicable laws and regulations, including but not limited to anti-corruption laws, and that it has not, and covenants that it will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it or GSKM in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery, and warrants that it has taken reasonable measures to prevent subcontractors, agents or any other third parties, subject to its control or determining influence, from doing so. For the avoidance of doubt this includes facilitating payments, which are unofficial, improper, small payments or gifts offered or made to Government Officials to secure or expedite a routine or necessary action to which we are legally entitled. For the purpose of this Agreement, "Government Official" (where 'government' means all levels and subdivisions of governments, i.e. local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) means: (a) any officer or employee of a government or any department, agency or instrumentality of a government (which includes public enterprises, and entities owned or controlled by the state); (b) any officer or employee of a public international Organisation such as the World Bank or United Nations; (c) any officer or employee of a political party, or any candidate for public office; (d) any person defined as a government or public official under applicable local laws (including anti-bribery and corruption laws) and not already covered by any of the above; and/or; (e) any person acting in an official capacity for or on behalf of any of the above. "Government Official" shall include any person with close family members who are Government Officials (as defined above) with the capacity, actual or perceived, to influence or take official decisions affecting GSKM business.

GSKM shall be entitled to terminate this Agreement immediately on written notice to Supplier, if Supplier fails to perform its obligations in accordance with this Clause 23. Supplier shall have no claim against GSKM for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Clause 23.

Supplier shall inform GSKM in writing, if, during the course of this Agreement, it is convicted of or pleads guilty to a criminal offence involving fraud or corruption, or becomes the subject of any government investigation for such offenses, or is listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

Supplier represents and warrants that except as disclosed to GSKM in writing prior to the commencement of this Agreement: (1) none of their significant shareholders (>25% shareholding) or senior management have influence over GSK's business; (2) no significant shareholders (>25% shareholding), members of senior management team, members of the Board of Directors, or key individuals who will be responsible for the provision of goods / services, are currently or have been in the past two years a Government Official with actual or perceived influence which could affect GSKM business; (3) it is not aware of any immediate relatives (e.g. spouse, parents, children or siblings) of the persons listed in the previous subsection (2) having a public or private role which involves making decisions which could affect GSKM business or providing services or products to, or on behalf of GSKM; (4) it does not have any other interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; and (5) it shall maintain arm's length relations with all third parties with which it deals for or on behalf of GSKM in performance of this Agreement. [Supplier shall inform GSK in writing at the earliest possible opportunity of any conflict of interest as described in this Clause [X] that arises during the performance of this Agreement.

GSKM shall have the right during the terms of this Agreement to conduct an audit of Supplier's activities under this Agreement to monitor compliance with the terms of this Agreement. Supplier shall cooperate fully with such audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of GSKM.

Supplier shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and each document upon which entries such books and records are based is complete and accurate in all material respects. Supplier must maintain a system of internal accounting controls reasonably designed to ensure that it maintains no off-the-books accounts.

Supplier agrees that in the event that GSKM believes that there has been a possible violation of the terms of this Agreement, GSKM may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and its agencies, and to whomsoever GSKM determines in good faith has a legitimate need to know.

#### **25. Compliance with laws and GSKM's provisions**

The relations between Purchaser and Supplier will be based on the following laws and principles:

- Laws related to pharmaceutical sector according to the Legislative Decree n. 219/06 "*Attuazione della direttiva 2001/83/CE (e successive direttive di modifica) relativa ad un Codice Comunitario concernente i medicinali per uso umano, e della Direttiva 2003/94/CE*";
- Legislative Decree n. 231/2001 and Law n. 190/2012;
- "*Codice Deontologico di Farmindustria*", if applicable;
- "*Codice of Conduct*" o at [www.gsk.it](http://www.gsk.it);
- "*Modello Organizzativo GSKM*", with regards to the sections, from time to time, notified by GSKM's nominated representative.