



# ND Pharma & Biotech



MEDICAL · HEALTHCARE  
PHARMACEUTICALS  
BIO · PHARMACEUTICALS  
BIOTECHNOLOGY  
STEM CELLS  
ANIMAL HEALTH  
FOOD & NUTRITION  
AGRIBUSINESS  
INDUSTRY SOLUTIONS  
LEADING SCIENCE  
ADVANCED R+D+i

**Making Life Better**  
**Transforming World**

FINE CHEMICALS

API's

NCE's

R+D+I

SOLUTIONS



ND Pharma & Biotech  
[www.ndpharmabiotech.com](http://www.ndpharmabiotech.com)

  
ND Pharma & Biotech

# PURCHASING CONDITIONS

**ND Pharma & Biotech** is a global Biopharmaceutical company with activity in different areas and sectors including a subspecialty chemical area that produces, market and transports a broad range of advanced materials, industrial additives and functional products, specialty chemicals, and many other compounds and products that are found in products people use every day. As a world leader in the diverse markets it serves, ND Pharma & Biotech is focused on delivering innovative and technology-based solutions while maintaining its commitment to safety and sustainability.

Any query regarding this document should be submitted in writing to:

Mrs. Mary S. Kay  
cfo@ndpharmabiotech.com

## **Purchasing Conditions**

### **1. General**

The ND Pharma & Biotech Purchasing Conditions are an integral part of the Purchase Agreement (PA) that ND Pharma & Biotech places with the Vendor.

The PA is the document that defines the purchase contract: if required the PA will state the references of other documents and correspondence which was the basis of the negotiation leading up to the agreement contained in the PA and is deemed to be made part of the agreement.

The Purchase Order solely and or a combination thereof (PA) formally commits ND Pharma & Biotech responsibility.

Both parties agree that in case of dispute the terms written by ND Pharma & Biotech in ND Pharma & Biotech documents known to the Vendor always take precedence. It is the responsibility of the Vendor to verify it has a complete and clear understanding of what is ND Pharma & Biotech's request as defined in the Purchase Agreement.

### **2. ND Pharma & Biotech responsibilities**

In relation to all Merchantable Goods to be supplied to ND Pharma & Biotech, it is ND Pharma & Biotech responsibility to provide Vendor with complete, accurate and timely information requested to the proper execution of the work as well as all the information relating to any regulations to which ND Pharma & Biotech is bound to, namely related to quality, health safety and environment. Vendor will not be responsible for any consequences that may arise from any delay or failure to do so and these may also result in additional fees for which invoices will be raised.

All critical issues, whether given as oral or telephone instructions, or decisions taken at meetings shall always be reduced in writing, ideally in the form of minutes prepared by Vendor and approved by both parties.

### **3. Purchase Agreement**

The PA shall clearly set the agreed value of the contract. The currency, the payment terms and the key time commitments shall be clearly expressed together with the accurate general description of the scope of the contract. Additional technical data shall be provided to define the purchased Merchantable Goods scope.

Vendor is requested to inform ND Pharma & Biotech on the acceptance of the PA and all its content.

The PA defines the approved conditions and any changes must be previously authorised. It is the responsibility of the Vendor to inform ND Pharma & Biotech of any changes to the conditions stated in the PA, namely value, delivery date

and characteristics of the Merchantable Goods or any consequence of it. ND Pharma & Biotech reserves the right to cancel the PA if any condition herein stated is not accomplished.

The PA shall be signed by the ND Pharma & Biotech representative within the policy in force at ND Pharma & Biotech.

#### **4. Warranties of suitability for the purpose and as to quality and durability**

ND Pharma & Biotech is a manufacturer of fine chemicals / APIs – Active Pharmaceutical Ingredients for the pharmaceutical industry and operates in a highly regulated environment.

The ND Pharma & Biotech facilities and laboratories and partner manufacturers operate under the appropriate strictest standards of GMP and ISO. ND Pharma & Biotech manufactures Products for human consumption. APIs are produced under conditions that involve hazardous (flammable, explosive, corrosive) conditions. ND Pharma & Biotech will therefore always advise of the specific conditions, these must therefore be identified and addressed to ensure a complete understanding of suitability of the Merchantable Goods.

These Merchantable Goods will be used in a pharmaceutical process and as such, the Merchantable Goods to be supplied shall be adequate to it (for example free of contamination) and shall be manufactured or executed under a system that should meet Quality and HSE (Health, Safety and Environment) applicable legislation and other requirements such as, but not limited to, ISO9000, ISO14001, OHSAS 18001, cGMP standards as understood by FDA and ICH Q7a, and ATEX directive 94/9/EC and 99/9/EC as well any EU Machinery Directive whenever applicable.

Any change to the Merchantable Goods that impacts or may impact in the quality or regulatory fillings (e.g. its manufacturing process) needs to be previously assessed by ND Pharma & Biotech to evaluate its impact in ND Pharma & Biotech's process. It is the responsibility of the Vendor to inform ND Pharma & Biotech in writing and get ND Pharma & Biotech's authorization prior to the implementation of the change.

In the process of defining what is the substance matter of the PA, ND Pharma & Biotech has been careful to explain to the Vendor what is the purpose that the purchased Merchantable Goods is destined to serve.

To the extent that ND Pharma & Biotech has been careful to explain in detail the reason for acquiring the Merchantable Goods, Vendor has a general duty to ensure that to the extent of his professional activity and the competencies it has represented to ND Pharma & Biotech to have is obligated to deliver a Merchantable Good that will substantially achieve the purpose desired by ND Pharma & Biotech to a reasonable extent and thus meet ND Pharma & Biotech's expectations. It is under this assumption that ND Pharma & Biotech has contracted with the Vendor and has agreed to the price.

If nothing else is stated in the Purchase Agreement, and without prejudice to other warranties provided by law, the Vendor provides ND Pharma & Biotech with warranties over the good quality of materials, building construction and/or erection works and craftsmanship that will ensure the sound operation of the purchased Merchantable Goods for the Intended purpose.

Such warranties will last for a period of at least twenty-four (24) months from the Goods Receipt issuance or for thirty-six (36) months from date of shipping (defined as per the shipping receipt when the purchased Merchantable Goods left the Vendor's premises), whatever comes first.

Notwithstanding the above, Vendor will take full responsibility, not subjected to any statute of limitation, for the quality and reliability of all parts of the Merchantable Goods that make up the PA including those parts and or services supplied by a third party Vendor or Sub Contractor.

## **5. Environment**

The protection of the environment is an imperative and strategic objective for the company business. ND Pharma & Biotech has subscribed the "Responsible Care Program". All ND Pharma & Biotech employees in their work follow those guidelines: - respect for the environment is an imperative in all ND Pharma & Biotech activities; - follows the current legislation and are continuously searching for new opportunities to optimize it and to recycle; - a management Waste Policy that is integrated, clear and autonomous.

The ND Pharma & Biotech's Health, Safety and Environment (HSE) Policy is known by all our Vendors, being also a part of ND Pharma & Biotech Purchasing Conditions.

If the merchantable goods supplied have a significant impact in terms of HSE, a risk assessment shall be made prior to the acquisition.

## **6. ND Pharma & Biotech's Policies on Quality, Health, Safety and Environment and Code of Ethics**

ND Pharma & Biotech's Policies are described in ND Pharma & Biotech Purchasing Conditions. Vendor is aware of it and accomplish with it, whenever it is applicable to the Merchantable Goods to be supplied to ND Pharma & Biotech.

Vendor agrees that is aware that ND Pharma & Biotech operates in a highly regulated environment. Vendor shall ensure that Vendor's work is performed to standards and guidelines that strengthen positively ND Pharma & Biotech's business. Vendor is also aware of ND Pharma & Biotech's policies and agrees that Vendor's work shall be aligned with such policies and regulations in force.

Specific HSE requirements should be evaluated during the negotiation phase and mentioned in the PA (for instance, noise level, identification and instructions in English and in the official language of the site to which it is intended for). Vendor is engaged to comply with all applicable legislation/regulations.

## **7. Payment**

A Vendor invoice is only eligible for payment if description is in accordance with the PA, if it refers the delivery date of the merchantable goods, if the date of issue is within the period of 5 days of the Merchantable Goods receipt applicable to ANY Vendors that supply ND Pharma & Biotech in ANY location, but not more than 90 days in any other circumstances, if states a correspondent PA number and if corresponds to the same original document that was used for customs clearance (when applicable).

Sending invoices with the Merchantable Goods delivered is acceptable, but an original invoice shall be sent by mail to the attention of ND Pharma & Biotech Accounting Department.

ND Pharma & Biotech shall only pay in advance monies that clearly correspond to the value of the Merchantable Goods that need to be acquired for the fabrication of the purchased Merchantable Goods. For each advanced monies the supplier has to issue a Bank Guarantee opened with a first class bank for the total advanced value, prevailing until the complete delivery of the Merchantable Goods.

The cost of any rental or trials shall be deducted from the final order.

ND Pharma & Biotech reserves the rights to open a letter of credit and or issue a bank guarantee by a First Class Bank instead of effecting advanced payments.

Payments are effective fortnight by e-banking and monthly by other means. If Vendors wish to be advised when a payment is made, please kindly send key contact person e-mail address to [cfo@ndpharmabiotech.com](mailto:cfo@ndpharmabiotech.com) or alternatively to [financial.ndpharma@gmail.com](mailto:financial.ndpharma@gmail.com).

Invoices are payable based on the purchase ledger system in place at ND Pharma & Biotech, after the Merchantable Goods has been approved for use and based on the payment terms agreed in the Purchase Agreement or contract signed between ND Pharma & Biotech and Vendor.

## **8. Variations**

Within the limitations of what the parties could reasonably expect when the Purchase Agreement was entered into, ND Pharma & Biotech has the right to request such variations to the Merchantable Goods as in ND Pharma & Biotech's opinion, in order to maintain the general purpose of the Purchase Agreement from a technical as well as commercial point of view are desirable. Such variations may include changes in the quantity, character, quality, kind or execution of the Merchantable Goods or any part thereof, as well as changes to the contract schedule by means of a variation order. Any variation shall be subject to all of the provisions of this Purchase Agreement.

The Vendor shall receive compensation for its additional work in implementing a variation order in accordance with the rates contained in the Purchase Agreement. If no applicable rates exist, ND Pharma & Biotech may at its own

discretion choose to compensate such variations according to the agreed actual cost expenditure and the Vendor shall agree on the compensation for the addition to the Works. If a variation order leads to a reduction in the Merchantable Goods, ND Pharma & Biotech shall correspondingly be credited in accordance with above referred principle.

Any adjustment to the Price or Delivery Schedule shall only be off effect when previously approved in writing by ND Pharma & Biotech.

On receipt of a variation order, the Vendor shall implement it without undue delay, even if the effect of the variation order on the contracted price, the Deliver Schedule and other provisions of the Purchase Agreement have not yet been agreed.

If the parties disagree as to the effect of the variation order on the contract price, then ND Pharma & Biotech shall pay the Vendor the undisputed amount calculated in accordance with the above stated. Payment shall be made in accordance with the provisions of art 7.

Compensation paid for a variation order shall be considered final unless, within 6 months of the issue of the variation order by ND Pharma & Biotech, the parties concerning the payment have instituted arbitration proceedings.

If ND Pharma & Biotech requires the performance of Merchantable Goods which in the Vendor's opinion is not part of its obligations under the contract, then the Vendor shall issue a variation order request and shall within 14 days thereafter prepare an estimate detailing:

a) Description of the variation Merchantable Goods.

b) A Detailed schedule for the execution of the variation Merchantable Goods showing the required resources and significant milestones, c) Effect on the Price with detailed supporting documentation based on relevant rates in accordance with the above stated, and

d) Effects on the Delivery Schedule, if any, with explanatory support documentation.

If the Vendor has not presented a variation order request within 30 Days after ND Pharma & Biotech has required the Merchantable Goods to be performed / supplied, then the Vendor loses the right to consider the Merchantable Goods as variation in accordance with this Art. 8.

When the Vendor made a request within the above stated time limit, ND Pharma & Biotech shall, within a reasonable time, issue a variation order. If ND Pharma & Biotech is of the opinion that this Merchantable Goods is a part of the Merchantable Goods under the Purchase Agreement, then it shall instead, within a reasonable time, issue a disputed variation order. After receiving a disputed variation order, the Vendor shall implement it without undue delay.

If the Vendor has not instituted court proceedings, nor agreed with ND Pharma & Biotech to submit the decision to arbitration within 6 months after the issue of

the disputed variation order, it shall be recorded on the disputed variation order that it is deemed to be a part of the Merchantable Goods.

## **9. Retention of Moneys**

ND Pharma & Biotech reserves the right to request from the Vendor to retain up to 15% of the agreed purchase price as security. These retention moneys shall be released in full within 12 months of delivery to ND Pharma & Biotech of the Merchantable Goods purchased. ND Pharma & Biotech will accept to release part or all the funds in exchange for a suitable bank guarantee that the Vendor will provide ND Pharma & Biotech with, and after successful start-up as evidenced by a handing over document.

Furthermore, and in case nothing else is stated in the Purchase Agreement, ND Pharma & Biotech at its one description can retain 10% of the agreed purchase price as a warranty until all legal and remaining agreed upon documentation is handled as per article 10.

## **10. Fines for late delivery**

The PA placed with the Vendor will usually be part of a wider number of PAs, which aims to complete a system, to be incorporated into a new installation or a manufacturing campaign. The scheduling of such a project will therefore involve multiple parties and key dates. It is imperative that the Vendor respects the time commitments, which the PA will define clearly. Should the Vendor fail to observe such time commitments ND Pharma & Biotech reserves the right to deduct "fines for late delivery" from the purchase price/s.

The fine shall be up to 0.5% per day of delay, limited to 15% of the total agreed purchase price, from the agreed delivery date of the Merchantable Goods which is delayed and where such delay clearly affects negatively the management of the overall project.

The liquidated damages become due at ND Pharma & Biotech request in writing and may be set off against the Purchase Price. If nothing else is stated in the Purchase Agreement, the delivery date shall always be regarded as a penalty milestone.

## **11. Drawings and Information**

The Vendor shall prepare and submit to ND Pharma & Biotech all execution drawing to be followed by "as-built" drawings, designs, and information required pursuant to any terms of the Purchase Agreement necessary for ND Pharma & Biotech to run, maintain and improve the facility as the case may be.

ND Pharma & Biotech shall have the right but not the obligation to approve the designs and drawings prepared by the Vendor. Any comment on or approval of the Vendor's drawings or designs by ND Pharma & Biotech shall not in any way relieve the Vendor of its obligations for the correctness, sufficiency and accuracy of its designs and drawings.

If for any reason the Vendor's designs/drawings show any deviation from any of the provisions of the Purchase Agreement, the Vendor shall not be relieved of its obligation of full compliance with the provisions of the Purchase Agreement.

These can be sent by mail or electronic means, in the form of paper as well as magnetic or other format that may be used more efficiently by ND Pharma & Biotech. The Vendor shall supply two copies of all the commissioning and operating instructions, parts list and user's manual in English as well as in the languages of the applicable ND Pharma & Biotech Site.

The Vendor shall supply ND Pharma & Biotech with additional copies upon request, at no further cost, at any time during at least the expected life of the Merchantable Goods.

## **12. Retention of files**

In absence of any alternative instructions from ND Pharma & Biotech, Vendor will retain records related to the Merchantable Goods supplied to ND Pharma & Biotech, at least, for ten years after the supply date.

## **13. Insurance and Transport**

Insurance of transport Institute Cargo Clauses (A) must be in force, as per the Purchasing Conditions agreed and stated in the PA. Insurance should cover the transport from warehouse to warehouse. In case Insurance is to be covered by ND Pharma & Biotech the Vendor will ensure that ND Pharma & Biotech is duly notified of the readiness to ship, and of the shipping details. All necessary documents shall be provided to ND Pharma & Biotech by fax or/and electronic mail as soon as available. Unless specified in the negotiation documentation the Vendor is obliged to provide at no cost to ND Pharma & Biotech suitable export packing. Every shipment shall be marked with: Name of Vendor, PA number, ND Pharma & Biotech. Suitable markings such as "fragile", shall be prominently displayed.

Insurance that covers accidents and losses during erection, start-up and commissioning activities must also be in force, and agreed with all contractors that are involved in the works.

The Vendor shall prior to commencing the Works provide the following insurance: a) For the Works against loss or damage, b) Liability insurance covering injuries and property damage to third party. c) Employment compensation insurance concerning its personnel and for sub contractors' personnel covering losses connected with illness, personal injury or accidental death.

The liability and personal insurance shall be provided up until issue of the Goods Receipt. The Vendor is obligated to have ND Pharma & Biotech made loss payee under the insurance policy under item a) (above).

The Vendor's insurance shall state that the insurers waive all rights of subrogation against ND Pharma & Biotech.

The Vendor shall ensure that all insurance policies contain a clause requiring the insurer to notify ND Pharma & Biotech in good time before the insurance is cancelled, or lapses for any other reason.

Whereas the Vendor bears the risk for the Works until delivery has taken place, the Vendor shall indemnify and hold ND Pharma & Biotech harmless from and against all losses or damages to the Vendor's properties or personnel hereunder, that may arise in connection with or as a result of the Purchase Agreement.

At ND Pharma & Biotech's request, the Vendor shall produce certified copies of the policies and or insurance-certificates including conditions for the insurance he is obligated to take out under the Purchase Agreement. Vendor's failure to comply, shall entitle ND Pharma & Biotech to apply penalties either under article 9, cancel the Purchase Agreement or take other actions deemed appropriate.

The Vendor will ensure that ND Pharma & Biotech is duly notified of the insurance limit that is applicable to each Work. ND Pharma & Biotech will provide an extension to the insurance of these contractors so that full value involved is covered. However, when evaluating the maximum value for the insurance, it should be considered the reasonable value of the damage that may happen in each step and not the sum of the individual value of all equipment.

All Merchantable Goods supplied by the Vendor shall be suitably packed and protected during transportation and storage at Site.

Unless otherwise expressly set forth in the Purchase Agreement, terms and conditions of delivery shall be interpreted in accordance with the current edition of INCOTERMS.

#### **14. Confidentiality**

ND Pharma & Biotech operates in a very competitive environment. **Its activities and manufacturing processes involve proprietary technologies.** ND Pharma & Biotech's *know-how* is very valuable and a key competitive advantage. It is only made available to the Vendor to assist him in carrying out his business and best serve ND Pharma & Biotech's needs. The Vendor agrees to respect the confidentiality of all the information it receives from ND Pharma & Biotech, this shall be held in trust by the Vendor and is to be used solely to the benefit of ND Pharma & Biotech through the supply of the purchased Merchantable Goods.

Vendor also recognize that **ND Pharma & Biotech has much proprietary confidential information belonging to both ND Pharma & Biotech and to ND Pharma & Biotech's customers which ND Pharma & Biotech holds in trust for the customers whilst performing services for them.** If ever, during the performance of Vendors duties, Vendor becomes exposed to such information; Vendor agrees to respect its confidential nature and not to disclose it to any third party. Furthermore Vendor confirms that all its employees that are

involved in ND Pharma & Biotech business are also under a similar personal obligation of confidentiality, and accept the responsibility for any breach by them.

ND Pharma & Biotech needs to share some confidential information to Vendor to allow that the supplies of Merchantable Goods, parties now wish to establish a contractual framework that shall protect their respective proprietary information and longer term interests.

Vendor shall observe the highest standards of confidentiality over Confidential Information provided to it by ND Pharma & Biotech as such data includes information that ND Pharma & Biotech itself has received on trust and under strict obligations of confidentiality to its customers. In the course of these communications and activities, ND Pharma & Biotech and Vendor may disclose or deliver to each other certain Confidential Information (defined below).

**14.1 “Confidential Information”** means any scientific, technical trade or business information possessed or obtained by, developed for or given to the disclosing party which is treated by the disclosing party as confidential or proprietary including, without limitation, Research Materials (defined below), gene sequences and loci, formulations, techniques, methodology assay systems, formulae, procedures, tests equipment, data computer software (including, without limitation, object code and source code), documentation, reports, know-how, sources of supply, patent positioning, technical, engineering, financial and commercial information, architecture works, flow diagrams, layout drawings, equipment details, calculations, drawings graphs, blueprints, tables, photographs, copyright material, trade secrets, unpatented inventions, relationships with consultants and employees, business plans and business developments, information concerning the existence, scope or activities of any research, development, manufacturing, marketing or other projects of the disclosing party, and any other confidential information about or belonging to the disclosing party’s Vendors, licensors, licensees, partners, affiliates, customers, potential customers or others.

The Parties will use commercially reasonable efforts consistent with reasonable practices to: - Label or identify as “CONFIDENTIAL” at the time of disclosure or, by written notice to the other party, within thirty (30) days following such disclosure, Confidential Information which is disclosed in writing or other tangible form: - all confidential information shall be disclosed in writing or electronically and marked confidential or if disclosed orally or visually or gained by visiting plants/labs and shall include any tangibles such as strains and product samples or in any other way, shall be summarized and identified as confidential by the disclosing party in writing with 30 days of the disclosure. - Vendor shall receive the Confidential Information in the strictest confidence and in Good faith, and shall not at any time without the prior written consent of ND Pharma & Biotech use the Confidential Information, or any knowledge or information which Vendor may acquire as a result of receiving the Confidential Information, in any way which is in furtherance of competition with ND Pharma & Biotech, or otherwise directly or indirectly detrimental to the interest of ND Pharma & Biotech, or any purpose whatever other than for the purpose of the project under an agreement and or contract with ND Pharma & Biotech.

“Confidential Information” does not include information which:

- . a) *was known to the receiving party at the time it was disclosed, other than by previous disclosure by the disclosing party, as evidenced by the receiving party’s written records at the time of disclosure;*
- . b) *is at the time of disclosure or later becomes publicly known under circumstances involving no breach of a specific agreement; (Mutual CDA, MoU, EA, etc.)*
- . c) *is lawfully and in good faith made available to the receiving party by a third party who did not derive it, directly or indirectly, from the disclosing party;*
- . d) *is independently developed by a receiving party without the use of the disclosing party’s Confidential Information;*

**14.2 Research Materials** include, without limitation, all reagents, chemical compounds, together with all related impurities, intermediates, raw-material or other materials – as well as the analytical, engineering and process chemistry know-how to produce such Research Materials and all regulatory documentation necessary to obtain authorization to sell by a health authority.

**14.3 Ownership:** ND Pharma & Biotech and Vendor shall at all times remain the sole owner of their respective Confidential Information. However any inventions that may arise as a result of a specific collaboration shall belong to ND Pharma & Biotech and should any invention give rise to an opportunity to patent, parties shall collaborate so that, at ND Pharma & Biotech’s expense, one or more patents are applied for and assigned to ND Pharma & Biotech or to any 3<sup>rd</sup> Party ND Pharma & Biotech shall direct.

**14.4 Nondisclosure of Confidential Information:** ND Pharma & Biotech and Vendor shall not, directly or indirectly, publish, disseminate or otherwise disclose, deliver or make available to any person outside its organization any of the other party’s Confidential Information. ND Pharma & Biotech and Vendor may disclose the other party’s confidential Information to persons within their respective organizations and to their respective affiliates and collaborators who/which have a need to receive such Confidential Information in order to further the supply of the purchased Merchantable Goods and who/which are bound to protect the confidentiality of such Confidential Information, as set forth below. It is the responsibility of the Vendor to ensure that all its employees that may have access to ND Pharma & Biotech’s information are under an obligation not to disclose to third parties such confidential information (for example: name of ND Pharma & Biotech as a client, name of ND Pharma & Biotech’s clients, nature of Merchantable Goods to ND Pharma & Biotech, nature of business). Vendor shall not disclose to any party the existence of an agreement with ND Pharma & Biotech. ND Pharma & Biotech shall however have the right to disclose the identity of the Vendor to the customer for whom it is supplying if this is being done on an exclusive basis.

**14.5 Required Disclosure:** If required, ND Pharma & Biotech and Vendor may disclose the other party’s Confidential Information to a governmental authority

or by order of a court of competent jurisdiction, provided that such disclosure is subject to all applicable governmental or judicial protection available for like information and reasonable advance notice is given to the other party.

**14.6 Use of Confidential Information:** ND Pharma & Biotech and Vendor shall use the other party's Confidential Information solely for the purpose to the Merchantable Goods or for such other purposes as may be approved by the other party in writing, nor will it disclose such Confidential Information to any third party (other than to its employees and consultants whose duties justify the need to know such Confidential Information and who have agreed to be bound by the terms of this conditions).

**14.7 Expiration; Termination Expiration; Return of Research Materials and Other Confidential Information:** Confidential Information obligations will expire ten (10) years from the last date of disclosure of any confidential information. Upon expiration, or sooner upon disclosing party's request, the receiving party shall promptly return to the disclosing party all Research Materials and any other tangible Confidential Information.

**14.8 Agreements with Personnel and Affiliates.** ND Pharma & Biotech and Vendor have or shall obtain agreements with all parties who are permitted access to the other party's Confidential Information under this Agreement which impose comparable confidentiality obligations on such parties

## **15. Suspension and Cancellation**

ND Pharma & Biotech shall have the right at any time at ND Pharma & Biotech convenience, upon written notification to the Vendor, to suspend or cancel the Purchase Agreement or any part thereof.

In the event of such suspension or cancellation, the Vendor shall immediately discontinue all related work and immediately suspend or cancel, as the case may be, all outstanding subcontracts, on terms satisfactory to ND Pharma & Biotech, or at ND Pharma & Biotech option, assign any of such subcontracts to ND Pharma & Biotech

In the event of such cancellation, the Vendor shall be entitled to the cost of the Merchantable Goods done and delivered in accordance with the Purchase Agreement up to the time of cancellation.

In the event of such suspension or cancellation, the Vendor shall be entitled to additional cost and expense which has been authorized in advance by ND Pharma & Biotech but which in any event shall be limited to that reasonably incurred by the Vendor as a direct result of such suspension or cancellation, taking into account in the case of cancellation the realizable value of the materials included to form part of the Merchantable Goods, provided always that such additional cost and expense shall be fully substantiated by the Vendor to ND Pharma & Biotech.

## **16. Termination for Breach**

Either party may terminate this Agreement immediately upon written notice to the other party if it determines that the other party has breached its confidentiality obligations and any other terms of this Purchasing Conditions. In this event, the party in breach shall promptly return to the other all Confidential Information and its confidentiality obligations will continue indefinitely.

ND Pharma & Biotech is entitled to terminate the Purchase Agreement with immediate effect by notifying the Vendor when:

a) The Vendor is in substantial breach of the Purchase Agreement,

b) The Vendor becomes insolvent or stops his payments,

c) ND Pharma & Biotech has become entitled to be paid any liquidated damages or it is evident that the completion of the Works will be delayed by more than 15% of the time period from contract award until the delivery date.

In the event of such termination, ND Pharma & Biotech may take possession of the Merchantable Goods, and all relevant drawings, specifications, materials, tools and construction equipment necessary to enable ND Pharma & Biotech to complete the Works.

ND Pharma & Biotech may upon such termination claim compensation based on the delay that would have occurred if the Vendor were to complete the Work by itself.

## **17. Set-Off**

ND Pharma & Biotech shall have the right to withhold or to set-off against amounts due to the Vendor, amounts which could reasonably be expected to become due to ND Pharma & Biotech

## **18. Proprietary Rights**

The Vendor guarantees that the Merchantable Goods have been carried out / supplied without infringement of patents, trade marks or other proprietary rights.

The Vendor shall, at no cost or expense to ND Pharma & Biotech, defend all actions or suits charging any infringement or alleged infringement thereof and shall indemnify and hold ND Pharma & Biotech harmless in respect of the same.

The Vendor shall indemnify ND Pharma & Biotech from claims due to infringement of patents or industrial property rights in connection with the Merchantable Goods. Vendor shall in case of infringement seek to obtain a license to allow ND Pharma & Biotech to use the Merchantable Goods for its intended purpose. If this is not achieved in 40 days of the discovery of infringement, the Vendor shall change the Merchantable Goods in such a

manner – still observing the specifications of the Purchase Agreement – that the Merchantable Goods do not conflict with the rights of third parties.

Documents and computer programs provided by ND Pharma & Biotech to the Vendor, or documents and computer programs that are developed mainly on the basis of such documents and computer programs shall be and remain the property of ND Pharma & Biotech. Such documents, computer programs or copies shall not be used by the Vendor others than for the purpose of the Merchantable Goods. Such documents, computer programs or copies shall be returned to ND Pharma & Biotech upon completion of the Works, except that the Vendor may keep one copy of all such information in its confidential files for record purposes, to be used only for matters which are related to the Purchase Agreement.

Documents and computer programs provided by the Vendor to ND Pharma & Biotech, or documents and computer programs, which are developed mainly on the basis of such documents and computer programs, shall be the property of the Vendor. ND Pharma & Biotech shall only be entitled to use such documents, computer programs, and copies in connection with the operation, repair, modification and maintenance of the Merchantable Goods.

All other documents computer programs and copies thereof developed by the Vendor in connection with the Merchantable Goods, shall be the property of the Vendor. ND Pharma & Biotech may use, without restriction, such documents, computer programs and copies for the performance of the Merchantable Goods.

**19. Promotion:** Vendor shall not list, feature or mention ND Pharma & Biotech or the supplied Merchantable Goods as a reference in its documentation or client list. On a case-by-case basis, ND Pharma & Biotech may make exceptions to this rule, but any and every authorization to make a specific disclosure shall require a specific written consent by ND Pharma & Biotech.

## **20. Auditing**

Vendor accepts to be audited by ND Pharma & Biotech to verify compliance with these Purchasing Conditions and or any other contract and agreement signed. An authorized representative acceptable to ND Pharma & Biotech can also perform such audits, carried out with a minimum 24 hours notice period.

ND Pharma & Biotech shall have this right for the period from date of the Purchase Agreement until the end of the guarantee period in accordance with article 4. (Above).

## **21. Public Liability Disclaimer**

When visiting ND Pharma & Biotech's premises, Vendor and its employees shall be subject to ND Pharma & Biotech's badge and pass requirements in effect at the site visited. Vendor and its employees agree to be bound by all orders, rules, and regulations of ND Pharma & Biotech pertaining to the use of ND Pharma & Biotech facilities. ND Pharma & Biotech shall not be liable under

any circumstances for any personal or property injury or damage done or suffered by Vendor or its employees on ND Pharma & Biotech premises and Vendor shall assume all such risk of injury or damage.

Any and all damages or harm caused by Vendor to ND Pharma & Biotech's installation and employees or those of subcontractors, Vendors, clients and independent workers is the sole and entire responsibility of the Vendor.

## **22. Conflicts of Interest and Non-Compete Clause**

Vendor accepts not to seek to hire anyone employed by ND Pharma & Biotech, similarly ND Pharma & Biotech accepts mirror like obligations. Vendor accepts the obligation to disclose to ND Pharma & Biotech any work that Vendor do for others which could present a conflict of interests.

Vendor declares that it will not compete and or create competition to ND Pharma & Biotech, directly or indirectly via third parties on the business of any API and or any relevant raw material, intermediates, building blocks and impurities which are used in the manufacturing process of ND Pharma & Biotech APIs.

## **23. Subcontractors**

Vendor shall not make use of subcontractors in any activity directly related to the Merchantable Goods supplied/to be supplied to ND Pharma & Biotech, except with the ND Pharma & Biotech's written authorization. In the event that a subcontractor is chosen, the responsibility of the totality of the works performed to ND Pharma & Biotech will lie exclusively in the Vendor, whatever the executor of the work may have been.

## **24. No License**

Nothing contained herein shall be construed to grant Vendor any immunity or license under any ND Pharma & Biotech intellectual property right.

## **25. Non-Waiver**

No provision of this ND Pharma & Biotech Purchasing Conditions shall be interpreted as a waiver of any right or remedy of the parties, unless expressly stated as being a waiver of a particular right or remedy.

Failure of a party to insist upon strict performance in accordance with any of the provisions of the Purchase Agreement shall not be deemed to be a waiver of such provision(s) and shall not in any way relieve the other party of any of its obligations or liabilities. It shall not in any way prejudice any of the parties' rights or remedies.

## **26. No Violation**

ND Pharma & Biotech and Vendor represents that its compliance with the terms of these Purchase Conditions will not violate any duty which such party may have to any other person or entity, including obligations concerning providing services to others, confidentiality of proprietary information

## **27. Gifts and benefits**

It is ND Pharma & Biotech's Policy that all its employees and their family members are not allowed to solicit or accept any money, valuables gifts or benefits from ND Pharma & Biotech customers or Vendors. ND Pharma & Biotech believes that giving and accepting of any valuable gifts are unnecessary and may even be detrimental to the development of business relationships. Received gifts will be remitted to ND Pharma & Biotech Human Resources to be used for the ND Pharma & Biotech Christmas party's lucky draw.

## **28. Associated” shall mean:**

- . a) Any corporation, company or other business entity, which is owned directly or indirectly less than twenty five per cent (25%) by the company;
- . b) Any corporation, company or other business entity, which owns directly or indirectly fifty per cent (50%) or more of the voting stock of a corporation, company or other business entity described in a) above; or
- . c) Any corporation, company or other business entity under the direct or indirect Control of a corporation, company or other business entity described in a) and b) above.

## **“Affiliated” shall mean:**

- . a) Any corporation, company or other business entity, which is owned directly or indirectly twenty five percent (25%) to fifty percent (50%) by the company;
- . b) Any corporation, company or other business entity, which owns directly or indirectly fifty percent (50%) or more of the voting stock of a corporation, company or other business entity described in a) above; or
- . c) Any corporation, company or other business entity under the direct or indirect Control of a corporation, company or other business entity described in a) and b) above.

**“Subsidiary”** shall mean any corporation, company or other business entity, which is owned directly or indirectly fifty one per cent (51%) or more by the company.

## **29. Severability**

If any one or more of the provisions of the Purchase Agreement should be held to be invalid because of enactment or rule of law, such provision(s) shall to that extent be deemed to be omitted from the Purchase Agreement but the validity and enforceability of the remainder of the Purchase Agreement shall not be affected by such omission.

## **30. Nota Bene**

ND Pharma & Biotech Purchasing Conditions shall in no way reduce any rights that ND Pharma & Biotech may have under the Law of the country where the Merchantable Good was sold and/or may benefit from the general terms of sale of the Vendor; they are to be construed as applicable to all purchases that ND Pharma & Biotech may make and are therefore to be interpreted so as to suitably defend ND Pharma & Biotech's rights; these Purchasing Conditions are subordinated to the terms in the actual PA which are specific to the purchased Merchantable Goods.

## **31. Force Majeure**

Neither of the parties shall be liable for delay in performing or for failure to perform its obligations under the Purchase Agreement if the delay or failure results from any cause beyond the control of any party and the Purchase Agreement shall be suspended. Without prejudice to the generality of the foregoing, the following shall be regarded as causes beyond a party's control: (i) act of God, (ii) outbreak of war, riot, civil disturbance, acts of terrorism, (iii) the act of any government or authority (including refusal or revocation of any license or consent) and (iv) fire, explosion or flood.

The party claiming force majeure shall immediately give notice to the other party in writing stating the circumstances in reasonable detail. The onus of proving that force majeure exists shall rest upon the party so asserting.

Within seven (7) Days after the force majeure situation has ceased, the Vendor shall present to ND Pharma & Biotech its proposed adjustment to the Delivery Schedule, and ND Pharma & Biotech shall grant a fair and reasonable extension of time for the performance of the Purchase Agreement. Notwithstanding the foregoing, the Vendor shall use its best endeavours to minimize any delay in the performance of the Purchase Agreement.

If a force majeure situation continues without interruption for a period of 60 days or more, either of the parties shall be entitled to terminate the Purchase Agreement by written notice to the other party. In such case ND Pharma & Biotech may require the Merchantable Goods to be delivered in the condition existing at the cancellation date, upon paying a pro rata part of the price.

## **32. Law and Jurisdiction**

The Vendor shall ensure that the Merchantable Goods comply with all applicable laws, rules and regulations. The Vendor shall indemnify and hold ND

Pharma & Biotech harmless from all cost and expense, including without limitation all fines and penalties as a result of non-compliance of the Merchantable Goods in this respect.

The terms of business set forth (a) may not be assigned or transferred by Vendor without ND Pharma & Biotech's prior consent (b) shall be governed by and construed in accordance with the laws of Spain (alternatively England when previously agreed) without regard to any choice of law principle that would dictate the application of the law of another jurisdiction, and in case of questions and or dispute arising in connection with or relating to the execution, the implementation, the interpretation of any clause contained in these Conditions, which cannot be amicably settled by the Parties through negotiations in good faith within sixty (60) days from the first notice of such dispute, controversy or claim, Parties accepting to submit to the jurisdiction of the Rules of Arbitration and Conciliation of the International Chamber of Commerce (Paris) to be held in Zurich in the English language and may be executed by facsimile, which will be deemed an original.

### **33. ND Pharma & Biotech Policies and Rules 33.1 Quality Policy:**

We, at ND Pharma & Biotech, are committed to Quality. A demanding quality, which is adjusted to satisfy our Customers and Health Authorities.

- Our Quality System assures that we are in compliance with current GMP and regulatory requirements.
- Following the rules is very important because the products we make save lives.
- Quality is designed-in and built-in, it is a team effort, and everyone's individual work is very important.
- We do it right first time, and we improve all the time.
- In order to improve change is encouraged, but all changes are controlled.
- Deviations and complaints are recorded and investigated.
- Corrective and preventive actions are implemented through changes to controlled documentation and training.
- Traceability enables the identification of non-conformities, deviations and the trend that determines when change is appropriate.
- To do good work YOU
- must first understand what is expected of you,
- then you must be well trained and finally, you must do your best. You should listen to your colleagues and, when appropriate, you should inform the Customer before making changes.

### **33.2 Health, Safety and Environment Policy:**

The protection of people, facilities and the environment is a strategic imperative for development and is a constant source of concern for ND Pharma & Biotech, relying on the following principles:

- We comply with the applicable legislation and other requirements that the company subscribes to;
- We design facilities, processes and operations in agreement with principles that assure safety, health and the environment;
- We evaluate and prevent risks to health and safety and the impact on the environment of all areas of Company activity;
- We adopt adequate policies for the management of waste, emissions and natural resources that prevent pollution and are, whenever possible, integrated and autonomous;
- We inform and train our employees and demand that they act responsibly in the defence of health, safety and the environment using common sense and in alignment with the business;
- We investigate and record all non-compliance situations and implement corrective/preventive actions to avoid recurrences; communicate them promptly and effectively to all Company staff and all on-site sub-contractors, whenever appropriate.
- We maintain a cordial and constructive relationship with the community and other interested parties based on a spirit of mutual respect and dialogue, and aim to continuous improvement in Health, Safety and Environment matters, evaluating regularly our performance in order to reach the established objectives.

Additional information:

**33.3 The ND Pharma & Biotech Code of Ethics Fundamental Principles** Since its foundation, ND Pharma & Biotech's activity has been governed by ethical values that we are aimed to remain unalterable. ND Pharma & Biotech believes that the respect for these values is the basic principle for the healthy growth of the Company, permitting and guiding its business conduct and human relations. This behaviour is based on Compliance with the Law, Honesty, Loyalty, Courtesy, Respect, Diligence and a Sense of Responsibility.

The ND Pharma & Biotech Code of Ethics establishes fundamental rules of conduct that govern relationships between the Company and the Staff, Clients, Suppliers, Competitors, Shareholders, Public Authorities and the Community. ND Pharma & Biotech's ethical principles aim to establish and develop Trust in

all of its relationships. While the Company strives to defend and promote its scientific, industrial, commercial and financial interests, Truth and Honesty shall prevail above all.

ND Pharma & Biotech is dedicated to serving the Pharmaceutical Industry with products that may save human lives and improve quality of life – the mission of our Company and the nature of our activities implies great responsibility in our work, not only in the quest for sound science but also in achieving a constant state of compliance with the regulations and best practices in the industry. Our daily activity is further based on observing our obligations towards confidentiality and protecting the valuable know-how and information of the Company and that of our Clients.

ND Pharma & Biotech operates in several continents and represents a multitude of different cultures, races, nationalities and religions. A written document describing certain fundamental rules of conduct that reflects the values we have always held is now necessary.

**This document applies to all members of the Company; it also applies to persons who are conducting business on behalf of ND Pharma & Biotech and who are seen by third parties as representing the Company.** ND Pharma & Biotech expects from all members of its staff, irrespective of their level of responsibility, a conduct in accordance with these principles and rules of conduct. In case of doubt in the application of any of the present rules, it is each one's responsibility to seek advice from his or her hierarchical head or from Human Resources.

This Code of Ethics is a set of principles. Local ND Pharma & Biotech companies will use them to develop additional internal procedures if required by their own laws, regulations and local custom or business.

### **Rules of Conduct - Summary Dealing with our business partners**

- . 1.1 The prosperity and future of ND Pharma & Biotech is based on serving our clients to their satisfaction and best expectations.
- . 1.2 We treat clients with honesty, professionalism and openness.
- . 1.3 We endeavour to supply products and services as agreed, namely in terms of quantity, quality, price, and delivery date, always confirming to specification and to the regulations.
- . 1.4 We inform clients of any relevant or unexpected deviation from the agreed terms, conditions and specifications, whether technical, scientific or commercial.
- . 1.5 We promote with our customers and other business partners long lasting partnerships, which are based on trust and are mutually beneficial.
- . 1.6 We select our suppliers through an objective evaluation of competence, price, quality, delivery dates, payment terms, shared values and other due diligence issues, according to our requirements and interests.

- . 1.7 Loyal competition is essential to establish a level playing field for all participants in the industry and for its sound development and we will work to uphold and preserve it.
- . 1.8 We will not obtain or acquire information about competitors in an illegal or irregular manner; we will not denigrate their reputation but endeavour to make objective comparisons.
- . 1.9 We will not undertake any unethical business practices to attract a client to the detriment of a competitor.
- . 1.10 We will not increase profits by any illegal or dishonest means. We will not accept any personal presents or personal favours, which are intended to influence the business relationship with the Company.
- . 1.11 We work with our business partners under contractual obligations of confidentiality. We protect and keep confidential all scientific, industrial and business information obtained under that relationship, in the present and for the future.
- . 1.12 We never promise what we cannot keep or what is not ours to guarantee, as our promises bind the Company.
- . 1.13 We investigate and respond to all complaints, striving to give each one equal attention, irrespective of origin.

### **Respecting and obeying laws and regulations**

- . 2.1 We respect the Law. We observe the truth; act honestly and in accordance with Industry regulations.
- . 2.2 When we become aware of any instance of non-compliance with these rules or with this Code of Ethics, we will inform the Company of any such instance.
- . 2.3 We report our activities to Authorities as required by law.

### **ND Pharma & Biotech and the Community**

- . 3.1 ND Pharma & Biotech strives to maintain Good and stable neighbourly relations within its Community and takes an interest in its needs.
- . 3.2 ND Pharma & Biotech encourages dialogue and informs the public in a clear and accessible language of its activity and undertakings, opening its doors regularly to the Community, Authorities, Press, Academia and the Public in general.
- . 3.3 ND Pharma & Biotech organizes plant visits for schools, students or other parties with an educational intent.
- . 3.4 ND Pharma & Biotech strives to constantly improve the conditions of its facilities and its performance in terms of safety, health and environmental

protection and communicates its performance to the public.

- . 3.5 ND Pharma & Biotech takes all necessary measures within its possibilities to prevent or reduce environmental, material or personal damage.
- . 3.6 ND Pharma & Biotech will offer help to Authorities in case of an incident outside the Company in the field of its expertise and available means.
- . 3.7 ND Pharma & Biotech collaborates with Authorities in issues relating to safety and environmental protection.
- . 3.8 Partisan politics shall not take place within the Company.

### **33.4 Basic access rules to ND Pharma & Biotech facilities**

Vehicles without a flameproof device are not allowed to enter ND Pharma & Biotech's industrial facilities or operated plants. Drivers are responsible to place the flameproof device during the time they are inside the facilities. Vehicles already having another type of security device flameproof must show it. If the exhaust pipes or the exhaust silencers of the vehicles are damaged, they will not be allowed to enter ND Pharma & Biotech areas.

The vehicles will be inspected when leaving ND Pharma & Biotech facilities. This action is part of a rigorous system of security rules for entrance and exit control of materials and equipment with or without delivery notes. This inspection is compulsory and therefore we ask for your understanding.

Photocopies can only be taken and original removed from premises with prior authorization. Access to our internal computer system is not allowed, unless controlled by ND Pharma & Biotech personnel. Other security rules:

- SMOKING is not allowed. There are duly identified areas where smoking is allowed;
- Speed Limit in the facilities is 20km/h;
- Please switch off your mobile phone. For security reasons, mobile phones can only be used in administrative areas.
- Drivers are not authorized to remain within the safety restricted area during the transfer/unload of the product from the car/truck.

### **34. Glossary**

- AIF Approval Investment Form
- ATI Approval for Alterations, Technical Innovation and Investments
- Completion Certificate means the certificate to be issued by ND Pharma & Biotech when the Works, including all documentation but with the exception of guarantee work, has been completed. For the avoidance of doubt, the Completion Certificate issuance corresponds to final acceptance of the Merchantable Goods
- Delivery Protocol means the document to be concluded by both parties in accordance upon delivery of the Merchantable Goods. The Delivery Protocol corresponds to the provisional acceptance of such Merchantable Goods
- Delivery Schedule is the delivery schedule stating with the Merchantable Goods to be completed by the Vendor in total or partiality
- ERP Enterprise Resources Planning
- Facility is the facility into which the Merchantable Goods and/or Works are to be erected/delivered/realized.
- GMP Good Manufacturing Practices
- ND Pharma & Biotech is deemed to include any Associated, Affiliated and Subsidiary of ND Pharma & Biotech CompanyLtd
- HSE Health Safety & Environment
- IN Engineering
- Merchantable Goods is deemed to include raw packaging material, product, assets equipment and all machinery material processed materials, fabricated products, services, drawings and other documentation and work to be supplied under the Purchase Agreement or know-how or a combination thereof
- MN Manufacturing area
- MRO Materials for repair and operation

-MRP Material Requirement Planning

-PA Purchase Agreement

-PDS Project Data Sheet

-PM Project Manager

-PO Purchase Order Price is the total sum payable to the Vendor in accordance with the Purchase Agreement Product is deemed to include a manufacturing process and their related components, raw materials, intermediates, building blocks, impurities, specifications and analytical methods

-PT Project Team

-PU Purchasing/Purchase Agreement is deemed to include the ND Pharma & Biotech Purchasing Conditions, The Purchase Order, the Scheduling Agreement, Quantity and Value Contractors, Letter of Intent, Supply Agreements, Engagement Letters, Confidential Disclosure Agreements, Delivery Schedules and other documentation that will form part of the Purchase Agreement by special reference by parties and related to an ND Pharma & Biotech Purchase Order.

-Q Quality

-QAU Quality Assurance Unit

-QCU Quality Control Unit

-RD Research and Development Site means ND Pharma & Biotech site, at which the Goods and/or Works are to be realized. Vendor is deemed to include suppliers and manufactures the entity named on the Purchase Agreement supplying the Merchantable Goods. Works is deemed to include Merchantable Goods including erection and other work to be carried out by the Vendor under the Purchase Agreement.