**Self-Evaluation Questionnaire to Raw Material Manufacturer**

1. This questionnaire must be filled out exclusively by the qualified person or quality assurance responsible.
2. Answer all questions that apply to the material(s) that your company provides to Farmanguinhos, if any question is considered not applicable, mark it as “Not applicable”.
3. Statements and other documents required in this questionnaire must be sent to Farmanguinhos following it.
4. If the supplied products are manufactured in more than one plant, this questionnaire must be answered for each unit.

###### **GENERAL INFORMATION**

|  |  |
| --- | --- |
| Company Name: | Click here to enter text. |
| Commercial Address: | Click here to enter text. |

###### **SITE LOCATION AND STRUCTURE**

|  |  |
| --- | --- |
| Company name of manufacturer: | Click here to enter text. |
| Manufacturing site address: | Click here to enter text. |
| Qualified person: | Click here to enter text. |
| Number of employees (total): | Click here to enter text. |
| Number of employees in quality area: | Click here to enter text. |
| Number of employees in production area: | Click here to enter text. |

###### **MANUFACTURING SITE**

|  |  |  |
| --- | --- | --- |
| Is the factory that manufactures this material a Mono-plant (exclusively for this material) or is a Multiproduct (manufactures other materials)? | [ ]  Mono-plant[ ]  Multiproduct | **INF** |
| Is (are) the material(s) in question produced only in this unit? | Choose an item | R |
| Are the folowing operations always executed in this same manufacturing site? |  | **R** |
| - synthesis | **Choose an item** |
| - manufacturing | Choose an item |
| - purification | Choose an item |
| - packaging | **Choose an item** |
| - quality control analysis | **Choose an item** |
| - product release | **Choose an item** |
| - warehousing | **Choose an item** |
| Is it possible that any of the manufacturing steps be executed in other factories? | **Choose an item**  | R |
| If **YES**, inform below, material name, step, company name and address:Click here to enter text. |  |
| Is it possible to identify the manufacturing in the certificates of analysis that will be provided to Farmanguinhos with each batch? | **Choose an item** | N |
| What are the applications of the materials manufactured in this site? | [ ]  Pharmaceutical[ ]  Food[ ]  Cosmetic[ ]  Others | **INF** |
| Are the equipment used in the manufacture of the material exclusive / dedicated? | **Choose an item** | R |

###### **MATERIAL CHARACTERISTICS**

|  |  |  |
| --- | --- | --- |
| CAS Number(Only for active pharmaceutical ingredients or excipients, forother types of material, mark Not applicable). | Click here to enter text.[ ]  Not applicable. | **INF** |
| Describe the starting materials used in manufacture of each supplied product:Click here to enter text. | **INF** |
| Mark the options below that better define the starting materials used in the manufacture of the product: | **INF** |
| [ ]  Plastic |
| [ ]  Synthetic |
| [ ]  Biotechnological, fermentative ou using cells |
| [ ]  Human |
| [ ]  Inorganic |
| [ ]  Vegetable |
| [ ]  Others |
| [ ]  Animal (for example: tissue, tissue, tissue or fluid extract such as milk, whey, blood). |
| Does the product incorporate or is processed with animal derivatives? | **Choose an item** | **INF** |
| Does any other product incorporate or is processed with animal derivatives? | **Choose an item** | **INF** |
| If **YES**, are there control measures to avoid contamination of the product by animal derivatives? | **Choose an item** |  |

###### **TRANSPORT AND CONSERVATION**

|  |  |  |
| --- | --- | --- |
| Does the material have mechanisms to prevent tampering, such as a security seal or anti-tamper seal? | Choose an item | R |
| Specify below special conservation precautions in place (for example: nitrogen atmosphere, use of desiccant, others.) or mark “Not applicable”.Click here to enter text. | [ ]  Not applicable | **INF** |
| Are there specific temperature and humidity requirements for handling, transport and storage applicable e product? | Choose an item | INF |
| If **YES**, specify below:Click here to enter text. |  |  |
| Is the product delivered in pallets? | **Choose an item** | N |
| If **YES**, does your company use chemically treated pallets? | **Choose an item** |  |
| Are there action plans to ensure the continuity of supply in the event of incidents involving the location or resources used to manufacture the product? | **Choose an item** | R |

###### **REGULATORY INFORMATION**

|  |  |  |
| --- | --- | --- |
| Would FARMANGUINHOS personnel be allowed to audit and examine facilities and documents related to the product? | **Choose an item** | **R** |
| Has your company facilities ever been audited by your local Health Authority? | **Choose an item** | **INF** |
| If **YES**, inform date and outcome of the last audit below.Click here to enter text. |  |
| Has your company facilities ever been audited by Brazilian Healthy Authority (ANVISA)? | Choose an item | **INF** |
| If **YES**, inform date and outcome of the last audit below.Click here to enter text. |  |
| Has your company facilities ever been audited by other foreign health authority? |  **Choose an item** | **INF** |
| If **YES**, inform date and outcome of the last audit below.Click here to enter text. |  |  |
| Has your company awarded any nationally or internationally recognized quality standard certification (for example, ISO 9001, 14001, OHSAS 18001, etc.)?If **YES**, please send a copy of the certificate. | Choose an item | **INF** |

###### **DOCUMENTATION AND GOOD PRACTICES**

|  |  |  |
| --- | --- | --- |
| Are the batch records and specifications prepared, reviewed, approved, updated and distributed according to written procedures? | Choose an item | **I** |
| Are the records of all manufacturing and quality control operations reliable and recorded at the time the activities are carried out? | Choose an item | **I** |
| How long are analytical and production records maintained? | Click here to enter text. | **INF** |
| Does quality area review the manufacturing and quality control records for each batch before it is released? | **Choose an item** | **I** |
| Do people with this responsibility have the appropriate qualifications and experience? | **Choose an item** |  |
| Indicate below the documents related to the product that can be made available to Farmanguinhos:[ ]  Instructions for using[ ]  Material safety data sheet (MSDS)[ ]  Certificate of analysis (CoA)[ ]  Certificate of conformity (CoC)[ ]  Material data sheet[ ]  OthersPlease provide copies of them as examples. | **INF** |
| Indicate compendia references for the product, if applicable:[ ]  Farmacopeia Brasileira[ ]  USP (United States Pharmacopoeia)[ ]  EP (European Pharmacopoeia)[ ]  BP (British Pharmacopoeia)[ ]  JP (Japanese Pharmacopoeia)[ ]  Others[ ]  Not applicable. | **INF** |
| Is there a Drug Master File (DMF) or Suitability Certificate for the product? If **YES**, send a copy of the document. | Choose an item | **INF** |
| Does the material contain plastic components?If **YES**, provide the documentation that indicates the polymer material grade used (For example: Technical, Food, USP <88> Class VI, etc.). | Choose an item | **R** |
| Does the product comply with the TSE note for the EMEA/410/01?Provide a conformity statement. | Choose an item | **R** |
|  Does the product comply with German Guidance "Aflatoxin Verbots V dated 19.07.00"?Provide a conformity statement. | Choose an item | **R** |
| Does the product comply with FDA Guidance for Industry “Pharmaceutical Components at Risk for Melamine”?Provide a conformity statement. | Choose an item | **R** |
| Does the material comply with European Directive 2006/142/EC (Allergens-declaration of intolerance agents), including natural rubber latex?Provide a conformity statement. | Choose an item | **R** |
| Does the material comply with Q5 Viral Safety (Product derived from Cells Lines of Human or Animal origin)?Provide a conformity statement. | Choose an item | **R** |
| Does the material comply with the Regulations of Genetically Modified Organisms, for example, 1829/2003/EC and 1830/2003/EC?Provide a conformity statement. | Choose an item | **R** |
| Does the product contain genotoxic impurities or impurities which are suspected of being genotoxic? According to CPMP/SWP/5199/02 or alternatively EMEA/CHMP/QWP/251344/2006).Provide a conformity statement. | Choose an item | **R** |
| Does the product comply with ICH Q3C Guideline (Residual Solvents)?Provide a conformity statement. | Choose an item | **N** |
| 1 - Is the product manufactured (including all manufacturing steps) with the use of Class 1 Solvents? | Choose an item |
| 2 - Is the product manufactured (including all manufacturing steps) with the use of Class 2 Solvents? | Choose an item |
| 3 - Is the product manufactured (including all manufacturing steps) with the use of Class 3 Solvents? | Choose an item |
| 4 - Are the concentrations of these solvents controlled during the process and verified in the final product according to ICH Q3C Guideline (Residual Solvents)? | Choose an item |
| Is the product subjected to any irradiation or sterilization process? | Choose an item | **INF** |
| Specify or mark “Not applicable”.[ ]  Decontamination with steam[ ]  Ethylene oxide[ ]  Gama rays[ ]  Others[ ]  Not applicable. |  |  |
| Is this process validated and is its effectiveness checked as part of the batch release? | Choose an item |  |
| Inform about (if applicable):- Status Kosher / Halal- Bioburden / pyrogens | [ ]  Not applicable.Click here to enter text. | **INF** |

###### **MANUFACTURING PROCESS INFORMATION**

|  |  |
| --- | --- |
| Mark the options below that better defines the manufacturing process of the supplied products: | **INF** |
| [ ]  Synthetic |
| [ ]  Semi-synthetic |
| [ ]  Vegetable |
| [ ]  Animal (for example: tissue, tissue, tissue or fluid extract such as milk, whey, blood).[ ]  FermentationIf different processes are used for the supplied products, describe below:Click here to enter text. |
| What is the size of a homogenous production batch of the material (mass, volume or number of units per batch)? | Click here to enter text. | **INF** |
| What is the processing time required to manufacture one batch of the product? | Click here to enter text. | **INF** |
| Is there a batch numbering system in place? | Choose an item | **I** |
| Does each production batch have a unique and traceable number? | Choose an item | **I** |
| Is a batch record issued for each batch manufactured? | Choose an item | **I** |
| What is the shelf life and / or recommended re-evaluation interval of the product? | Click here to enter text. | **INF** |
| Does your company have any data / rational supporting this period? | Choose an item | **R** |
| Describe the types of containers used for the product (fiber drums, inner linings, rolls, tamper evidence devices, etc.).Click here to enter text.[ ]  Not applicable | **INF** |
| Are the monotoring of critical points and in process control during the manufacture of the product carried out and documented? | Choose an item | **I** |
| During the production processes, are the containers used identified by labels containing information such as: batch number, name of the product, cleaning status, among others? | Choose an item | **N** |
| Are only starting materials (including water, if applicable) approved by quality control used in the manufacture of the material (s)? | Choose an item | **I** |
| Are there cleaning procedures that take into account each process, area, equipment and its componentes in place? | Choose an item | **N** |
| Are there acceptance requirements for cleaning areas and equipment? | Choose an item | **N** |
| Are the logbooks of rooms and equipment available? | Choose an item | **R** |
| Is there microbiological monitoring of the equipment surface? | Choose an item | **N** |
| Is the synthesis route / way of obtaining the product duly defined? | Choose an item | **I** |
| Is the stereochemical behavior of the molecules of the synthesis route known? | Choose an item |  |
| Can the synthesis process generate isomers with adverse pharmacological effects? | Choose an item |  |
| If **YES**, is there a validated analytical methodology to ensure that the quantities of these isomers are within acceptable limits? | Choose an item |

###### **ORGANIZATION / QUALITY SYSTEMS**

|  |  |  |
| --- | --- | --- |
| Does the company quality system use a risk management approach taking into account compliance with good practices? | Choose an item | **I** |
| Is there a Site Master File in place? | Choose an item | **R** |
| If **YES**, can your company provide a copy to Farmanguinhos?If **NO**, please provide a copy of your organization chart indicating key personnel including their job descriptions. | Choose an item |  |
| Are quality and production areas independent of each other? | Choose an item | **I** |
| Is there a traning program in place? | Choose an item | **N** |
| Does this program include new and third-party employees? | Choose an item |
| Does this program include initial and refreshing training on good manufacturing practices? | Choose an item |
| Are records of dates, times, subject of training available? | Choose an item |
| Does your company have a formal continuous improvement program in place? | Choose an item | **R** |
| Does your company have a document that describes its quality systems, e.g. Quality Manual? | Choose an item | **R** |
| Is there an internal auditing program (self-inspection)? | Choose an item | **I** |
| Are there internal programs for calibration and maintenance for all equipment that require them, including laboratory equipment in place? | Choose an item | **I** |
| Are the manufacturing and the cleaning processes validated?  | Choose an item | **N** |
| Are the computerized systems with impact in the product quality validated? | Choose an item |
| Is there a validation master plan? | Choose an item |
| If **YES**, inform the identification and version below:Click here to enter text. |  |
| Are non-conformities and deviations properly investigated, documented and filed according to the current procedure? | Choose an item | **I** |
| Is there a change control procedure in place? | Choose an item | **I** |
| Are customers informed about changes in product manufacturing processes? | Choose an item | **I** |
| Are customers informed about changes in product manufacturing site? | Choose an item | **I** |
| Are customers informed about changes in product specifications? | Choose an item | **I** |
| Does your company carry out an Annual Product Review or does it have any other mechanism to monitor its consistency and quality trends? | Choose an item | **I** |
| Do these reviews consider all batches manufactured in a period? | Choose an item |
| Are there mechanisms to prevent non-compliant product from being mixed with compliant material to achieve specifications? | Choose an item | **R** |
| May batches of product that have been returned from the market be released for sale again? | Choose an item | **N** |
| If **YES**, do these batches undergo a new analysis before being released for sale? | Choose an item |  |
| Is there a process for segregating and controlling materials when it is approved, quarantined and rejected? | Choose an item | **I** |
| Does your company have procedures in place for the following processes: | **N** |
| Procedure index? | Choose an item |
| Change control? | Choose an item |
| Complaints handling? | Choose an item |
| Gowning in different zones? | Choose an item |
| Deviation / out of specification results handling? | Choose an item |
| Batch numbering? | Choose an item |
| Specification / Testing? | Choose an item |
| Corrective / preventive Maintenance?? | Choose an item |
| Rework / reprocessing of materials returned from the market? | Choose an item |
| Approval of New Supplier / Material? | Choose an item |
| Pest control? | Choose an item |
| Incoming control of raw materials? | Choose an item |
| Environmental and safety policies? | Choose an item |
| Waste disposal? | Choose an item |
| Installation Qualification / Operation Qualification / Performance Qualification for Equipmen? | Choose an item |
| Separation and weighing of starting materials? | Choose an item |
| Training program? | Choose an item |
| Quality self-inspections? | Choose an item |
| Equipment cleaning? | Choose an item |
| **IMPORTANT:** Provide a list containing identification and description of the procedures marked with **YES** above**.** |

###### **FACILITIES AND EQUIPMENT**

|  |  |  |
| --- | --- | --- |
| Is there an access control procedure in place? | Choose an item | N |
| Are processes and material flows among the manufacturing steps adequate to avoid cross contamination? | Choose an item | I |
| Is there a zoning concept in place at your facilities? | Choose an item | R |
| Are there resting and eating areas separate from other areas? | Choose an item | N |
| Do the toilets not have direct communication with the production and storage areas and are they cleaned and sanitized regularly? | Choose an item | N |
| Do the storage areas have the capacity to allow an ordered warehousing of the materials, keeping them away from floors and walls, according to their modes of conservation and status of approval (under quarantine conditions, approved, disapproved, returned and recalled)? | Choose an item | R |
| Does your company manufacture / handle products of high activity or toxicity such as beta-lactams, other antibiotics, cytotoxins, hormones or pesticides on this site? | Choose an item | R |
| If **YES**, specify below:Click here to enter text. |  |
| Are the equipment and facilities used in the processes of these materials dedicated to their manufacture? | Choose an item |
| Are the facilities, utilities and equipment appropriate to the processes, designed and built to minimize contamination risks? | Choose an item | N |
| Are the facilities, utilities and equipment qualified? | Choose an item | N |
| Do the facilities and equipment allow cleaning, corrective and preventive maintenance without risk to the manufacturing processes? | Choose an item | R |
| Is the quality control laboratory separate from the production areas? | Choose an item | R |

###### **TESTING AND QUALITY INSPECTION**

|  |  |  |
| --- | --- | --- |
| Are there specifications, acceptance criteria and validated analytical methodologies for raw materials, intermediate products, finished products and other materials used in manufacturing operations? | Choose an item | I |
| Is the quality of the water used in production and cleaning steps monitored and suitable for the intended use? | Choose an item | N |
| Does your company provide a Certificate of Analysis (CoA) for all deliveries of the product? | Choose an item | I |
| Does your company test all raw materials on its own? | Choose an item | R |
| For tests not performed on its own, is a third party laboratory contracted? | Choose an item |  |
| Are the raw data from tests performed internally or by third parties kept in the analytical records? | Choose an item |  |
| Identification tests are performed on every volume of raw material received? | Choose an item | I |
| Is there a representative sampling plan in place? | Choose an item | I |
| Are retention samples of the product collected and maintained for at least one year after the batch expires? | Choose an item | I |
| Are all tests on finished product specifications performed for each batch (including microbiology, where applicable)? | Choose an item | R |
| If **NO**, inform below the tests that may be omitted and the reason:Click here to enter text. |
| Are out-of-specification results (OOS) investigated and documented by the quality control laboratory? | Choose an item | I |

###### **SUPPLY CHAIN**

|  |  |  |
| --- | --- | --- |
| Are receipt, identification and storage of raw materials and packaging materials defined in procedures? | Choose an item | I |
| Does different batch of the same material received in an unique delivery, receive a different internal batch number each? | Choose an item | I |
| If the same batch from the manufacturer is received in more than one different delivery, are generated different internal batch numbers for each delivery? | Choose an item | R |
| Is there a supplier qualification program managed by the quality area? | Choose an item | N |
| Are the companies in charge of transportation included in the supplier qualification program? | Choose an item | N |
| Is there a list of approved suppliers? | Choose an item | N |
| Is it possible to track the raw materials, and their respective suppliers, used in the manufacture of a batch of a product? | Choose an item | N |
| Are there records of all shipments of products to your customers, including the batch number and quantity? | Choose an item | I |

###### **RESPONSIBLE FOR ANSWERING THE QUESTIONNAIRE**

|  |  |
| --- | --- |
| Name: | Click here to enter text. |
| Job title: | Click here to enter text. |
| Date: | Click here to enter text. |
| Telephone: | Click here to enter text. |
| E-mail: | Click here to enter text. |

###### **ANSWERS EVALUATION**

###### **(Fields to be filled in by Farmanguinhos after receiving the completed questionnaire)**

|  |  |
| --- | --- |
| Obtained IQF: |  |
| Responsible for the evaluation: |  |
| Signature: |  |
| Date: |  |