**Self-Evaluation Questionnaire to Packaging 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 site, 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**

|  |  |  |
| --- | --- | --- |
| 1. 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** |
| 2. 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** |
| 3. Manufacturing | **Choose an item** |
| 4. Laminating | **Choose an item** |
| 5. Layer application (in example: primers or thermo-sealant resin application, multi-layer films application, and others) | **Choose an item** |
| 6. If so, describe which layers are applied on the material:  |  |
| Click here to enter text. | **Choose an item** |
| 7. Cutting | **Choose an item** |
| 8. Print | **Choose an item** |
| 9. Hygienization (Example: washing, blowing, among others) | **Choose an item** |
| 10. Packaging | **Choose an item** |
| 11. Quality control analysis | **Choose an item** |
| 12. Product release | **Choose an item** |
| 13. Warehousing | **Choose an item** |
| 14. 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.  |  |
| 15. 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 |
| 16. What are the applications of the materials manufactured in this site? | [ ]  Pharmaceutical[ ]  Food[ ]  Cosmetic[ ]  Others | **INF** |
| 17. Are the equipment used in the manufacture of the material exclusive / dedicated? | **Choose an item** | R |

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

|  |  |
| --- | --- |
| 18. Describe the starting materials used in manufacture of each supplied product:Click here to enter text.  | **INF** |
| 19. 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 |

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

|  |  |  |
| --- | --- | --- |
| 20. 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** |
| 21. 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. |  |  |
| 22. Is the product delivered in pallets? | **Choose an item** | **N** |
| 23. If **YES**, does your company use chemically treated pallets? | **Choose an item** |  |
| 24. 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**

|  |  |  |
| --- | --- | --- |
| 25. Would FARMANGUINHOS personnel be allowed to audit and examine facilities and documents related to the product? | **Choose an item** | **R** |
| 26. 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.  |  |
| 27. 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** |
| 28. Have the company facilities audited by any other pharmaceutical industry client? | Choose an item | **INF** |

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

|  |  |  |
| --- | --- | --- |
| 29. Are the batch records and specifications prepared, reviewed, approved, updated and distributed according to written procedures? | Choose an item | **I** |
| 30. 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** |
| 31. How long are analytical and production records maintained? | Click here to enter text. | **INF** |
| 32. Does quality area review the manufacturing and quality control records for each batch before it is released? | **Choose an item** | **I** |
| 33. Do people with this responsibility have the appropriate qualifications and experience? | **Choose an item** |  |
| 34. 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[ ]  Others | **INF** |
| 35. 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** |
| 36. 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. |  |  |
| 37. Is this process validated and is its effectiveness checked as part of the batch release? | Choose an item |  |
| 38. Inform about (if applicable):- Status Kosher / Halal- Bioburden / pyrogens | [ ]  Not applicable.Click here to enter text.  | **INF** |

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

|  |  |  |
| --- | --- | --- |
| 39. 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** |
| 40. What is the processing time required to manufacture one batch of the product? | Click here to enter text. | **INF** |
| 41. Is there a batch numbering system in place? | Choose an item | **I** |
| 42. Does each production batch have a unique and traceable number? | Choose an item | **I** |
| 43. Is a batch record issued for each batch manufactured? | Choose an item | **I** |
| 44. What is the shelf life and / or recommended re-evaluation interval of the product? | Click here to enter text. | **INF** |
| 45. Does your company have any data / rational supporting this period? | Choose an item | **R** |
| 46. Are the monitoring of critical points and in process control during the manufacture of the product carried out and documented? | Choose an item | **I** |
| 47. 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** |
| 48. Are only starting materials (including water, if applicable) approved by quality control used in the manufacture of the material (s)? | Choose an item | **I** |
| 49. Are there cleaning procedures that consider if each process, area, equipment and its components are in place? | Choose an item | **N** |
| 50. Are there acceptance requirements for cleaning areas and equipment? | Choose an item | **N** |
| 51. Are the logbooks of rooms and equipment available? | Choose an item | **N** |
| 52. Are there a system and control for color scheme (color palette) for the products?  | Choose an item | **I** |
| 53. Is there a system for mold maintainance and control, if applicable to the production lines? | Choose an item | **N** |
| 54. Is there a procedure for refurbished material control and incorporation to the process?  | Choose an item | **I** |
| 55. If it is necessary to input any additional quantity of raw material in the ongoing process, are they reported in the batch manufacturing records? | Choose an item | **I** |
| 56. Is there impurities/contamination/dirt control for the product inner and surface? | Choose an item | **I** |

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

|  |  |  |
| --- | --- | --- |
| 57. Does the company have a quality system in place? | **Selecione um item** | **I** |
| 58. Does the company quality system have a risk management? | **Selecione um item** | **I** |
| 59. Does the company quality system use a risk management approach taking into account compliance with good practices? | Choose an item |  |
| 60. Are quality and production areas independent of each other? | Choose an item | **I** |
| 61. Is there a training program in place? | Choose an item | **I** |
| 62. Does this program include new and third-party employees? | Choose an item |
| 63. Does this program include initial and refreshing training on good manufacturing practices? | Choose an item |
| 64. Are records of dates, times, subject of training available? | Choose an item |
| 65. Does your company have a formal continuous improvement program in place? | Choose an item | **R** |
| 66. Does your company have a document that describes its quality systems, e.g. Quality Manual? | Choose an item | **R** |
| 67. Is there an internal auditing program (self-inspection)? | Choose an item | **I** |
| 68. Are there internal programs for calibration and maintenance for all equipment that require them, including laboratory equipment in place? | Choose an item | **I** |
| 69. Are non-conformities and deviations properly investigated, documented and filed according to the current procedure? | Choose an item | **I** |
| 70. Is there a change control procedure in place? | Choose an item | **I** |
| 71. Are customers informed about changes in product manufacturing processes? | Choose an item | **I** |
| 72. Are customers informed about changes in product manufacturing site? | Choose an item | **I** |
| 73. Are customers informed about changes in product specifications? | Choose an item | **I** |
| 74. Is Quality Assurance responsible for batches documentation review? | Choose an item | **I** |
| 75. Is Quality Assurance responsible for batch documentation archiving? | Choose an item | **N** |
| 76. Are batches released only after Quality Assurance review and approval? | Choose an item | **I** |
| 77. 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 | **R** |
| 78. Are there mechanisms to prevent non-compliant product from being mixed with compliant material to achieve specifications? | Choose an item | **I** |
| 79. May batches of product that have been returned from the market be released for sale again? | Choose an item | **N** |
| 80. If **YES**, do these batches undergo a new analysis before being released for sale? | Choose an item |  |
| 81. Is there a process for segregating and controlling materials when it is approved, quarantined, and rejected? | Choose an item | **I** |
| 82. Are there pest control program and procedures? | Choose an item | **I** |
| Does your company have procedures in place for the following processes: | **N** |
| 83. Change control? | Choose an item |
| 84. Complaints handling? | Choose an item |
| 85. Deviation / out of specification results handling? | Choose an item |
| 86. Batch numbering? | Choose an item |
| 87. Specification / Testing? | Choose an item |
| 88. Corrective / preventive Maintenance?? | Choose an item |
| 89. Development and Approval of New Supplier / Material? | Choose an item |
| 90. Incoming control of raw materials? | Choose an item |
| 91. Training program? | Choose an item |
| 92. Quality self-inspections? | Choose an item |
| 93. Equipment cleaning? | Choose an item |
| **IMPORTANT:** Provide a list containing identification and description of the procedures marked with **YES** above**.** |

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

|  |  |  |
| --- | --- | --- |
| 94. Is there an access control procedure in place? | Choose an item | **N** |
| 95. Are processes and material flows among the manufacturing steps adequate to avoid cross contamination? | Choose an item | **I** |
| 96. Are there resting and eating areas separate from other areas? | Choose an item | **N** |
| 97. Do toilets not have direct communication with the production and storage areas and are they cleaned and sanitized regularly? | Choose an item | **N** |
| 98. 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** |
| 99. Are the facilities, utilities and equipment appropriate to the processes, designed and built to minimize contamination risks? | Choose an item | **N** |
| 100. Do the facilities and equipment allow cleaning, corrective and preventive maintenance without risk to the manufacturing processes? | Choose an item | **R** |
| 101. Is the quality control laboratory separate from the production areas? | Choose an item | **R** |

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

|  |  |  |
| --- | --- | --- |
| 102. 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** |
| 103. Is the quality of the water used in production and cleaning steps monitored and suitable for the intended use? | Choose an item | **I** |
| 104. Does your company provide a Certificate of Analysis (CoA) for all deliveries of the product? | Choose an item | **I** |
| 105. Tests are performed on every incoming raw material? | Choose an item | **R** |
| 106. Os dados brutos de testes realizados internamente ou por terceiros são mantidos nos registros analíticos? | Selecione um item | **I** |
| 107. Is there a representative sampling plan in place? | Choose an item | **I** |
| 108. Are retention samples of the product collected and maintained for at least one year after the batch expires? | Choose an item | **R** |
| 109. 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. |
| 110. Are out-of-specification results (OOS) investigated and documented by the quality control laboratory? | Choose an item | **I** |

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

|  |  |  |
| --- | --- | --- |
| 111. Are receipt, identification and storage of raw materials and packaging materials defined in procedures? | Choose an item | **I** |
| 112. Is there a supplier qualification program managed by the quality area? | Choose an item | **N** |
| 113. Are the companies in charge of transportation included in the supplier qualification program? | Choose an item | **N** |
| 114. Is there a list of approved suppliers? | Choose an item | **I** |
| 115. 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 | **I** |
| 116. 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: |  |