# Female Condom Prequalification Document Review Check-List

**Product Name**:

**Manufacturer**:

**Application Number**:

**Review date**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Preparation** | | | | |
| **Document Checklist** | **Yes** | **No** | **Not Required** | **Comments** |
| Expression of interest |  |  |  |  |
| **Clinical Evidence** | | | | |
| Functionality study or contraceptive efficacy study |  |  |  |  |
| Information on participant selection and characteristics |  |  |  |  |
| Study protocol |  |  |  |  |
| Drop-out rate with reasons |  |  |  |  |
| Acceptability of the product |  |  |  |  |
| Rates of all failure modes |  |  |  |  |
| Statistical analysis of results |  |  |  |  |
| Ethics committee approval and composition |  |  |  |  |
| CV of principal investigator |  |  |  |  |
| If applying for waiver of functionality study, detailed material and design specifications and reasons for waiver |  |  |  |  |
| **Product Dossier** | | | | |
| **Document Checklist** | **Yes** | **No** | **Not Required** | **Comments** |
| Sketch of assembled product |  |  |  |  |
| Dimensional, labeled, drawings of each component, including length, widths at relevant points |  |  |  |  |
| Descriptions of surface textures and any colour, flavor, finishing powders, and lubricants used |  |  |  |  |
| Local, country& regional regulatory product approvals |  |  |  |  |
| List of countries where products have been registered, granted market authorization, application for marketing authorization is currently pending, marketing approvals that have been revoked within the last five years. |  |  |  |  |
| Raw materials, including lubricants |  |  |  |  |
| Contact information for all suppliers |  |  |  |  |
| Sites of manufacture |  |  |  |  |
| Risk management of product and risk assessment |  |  |  |  |
| Specifications for the finished products including data sheet |  |  |  |  |
| Statement FC meets the requirements of the ISO 25841 and/or WHO/UNFPA Specification or indication of differences |  |  |  |  |
| Verification that clinical assessment has been carried out |  |  |  |  |
| Verification that appropriate viral barrier studies have been completed |  |  |  |  |
| Summary reports of biocompatibility evaluations |  |  |  |  |
| If product made from NR latex, confirmation whether or not protein levels on finished products are periodically monitored and summary of data as appropriate |  |  |  |  |
| Confirmation whether or not bio burden levels on finished products are monitored |  |  |  |  |
| Stability data |  |  |  |  |
| Examples of labeling for individual packages, inner boxes, and exterior shipping cartons |  |  |  |  |
| Samples |  |  |  |  |
| **Site Master File** | | | | |
| **Document Checklist** | **Yes** | **No** | **Not Required** | **Comments** |
| Name and exact address of the site |  |  |  |  |
| Brief information about the corporate structure |  |  |  |  |
| Total manufacturing capacity of the site including: primary manufacturing capacity, electronic testing capacity, and packaging capacity |  |  |  |  |
| Length of time manufacturing female condoms and male condoms (if applicable) at site and at other sites |  |  |  |  |
| What other, if any, manufacturing activities take place at this site |  |  |  |  |
| Summary of type of condoms manufactured at this site |  |  |  |  |
| Manufacturing certifications |  |  |  |  |
| Has a support and monitoring mechanism been established to assist the employee? |  |  |  |  |
| Total number of persons employed in female condom manufacturing |  |  |  |  |
| Number employed divided into categories |  |  |  |  |
| Organization chart |  |  |  |  |
| Qualifications, experience and responsibilities of key personnel |  |  |  |  |
| Summary of policy and procedure for health requirements for personnel engaged in productions |  |  |  |  |
| Confirmation that there is a written health and safety policy |  |  |  |  |
| Information on the use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis |  |  |  |  |
| Simple plan or description of manufacturing areas |  |  |  |  |
| Nature of construction of the building |  |  |  |  |
| Brief description of ventilation systems, including steps taken to prevent product contamination and excessive exposure of staff to ammonia and dust |  |  |  |  |
| Brief description of the areas for handling compounding ingredients (if appropriate) |  |  |  |  |
| Description of procedures and arrangements for storing quarantined materials, work in progress, and finished products |  |  |  |  |
| Description of water systems, including sanitation and effluent treatment, schematic drawing of systems are desirable |  |  |  |  |
| Summary of planned preventive maintenance programmes for manufacturing and testing equipment |  |  |  |  |
| Qualification and calibration arrangements, including the recording system, for computerized systems, validation, and external calibration laboratory accreditation for those laboratories providing traceable calibrations |  |  |  |  |
| Availability of written specification and procedures for cleaning manufacturing areas and equipment |  |  |  |  |
| Brief summary of procedures for monitoring and controlling microbiological contamination in production areas and of the product and procedures for controlling the purity of the air and water |  |  |  |  |
| Arrangements for the preparation, revision and distribution of all necessary management system documentation |  |  |  |  |
| Arrangements for safe storage, access and retrieval of records |  |  |  |  |
| A brief description of production operations |  |  |  |  |
| Overview of the manufacturing process |  |  |  |  |
| Summary of procedures for the handling of starting materials, work in progress, packaging materials and finished products, including product release and storage. |  |  |  |  |
| A brief description of the general policy for process validation and a summary of the validation plan |  |  |  |  |
| Provide a summary of the risk management assessment undertaken in accordance with ISO 14971 of the manufacturing process |  |  |  |  |
| Brief details of the quality control system and of the activities of the quality control department |  |  |  |  |
| Brief details of the sampling and testing requirements for any bought-in components |  |  |  |  |
| Brief details of the sampling and testing procedures for in process testing and final product release, including pass/fail criteria |  |  |  |  |
| Brief description of the procedures and arrangements for Lot traceability |  |  |  |  |
| Brief description of the arrangements for managing and recording complaints and product recalls |  |  |  |  |
| Short description of the self-inspection system |  |  |  |  |
| Brief description of procedures and arrangements for identifying the need for and implementation of corrective and preventive actions |  |  |  |  |
| Brief description of procedures used to control design and development |  |  |  |  |

**Concluding remarks**: