1. **OBJECTIVE**

To lay down a procedure for Room number and Equipment/ Instrument and Subcomponent Numbering System.

1. **SCOPE**

This procedure is applicable to all related user departments of ZUMA PHARMA LLC.

1. **RESPONSIBILITY**
	1. Engineering department shall be responsible to identify and affix the room numbers, equipment/ instrument and subcomponent numbers according to respective records.
	2. QA department shall be responsible for allotment of Room number, Equipment/ Instrument and label of subcomponent number and maintaining its record.
2. **ACCOUNTABILITY**

Head of department shall be accountable for the compliance of SOP.

1. **DEFINITIONS**

NA

1. **PROCEDURE**
	1. **Room Numbering system:**
		1. Engineering department shall identify the room which is to be numbered and request (Refer format No. SOP/QA/058-F03) to be send to QA to allot number.
		2. QA department shall allot specific room number to each room in the plant as per layout.
		3. The room number shall be written in alphanumeric type, consisting of 8 characters, which are as follows:

|  |  |  |
| --- | --- | --- |
| **XXX** |  | **ZZZ** |

3 Numerical digit room number

 Two or three letter for facility code (Refer Table 1)

 **Table 1**

| **S. No.** | **Facility** | **Code** |
| --- | --- | --- |
| 1. | Pre-filled syringes line | PFS |
| 2. | Vial line (solutions and lyophilized products in vial)  | LYO |
| 3. | Warehouse | WH |
| 4. | Admin Block | GEN |
| 5. | Quality Control (Analytical laboratory) | AL |
| 6. | Quality Control (Microbiological laboratory) | ML |
| 7. | Engineering / Utility block’s | UT |
| 8. | Guest Houses | GH |

**For Example:**

AL001 indicates room number 001 on first room of analytical laboratory of Quality Department.

PFS001 indicates room number 001 on first room of pre-filled syringes line of production.

* + 1. In case of some modifications in any room, due to which a single room is divided into 2 or more rooms, the room numbers can be differentiated by adding a suffix A, B, C…and so on to the original room number.
		2. Record shall be maintained as per **Annexure number SOP/QA/058-F04** - “Room Identification Number Record”.
		3. Manager or designee of QA Department shall duly approve the prepared Room Identification list.
		4. Respective department shall update the room numbering list as per **Annexure number. SOP/QA/058-F08 -** “Room Numbering List” when new room incorporated/removed/merged and changes will be done as per change control procedure.
		5. For numbering / ID of new room respective department shall give the request to QA Department as per **SOP/QA/058-F03 –** “Room number/ ID Request Form”.
		6. Engineering department shall affix & maintain the identification number label.
	1. **Equipment/ Instrument Identification Numbering System:**

**6.2.1** User department shall send request (Refer format No. SOP/QA/058-F01) to QA to allot specific Equipment/ Instrument Identification Number.

* + 1. QA department shall allot specific Equipment/ Instrument Identification Number.
		2. For making similarity in Equipment/ Instrument ID following procedure shall be followed.
		3. The equipment identification number shall be written in alphanumeric type, consisting of 9 characters, which are as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XX** | **/** | **YYY** | **-** | **ZZ** |

2-digit Numerical Equipment/ Instrument sequential number

Hyphen

 3-digit alphabetic equipment code

Slash

 Department code (Refer SOP/QA/001)

**For Example:**

AL/SHS-01 (Steam Heat Sterilizer in Quality Control) or AL/INC-01 (Incubator in Quality Control).

* + 1. Before preparing URS for new Equipment/ Instrument, User Department shall intimate QA department for allotting a new number as **SOP/QA/058-F01** - “Equipment Registration form”.
		2. QA department shall allot specific Equipment/ Instrument ID for each of the equipment/ Instrument.
		3. Record shall be maintained as per **Annexure number. SOP/QA/058-F05** - “Equipment/ Instrument Identification Number Record”.
		4. Manager or designee of QA Department shall duly approve the prepared Equipment/ Instrument Identification list.
		5. Engineering department shall affix & maintain the identification number tag.
		6. The identification number allotted once shall not be repeated.
		7. If any Equipment/ Instrument is replaced by new one then new identification number shall be given as per change control procedure and allocate new ID.
		8. Respective department shall update the equipment numbering list as per **Annexure number SOP/QA/058-F07** - Equipment/ Instrument Numbering List” as and when new equipment installed in department.
		9. Equipment identification number shall void if equipment is scrapped.
		10. QA department shall maintain the master copy of the same and the copy of the same shall be given

to respective department.

* 1. **Equipment Sub-Component Numbering System:**
		1. The identification number of sub-components installed on the equipment/instrument, consists of 9 alphanumeric characters given as follows:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **XX** | **/** | **YYY** | **-** | **ZZ** | **/** | **AA** | **-** | **BB** |

Equipment/ Instrument sub-component number starting from 01.

 Hyphen

 2-digit alphabet code of concerned Equipment/ Instrument sub-component (as per Table 2, but not limited to).

Slash

2-digit Numerical Equipment/ Instrument sequential number

Hyphen

3-digit alphabetic equipment code

Slash

Department code (Refer SOP/QA/001)

* + 1. **For example:** As Steam Heat Sterilizer is the first equipment in Quality Control department and the first component is Pressure Gauge in compressed air line, so the sub-component number shall be allocated as AL/SHS-01/PG-01.
		2. For abbreviations of Equipment/ Instruments Sub-components refer **Annexure Number SOP/QA/058-A06.**
		3. All other sub-components of a particular equipment/instrument shall bear different codes. For example, if Steam Heat Sterilizer of Quality Control Department. - Microbiology Section has 3 temperature sensor and 2 pressure gauges; they shall be numbered as AL/SHS-01/TS-01,

AL/SHS-01/TS-02, AL/SHS-01/TS-03 and AL/SHS-01/PG-01, AL/SHS-01/PG-02.

* + 1. On receipt of new component or replacement of old component with new one, User Department shall intimate QA department for allotting a new number as per **SOP/QA/058-F02** - “Sub-Component Registration form”.
		2. In case of AHU Components/Instruments numbering shall be done as mentioned below:
		3. **For example:** In HVAC system there are 17 AHU’s. So, for first AHU its first component is Temperature Gauge in hot water line, so the sub-component number shall be allocated as AHU-01/TG01.
		4. As soon as the Equipment/ Instrument is received in the respective department, the respective department shall inform QA department for allocation of its ID.
		5. QA department shall provide the Equipment/ Instrument ID to user department and shall intimate Engineering department to prepare a list of all the sub-components available in the Equipment/ Instrument.
		6. Engineering department shall prepare the list and allot the sub-component ID.
		7. Engineering department shall maintain the record as per **Annexure number SOP/QA/058-F06** “Equipment/ Instrument Sub-Component Identification Record”.
		8. Engineering Head or Designee shall review the sub-component list after allocating the code and final approval of the list shall be done by QA Head/ Designee.
		9. The respective numbering lists shall be revised shall be revised by engineering department at every six month or as when required.
1. **ABBREVIATIONS:**

|  |  |
| --- | --- |
| SHS | Steam Heat Sterilizer |
| HVAC | Heating Ventilation and Air Conditioning System |
| QA | Quality Assurance |
| ID | Identification |
| AHU | Air Handling Unit |
| NA | Not Applicable |
| PG | Pressure Gauge |
| TS | Temperature Sensor |

1. **REFERENCES**
	1. Preparation, Review, Approval, Control & Revision of Standard Operating Procedure. (SOP/QA/001)
	2. 21 CFR 211.105: Equipment Identifications
2. **DISTRIBUTION LIST**

SOP shall be distributed to Quality Assurance, Production, Quality Control, warehouse, Engineering and IT department as per user request.

1. **ANNEXURES**
	1. Equipment Registration Form : SOP/QA/058-F01
	2. Sub-Component Registration Form : SOP/QA/058-F02
	3. Room Number/ ID Request Form : SOP/QA/058-F03
	4. Room Identification Number Record : SOP/QA/058-F04
	5. Equipment/ Instrument Identification Number Record : SOP/QA/058-F05
	6. Equipment/ Instrument Sub-Component Identification Record : SOP/QA/058-F06
	7. Equipment/Instrument Numbering list : SOP/QA/058-F07
	8. Room Numbering list : SOP/QA/058-F08
	9. Equipment Sub-components/ Instruments Abbreviations : SOP/QA/058-A01
2. **REVISION HISTORY DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision** | **Reason for Revision** | **CCF. No.** | **Effective Date** |
| 00 | First issue |  |  |
|  |  |  |  |

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