QUALITY RISK ASSESSMENT & MITIGATION PLAN	
FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF CHANGE ROOMS & PRESSURE GAUGES INSTALLED IN SECONDARY CHANGE ROOM OF INJECTABLE	
Reference Document No.:	**Risk Assessment No.:**

QUALITY RISK ASSESSMENT & MITIGATION PLAN

(FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF CHANGE ROOMS& PRESSURE GAUGES INSTALLED IN SECONDARY CHANGE ROOM OF INJECTABLE)

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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1. **OBJECTIVE:** To provide the documented evidence that there is low level of risk of not having interlocking in Change rooms & Pressure Gauges in Secondary Change room of Injectable.

2. **SCOPE:** The scope of this document is limited to Interlocking & Pressure Gauges of all areas of Injectable sections at facility.

3. **RESPONSIBILITY:**

Department	Responsibility
Quality Assurance	• Preparation, Review, and Compilation of FMEA • Post Approval of FMEA
Production	• Review of FMEA
Engineering	• Review of FMEA

4. **REASON FOR RISK ANALYSIS:**

To mitigate & monitor the risk associated with the absence of inter locking in primary airlocks &pressure gauges in secondary airlock.

5. **SITE OF STUDY:**

6. **RISK COMMUNICATION & TRAINING:**

- The Risk analysis team shall be authorized by the Head-QA or his/her designee.
- Quality Risk Management Team shall be cross functional team comprised of expert from different areas.
- Training shall be imparted to the concerned team.

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7. RISK IDENTIFICATION, EVALUATION & MITIGATION:

In its simplest form, an interlocking system is composed of two doors electronically connected so that One cannot open until the other has closed. This will helps in prevention of contamination of the adjacent areas.

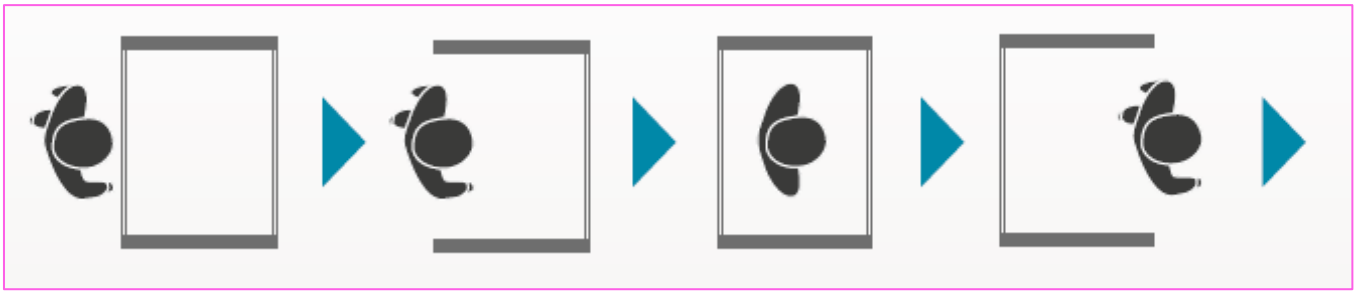

Figure 1: Entry procedure with interlocking

Figure 2: In case of door opening, shows Red indicator

Figure 3: Green indicator (Encircled), in case of door closed (Encircled) completely

As the person enter the first door, it must be closes behind you before the second door opens and allows the person to pass through. For controlling this, 02 push buttons are available (2 & 3 numbers encircled), So that when one door opens, Second door cannot be opened, it can be opened only in case of emergency button (02) is pressed.

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Figure 4: Entry to Change Room 1

Figure 5: Entry to Change Room 2

Figure 6: Entry to Packing Corridor

Figure 7: Entry to Secondary Change Room

Figure 8: Entry to Manufacturing Corridor

Interlocks installed in all Change Room (Entry Change Room 01, Entry Change Room 02, Entry to Packing Corridor, Entry to Secondary Change Room & Entry to Manufacturing Corridor)while pressure gauges installed in secondary change room which directly opens in Grade D manufacturing corridor. Interlocks helps in preventing contamination from adjacent CNC areas. On the other hand, Pressure gauges installed in Secondary change room shows that enough pressure differential is achieved to avoid any cross contamination during entry exit procedure.

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Figure 9: CNC area Slippers removed over cross over bench

Figure 10: Class D Slippers used for entry in manufacturing corridor

To avoid any cross contamination two type of slippers are used, Green slippers (Figure 9) are removed while entering the secondary change room& White slippers (Figure 10) are used for entering the Class D corridor area.

Cascade Pressure Differential is maintained, Manufacturing Corridor is having high pressure in comparison to Secondary Change Room & Secondary Change Room is having high pressure in comparison to CNC corridor. Figure 11 shows that the entry door (from wide passage corridor) opens towards high pressure (towards manufacturing corridor) & entry door (from Secondary Change room to manufacturing corridor).

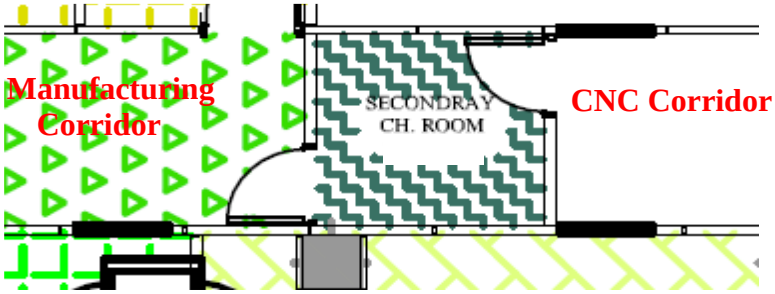

Figure 11: High Pressure of Manufacturing Corridor in comparison to Secondary change room & high pressure of Secondary Change room in comparison to CNC corridor helps in avoiding cross contamination of adjacent areas.

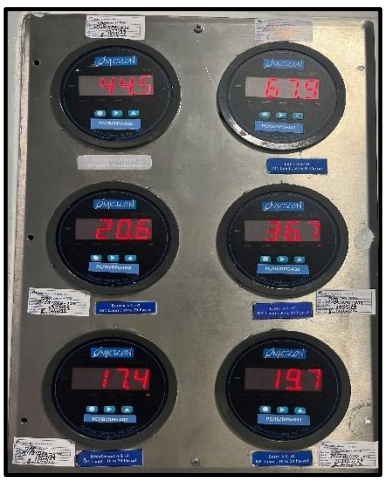

Figure 12: Adjacent areas having Pressure Differential within limit

Figure 13: Biometric system for core areas

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FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF PRIMARY CHANGE ROOM & PRESSURE GAUGES INSTALLED IN SECONDARY CHANGE ROOMS (AMPOULE SECTION)

Reference Document No.:	**Risk Assessment No.:**

Parameters	**Secondary Airlock**	**Manufacturing Corridor**	**Adjacent areas** (Entry A/L 01, Return A/L 02,Personal entry of Disinfectant preparation, Material A/L of Filtration, Personal entry of Manufacturing area, CIP/SIP entry, Personal entry of Garment washing, Ampoule Decartoning, Personal entry of Ampoule Washing & Depyrogenation & Airlock of Ampoule Hold room & Buffer Zone)	**Core Areas** (Ampoule filling, Unloading, Filtration, Disinfectant Filtration & Tool Room)
Pressure Differential	Cascade type airlock	Differential Pressure higher than adjacent areas	Differential Pressure lower than the inner Secondary airlocks & core areas	Core areas are having highest pressure
Classification	Grade D	Grade D	Grade D	Grade B (Product exposed under Hanging LAF)

RISK IDENTIFICATION	**RISK EVALUATION**	**RISK MITIGATION**
In case of absence or malfunction of interlocking in Secondary Change room: • There may be the chance of cross contamination during pressure differential failure. • Classified area may got disturbed. • Pressure Differential not maintained. • HEPA & Return risers got disturbed.	Malfunction or absence of interlocking does not have any direct impact on product quality.	• Door closures are available. • Cascade pressure differential is in place to control cross contamination. • One door is opened at a time. • Different slippers are used for entry in classified area. • Secondary gowning procedure to be done.
In case of absence of Pressure Gauge in Secondary Change room or failure of required pressure: • Cross Contamination may takes place from the adjacent CNC areas (Packing corridor). • Classification may got disturbed. • Core areas may got contaminated resulting into product failure.	Absence of Pressure gauges of Secondary Change room can indirectly contaminate the manufacturing corridor.	• Adjacent areas are having high pressure in comparison to manufacturing corridor. • All adjacent doors are interlocked. • Entry in core areas is through Biometric system.

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Reference Document No.:	**Risk Assessment No.:**

8. RISK ASSESSMENT TOOL:

In the following section a table is produced for the risk analysis using FMEA tool. The significance or Instruction for each column is described in the following paragraph.

Column 1	Serial number of Risk Analysis item.
Column 2	Item/Function: Identify the process step or component associated with the risk.
Column 3	Potential Failure Mode: Identify the type of risk associated with the process or component.
Column 4	Effect of Potential Failure/Cause: Verify that whether risk have GMP impact.
Column 5	Potential Cause
Column 6	Risk Mitigation as a Current Control: Write the risk mitigation strategy as considered in design.
Column 7	References
Column 8/9/10/11	Severity/Occurrence/Detection/Risk level/Risk Acceptance: Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.
Column 12	Recommended action: Recommended actions should be given for controlling failure occurrence.
Column13/14/15/16	Severity/Occurrence/Detection/Risk level/Risk Acceptance: After recommendation implementations, Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.

Table 1: Instruction for each column given above.

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Reference Document No.:	Risk Assessment No.:

QRA No.:……..

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation: Pressure Gauge &Interlocking in Change rooms	**Quality Risk Assessment Date:**

S.No.	Item/Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/Mechanism of failure	Current Control	Reference Document No.	S	O	D	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN (SxOxD)
1.	**Door Interlocking**	• Malfunction in interlocking • No Interlocking	• Cross-contamination • Door will remain open • Pressure differential not maintained • Chocking of HEPA & Riser filter • Air loss occur from Airlocks to adjacent area which leads to contamination. • Two Airlock door can open at a time which leads to disturb in differential pressure • Classified and Non classified area get disturbed • Microbial count increases • Non- Viable particle count increases	• Slight opening in door will decrease the pressure differential up to zero resulting into entry of contamination from CNC area. • Opened doors may result into contamination from CNC area which may choke the HEPA & Riser filters. • If interlocks are malfunctioned then two adjacent doors can opens at a time resulting into contamination and disturbance in pressure differential. • Packing corridor area is CNC while the adjacent Secondary airlock	• Cascade system is in place to avoid any cross contamination • Door closure are available, hence failure of interlocking does not have any impact on surrounding areas. • Doors automatically closed as doors opens towards high pressure. • Filters are qualified as per planner & risers are cleaned as per schedule. • Filters are cleaned as per schedule • Instructions are provided to follow GMP, means change room doors shall be opened once at a time.	• SOP of Contamination & Cross Contamination • Area Qualification. • Environment monitoring • Preventive maintenance • Building maintenance • Filter cleaning SOP	3	2	1	**6** **Severity** is high as failure of interlocking may result into area failure **Occurrence** is possible **Detectability** is high as failure can be easily detected.	Door interlocking to be done for Airlock I & II	2	2	1	4 Severity decrease to moderate after installation of interlocking in all airlocks

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Reference Document No.: | **Risk Assessment No.:**

S.No.	Item/Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/Mechanism of failure	Current Control	Reference Document No.	S	O	D	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN (SxOxD)
				is classified, hence malfunctioning in interlocking will disturb the area classification. • Leakage in doors will disturb the area ACPH, for compensating the loss AHU's will get overloaded. • As the Secondary airlock is adjacent to CNC area, so disturbance in pressure will disturb the Viable & Non- Viable count.	• Plates are exposed in classified area for environmental monitoring.										
2.	**Pressure Gauges not installed in Secondary Change room**	• Pressure Differential not maintained • Failure in pressure differential not monitored	Records of Pressure differential unavailable for any failure investigation.	Unavailability of Pressure gauges	• Cascade type of Pressure Differential is maintained. • Pressure Differential monitored for manufacturing corridor • Separate Slippers are available for classified area • Secondary gowning for classified area	Pressure Differential monitoring record of classified Corridor with respect to core areas.	3	3	3	27	Pressure Gauges to be installed	1	1	1	1 After installation of pressure gauges RPN reduces to low

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Where: S=Severity; O=Occurrence Probability; D=Detection

Assessment of Severity, Occurrence and Detection:

Severity Effect	Likelihood Occurrence	Likelihood of Detection	Rating
No Effect	Unlikely	Always Detected	1
Moderate Effect	Possible	Might Detect Failure	2
Serious Effect	Almost Certain (Every time)	Lack of Detection Control	3

Evaluation of RPN:

RPN Rating	Category
12 to 27	High
7 to 11	Medium
Upto 6	Low

S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.	Interlocking to be installed in all Airlocks on immediate basis.		
2.	Pressure Gauges to be installed in Secondary Change room & log book to be maintained.		

CAPA (Required/Not Required): Required

If required, mention CAPA No.: ……..

Quality Risk Management Team			Reviewed By Head Operations (Sign & Date)	Approved By Head QA (Sign & Date)
Name	**Department**	**Sign & Date**		

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Verification of Recommended Action:

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Remarks (if any):

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Verified By
Operating Person QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)

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Reference Document No.:	Risk Assessment No.:

9. CONCLUSION:……

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10. REFERENCES:

- Reference SOP of Risk Assessment.
- Related SOP's.

11. DOCUMENTS TO BE ATTACHED:

- Not Applicable

12. DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

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13. CHANGE CONTROL, IF ANY:

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14. ABBREVIATIONS:

FMEA	: Failure Mode Effect Analysis
RPN	: Risk Priority Number
CAPA	: Corrective action preventive action
SOP	: Standard Operating Procedure
QRM	: Quality Risk Management
QA	: Quality Assurance
QMS	: Quality Management System
DP	: Differential Pressure
RH	: Relative Humidity
ID	: Identification

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15. FMEAAPPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING PERSON (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			