8D-REPORT: Particle Contamination

Example: Visible particles in injectable solution

HEADER							
8D-No.	**Status**	**Trigger**	**Customer**	**Start**	**Target**	**End**	**K**
8D-2024-089	Completed	Internal Audit	FDA/EMA	2024-10-20	2024-11-09	2024-11-08	High

D1 – TEAM			
Role	**Name**	**Department**	**Contact**
Sponsor	Dr. Sarah Chen	Quality Dir.	s.chen@pharma.com
Team Lead	Dr. Michael Park	QA Manager	m.park@pharma.com
Member	Jennifer Walsh	Production	j.walsh@pharma.com
Member	David Kim	Engineering	d.kim@pharma.com
Expert	Dr. Anna Lee	Microbiology	a.lee@pharma.com

D2 – PROBLEM DESCRIPTION (5W2H)	
Question	**Description**
WHAT?	Visible particles in vials of injectable solution
WHERE?	Filling Line 2, Cleanroom B
WHEN?	Batch #2024-10-15, during routine inspection
WHO?	QC inspectors, patients (potential), regulators
WHY?	Patient safety risk, regulatory violation, recall
HOW?	Visual inspection, particle counter alarm
HOW MUCH?	3 batches affected, 15,000 vials, €2.1M value

D3 – CONTAINMENT ACTIONS						
ID	**Action**	**Type**	**Owner**	**Due**	**Status**	**✓**
D3-001	Quarantine all affected batches	Quarantine	Jennifer	2024-10-20	Completed	Yes
D3-002	Stop Filling Line 2	Stop Production	David	2024-10-20	Completed	Yes
D3-003	100% visual reinspection	100% Inspection	Dr. Park	2024-10-21	Completed	Yes

D4 – ROOT CAUSE ANALYSIS			
5-Why TUA (Technical Cause of Occurrence)			
No.	**Why?**	**Because...**	**Cat.**

1	Why particles?	Filter integrity failure	Material
2	Why failure?	Filter membrane damaged	Material
3	Why damaged?	Excessive differential pressure	Method
4	Why excessive?	Flow rate too high	Method
5	Why too high?	Pump setting incorrect	Machine
→ TUA Root Cause:	**Pump flow rate exceeded filter specification causing membrane damage**		

5-Why SUA (Systemic Cause of Occurrence)

No.	Why?	Because...	Cat.
1	Why incorrect?	No interlock with filter spec	Method
2	Why no interlock?	Legacy system design	Machine
3	Why legacy?	Validation cost concerns	Management
4			
5			
→ SUA Root Cause:	**Legacy filling system lacks automated parameter interlocks**		

5-Why TUN (Technical Cause of Non-Detection)

No.	Why?	Because...	Cat.
1	Why not detected?	Particle counter after filling	Measurement
2	Why after?	No inline monitoring	Machine
3	Why no inline?	Not in original design	Method
4			
5			
→ TUN Root Cause:	**Particle detection only at end of process, not inline**		

5-Why SUN (Systemic Cause of Non-Detection)

No.	Why?	Because...	Cat.
1	Why not inline?	Never retrofitted	Management
2	Why not?	No continuous improvement program	Management
3			
4			
5			
→ SUN Root Cause:	**No systematic equipment modernization program**		

D5 – SELECT CORRECTIVE ACTIONS

ID	Corrective Action	Addresses	Prio	Select	Remarks
D5-001	Correct pump settings immediately	TUA	High	Yes	Done
D5-002	Add flow rate interlock	SUA	High	Yes	
D5-003	Install inline particle monitor	TUN	High	Yes	
D5-004	Create equipment upgrade roadmap	SUN	Medium	Yes	

D6 – IMPLEMENT CORRECTIVE ACTIONS

ID	Implementation Task	Owner	Due	Status	Verification
D6-001	Reconfigure pump parameters	David	2024-10-22	Completed	IQ/OQ docs
D6-002	Validate flow interlock system	David	2024-10-30	Completed	Val report
D6-003	Install inline particle counter	David	2024-11-05	Completed	Installation qual

Effectiveness Validation	Method	Result	OK?
	Production Trial	3 consecutive batches particle-free	Yes

D7 – PREVENTIVE ACTIONS

ID	Preventive Action	Type	Owner	Status	Done
D7-001	Update Process FMEA	FMEA Update	Dr. Park	Completed	Yes
D7-002	Revise filling SOP	SOP/Work Instru	Jennifer	Completed	Yes
D7-003	Operator retraining	Training	Jennifer	Completed	Yes
D7-004	Annual filter integrity review	Audit	Dr. Lee	In Progress	No

D8 – CLOSURE & LESSONS LEARNED

Lessons Learned	Team Recognition
Critical process parameters need automated interlocks. Legacy systems require modernization roadmap.	GMP Excellence Certificate

⚠️ *NOTE: This example is based on fictional data and is for educational purposes only. Any resemblance to actual companies, persons, or events is purely coincidental.*