

INCIDENT CAPTURE FORM - PHARMA EXAMPLE

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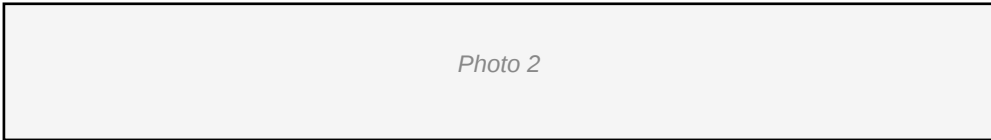
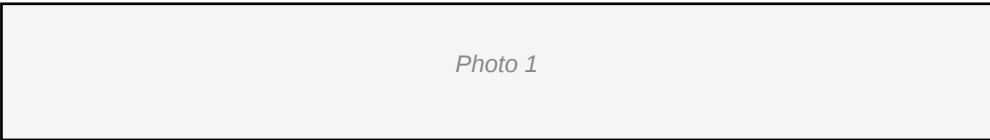
INCIDENT IDENTIFICATION

ID: INC-PH-001 Date: 01/15/2025 Priority: H Status: Open Category: GMP Deviation Owner: Dr. Sarah Chen

WHAT - What happened?		WHO - Who is involved?		WHEN - When?		WHERE - Where?	
Title:	Temperature excursion	Reported:	SCADA System	Occurred:	01/15/2025, 02:13	Location:	Building C, Room 3
Description:	Unit R-07 reached 9.2°C (spec: 2-8°...	Affected:	Batch #VX-2025-0892	Discovered:	01/15/2025, 02:15	Process:	Refrigerator R-07
Symptoms:	Alarm triggered	Responsible:	Facilities / QA	Duration:	47 minutes	Product:	Vaccine Batch

WHY - Why is it a problem?		HOW - How discovered?		HOW MUCH - Extent?	
Impact:	GMP deviation	Detection:	Auto temperature monitor	Quantity:	1,200 vials
Risk:	Critical - patient safety	Point:	Real-time SCADA	Cost:	\$2.4M value
Customer:	\$2.4M batch at risk	Frequency:	First in 6 months	Scope:	Isolated to R-07

PHOTO DOCUMENTATION



IMMEDIATE CONTAINMENT ACTIONS

Action 1: Batch quarantined

Action 2: Stability assessment

Action 3: Maintenance called

APPROVAL & SIGNATURES

Reported: SCADA System Date: 01/15/2025

Reviewed: Dr. S. Chen Date: 01/15/2025

Approved: Dr. M. Patel Date: 01/15/2025