Deviation Root Cause Analysis Template

A structured record for investigating a deviation, from containment through to root cause and corrective and preventive action (CAPA). Use it alongside your site's quality system.

1. Deviation details

Deviation reference	
Date and time found	
Found by	
Product, batch or system	
Area or process step	
Initial classification (minor, major, critical)	

2. What happened

Describe what happened, where and when, and what should have happened instead

3. Immediate actions and containment

Action taken	By	Date

4. Impact assessment

Consider the impact on	Yes	No	Notes
Product quality and patient safety			
Other batches, products or equipment			
Validated state of the process or system			
Data integrity			
Regulatory commitments or filings			

5. Five whys

Ask why the problem happened, then why that happened, until you reach a cause the organisation can control. Stop when a further why leads outside your control or adds nothing.

Problem statement	
Why 1	
Why 2	
Why 3	
Why 4	
Why 5	

6. Contributing factors (fishbone categories)

Record possible causes under each heading, then mark the ones the evidence supports.

People	Equipment	Method
Materials	**Measurement**	**Environment**

7. Root cause statement

Root cause, supported by evidence

8. CAPA plan

Action	Corrective or preventive	Owner	Due	Effectiveness check

Investigation approved by	
Date	

General guidance only. Adapt it to your organisation's own policies, procedures and legal or regulatory requirements before use.