Qualification Deviation Report

IQ/OQ/PQ Protocol Pack · Template 07 of 09

Deviation No. _____ **Date raised** _____

Equipment / area and ID _____ **Protocol No.** _____

Test / data sheet ref. _____ **Raised by** _____

Stage ☐ DQ ☐ IQ ☐ OQ ☐ PQ ☐ Requalification

1 Description

Expected (specified / acceptance criterion)	Observed (as found)

Description of the deviation _____

2 Impact assessment

Classification ☐ Critical ☐ Major ☐ Minor

Impact on qualification status, product or data _____

Product stored or affected? ☐ No ☐ Yes (attach product impact assessment)

3 Root cause

4 Corrective action

Action	Owner	Target date	Done

Retest required? ☐ No ☐ Yes Retest ref. _____

Change control required? ☐ No ☐ Yes CC No. _____

5 Closure

Close the deviation, or formally risk-assess it, before the next stage starts.

Closed before next stage started ☐ Yes ☐ Risk-assessed (attach)

Raised by	Reviewed by	Closed / approved by (QA)
Name _____	**Name** _____	**Name** _____
Designation _____	**Designation** _____	**Designation** _____
Signature _____	**Signature** _____	**Signature** _____
Date _____	**Date** _____	**Date** _____