3. Record the details of the occurrence in the area logbook.

## Section I (attached form)

4. Originator and line manager complete section I of the deviation form.
   4.1 Record the details of the occurrence in the area logbook.
   4.2 The date and time that the observation was made.
   4.3 A description of the event (what happened, where and when).
   4.4 The immediate action that was taken to contain the event.
   4.5 Identify all batches affected by the deviation, if applicable.
   4.6 Date and sign Section I (originator and line manager).
5. QA assigns a unique deviation number added to the top of section I form (QA log file No).

## Section II (attached form)

6. QA records the date/time of the observation and a description of the non-conformance, together with any affected batch numbers in the log / database and confirms that in section II.
7. QA confirms the reception of the deviation form by dating and signing section II and flag batch files for batches affected by the deviation. QA ensures that a copy of the completed section I is lodged with all affected batch files/records if applicable.

## Section III (attached form)

8. QA organizes together with the line manager the investigation team and determines the other members.
   8.1 Team nominates the Team Leader who is also holder of the original record.
   8.2 Determine the true nature of the deviation and complete the form.
   8.3 Determine and document the immediate cause and root cause of the deviation on the form. The investigation must be completed within 30 working days.
   8.4 Determine and document the full extent of the impact of the deviation including all quality implications.
   8.5 The Team Leader finalizes the summary of the failure investigation and signs and dates.