5.1.1 Deviation Reporting

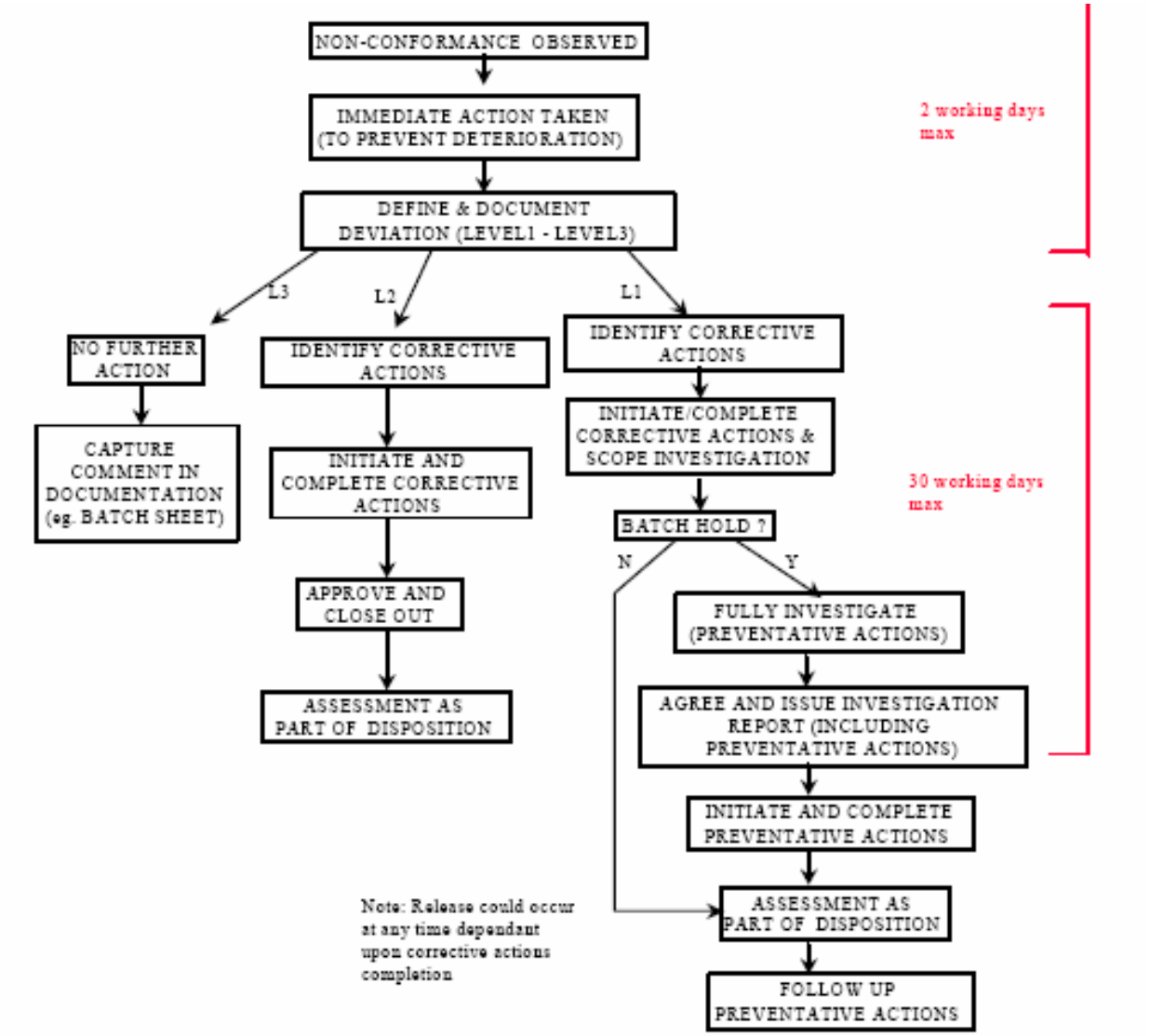
Requirement	Applicable to level		
	1	2	3
Description of the incident, including date & time of occurrence and date of discovery and person discovering	√	√	√
Product, including product code, and batch(es) directly impacted	√	√	√
Description of immediate corrective actions taken	√	√	√
Initial QA assessment of seriousness (may change after investigation starts)	√	√	√
Definition of scope (for example other batches and other products potentially affected)	√	√	
Definition of any appropriate additional actions (corrective and/or preventative actions)	√	√	
Documented investigations findings	√	√	
Investigation conclusion, including the cause and any batch disposition decisions	√	√	
Formal QA assessment and approval	√	√	
A tracking system for deviations, corrective actions and preventive actions must be in place	√	√	
More in depth investigation including rigorous root cause analysis	√		
Identification of preventative action(s) to prevent recurrence	√		
Consideration of any wider impact of the deviation (for example other sites)	√		

6.1 Appendix 1 Deviation Reporting Minimum Responsibilities

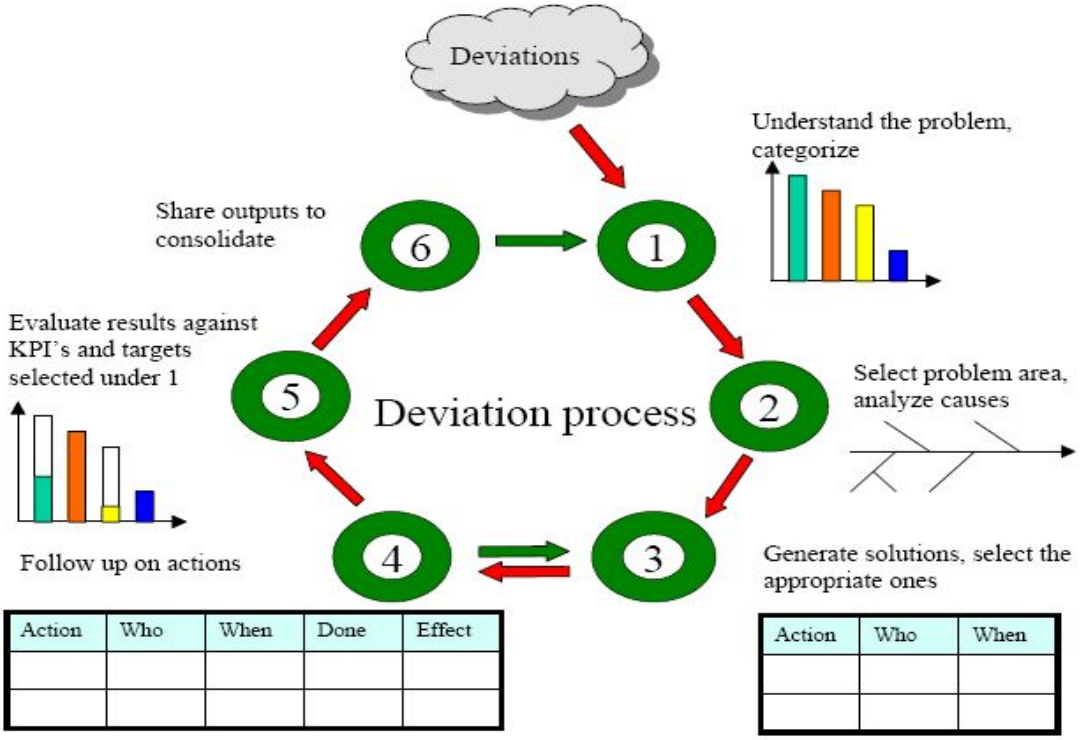
WHAT	WHO	HOW
Event occurs, document the incident	Anyone	Document according to local procedure (for example on Form, or in batch/test related documentation)
Immediate action taken	Anyone	Document what actions were immediately taken and identify and document any batches/materials impacted by the incident
Define deviation and document its seriousness (for example Level 1, 2 or 3)	Responsible Area and/or Quality Assurance	• What is the deviation? • What is the GMP issue (for example, from which standard did it deviate? [CFR#: SOP#: NDA#: etc]) • Are any batches, or materials impacted, what is their quality status? • How serious is the deviation?
Additional minimum requirements for Level 1and 2 deviations		
Define scope	Responsible area and QA	• Are multiple batches, or materials impacted? • Does any action need to be taken, with respect to their current quality status (for example, to prevent release, or recall)?
Investigate to identify the cause	Responsible Area	• Identify and document appropriate corrective/ preventative actions • Identify who will carry out these actions
Complete and document all actions	Responsible Area and/or Actionees	• Provide documented evidence of action(s) completion as appropriate
Determine any batch/material disposition	QA	• Decide if any batch/material impacted should be released, quarantined, or rejected • Consider regulatory, stability requirements
Approve / close out	QA	• Have all appropriate corrective/preventative actions been performed? • Document investigation
Additional minimum requirements for Level 1 deviations		
Investigate to identify the root cause	Responsible area and QA	Use appropriate tools to analyse the root cause of the deviation
Identify preventative actions to prevent recurrence	Responsible area and QA	Define preventative actions based on the defined root cause
Complete and document all preventative actions	Responsible Area and/or Actionees	Provide documented evidence of action(s) completion as appropriate
Consider any wider implications of the deviation	Responsible area and QA	• Document any assessment made, of the impact of the deviation on other products, other sites • Identify and implement any necessary actions from this assessment

6.2 Appendix 2

Deviation Lifecycle



6.3 Appendix 3 Systematic Process Scheme



Prioritization tool:

4-Box model

Easy but not under your control	Easy and under your control
Difficult and not under your control	Difficult but under your control