

## Functional Requirements

No.	Requirement Description	Do not comply	Comply	Can comply with customisation	Comments
<b>A. Deviations</b>					
1	Ability to process Registration of Deviations				
2	Ability to support Classifications, Type, Category, status etc.				
3	Ability to support Risk Assessments				
4	Ability to support Impact Analysis				
5	Ability to support investigations				
6	Ability to process Actions required				
7	Ability to route Deviations				
8	Ability to track Deviations by Status				
9	Ability to track trending by status				
10	Ability to update and close deviations				
11	Ability to produce listings, reports by: Product, Department, Type, Category, Building, Status etc.				
12	Ability to produce periodic reports: Daily, Weekly, Monthly, Quarterly, Yearly etc.				
13	Ability to produce exception reports: by start date, due date, etc.				
14	Ability to produce Statistical reports: Trends, Averages, etc.				
15	Ability to send escalations, reminders and notifications				
16	Ability to provide traceability				
17	Ability to support workflows from one stage to another				

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#### B. CAPA

1	Ability to process Registration of CAPA				
2	Ability to initiate a CAPA from within the Deviation Management System				
3	Ability to support Investigations, Root Cause Analysis, Risk Analysis, Impact Analysis, etc.				
4	Ability to support identification of Actions required, Corrective, Preventive, other				
5	Ability to support planning for implementation of actions required, scope, time, resources etc.				
6	Ability to support implementation of actions required, assignment, tracking etc.				
7	Ability to support verification of implementation of actions, proof, reports, other				
8	Ability to support determination of effectiveness of actions				
9	Ability to support reviews, management, audit, etc.				
10	Ability to support approval processes using workflow				
11	Ability to support Closure of actions				
12	Ability to track by status				
13	Ability to trend by status				
14	Ability to produce listings, reports by: Product, Department, Type, Category, Building, Status etc.				

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15	Ability to produce periodic reports: Daily, Weekly, Monthly, Quarterly, Yearly etc.				
16	Ability to produce exception reports: by start date, due date, etc.				
17	Ability to produce Statistical reports: Trends, Averages, etc.				
18	Ability to produce ad-hoc reports: Management queries, Auditors, regulators, etc.				
19	Ability to send escalations, reminders and notifications				
20	Ability to provide traceability				
No.	Requirement Description	Do not comply	Comply	Can comply with customisation	Comments
<b>C. Audit</b>					
1	Ability to manage internal and external audit findings				
2	Ability to track status, updates etc.				
3	Ability to support workflows				
4	Ability to support actions and close out of findings				
5	Ability to send escalations, reminders and notifications				
6	Ability to produce Statistical reports: Trends, Averages, etc.				

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### C. Complaints

1	Ability to process Registration of complaint				
2	Ability to support Classifications, Type, Category, status etc.				
3	Ability to support investigations				
4	Ability to support reviewing of information and acceptance				
5	Ability to support workflow of stages				
6	Ability to automatically close out complaint upon approval				
7	Ability to produce listings, reports by: Product, Department, Type, Category, Building, Status etc.				
8	Ability to produce periodic reports: Daily, Weekly, Monthly, Quarterly, Yearly etc.				
9	Ability to produce exception reports: by start date, due date, etc.				
10	Ability to produce Statistical reports: Trends, Averages, etc.				
11	Ability to send escalations, reminders and notifications				
12	Ability to provide traceability				

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### D. Training

1	Ability to present training material				
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2	Ability to run test after presentation of training material and track results with pass rates and to reissue test				
3	Ability to present corrections for incorrectly answered questions				
4	Ability to send escalations, reminders and notifications for new training and renewals				
5	Ability to produce periodic reports: Daily, Weekly, Monthly, Quarterly, Yearly etc.				
6	Ability to produce Statistical reports: Trends, Averages, etc.				
7	Ability to track and report on training records for individual personnel				
8	Ability to store training records				
9	Ability to retrieve training records				
10	Ability to link to the Document Management to track training of documents				
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#### D. Change

1	Ability to request change				
2	Ability to register a change from deviation or capa				
2	Ability to Identify, propose, justify change from deviation or capa				
3	Ability to review and evaluate request for change				
4	Ability to categorise change				
5	Ability to support approval workflow				

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6	Ability to track and report stages				
7	Ability to review post implementation				
8	Ability to produce listings, reports by: Product, Department, Type, Category, Building, Status etc.				
9	Ability to produce periodic reports: Daily, Weekly, Monthly, Quarterly, Yearly etc.				
10	Ability to produce exception reports: by start date, due date, etc.				
11	Ability to produce Statistical reports: Trends, Averages, etc.				
12	Ability to send escalations, reminders and notifications				
13	Ability to provide traceability				
No.	Requirement Description	Do not comply	Comply	Can comply with customisation	Comments
<b>E. Documents and Records</b>					
1	Ability to add and categorise meta data				
2	Ability to support seamless collaboration for co-authoring, review and approval				
3	Ability to support workflows: routing, approvals, reviews, etc.				
4	Ability to support Classifications, Type, Category, status etc.				
5	Ability to manage access permissions based on level of classification of document				
6	Ability to archive expired documents within given retention periods				

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7	Ability to track and report on document or record expiry date				
8	Ability to send escalations, reminders and notifications pertaining to expiring documents, pending actions etc.				
9	Ability to provide or integrate electronic signatures system				
10	Ability to track and retain versions (version control)				
11	Ability to support distribution workflows				
12	Ability to track or time and date stamp documents printed				
13	Ability to provide traceability				