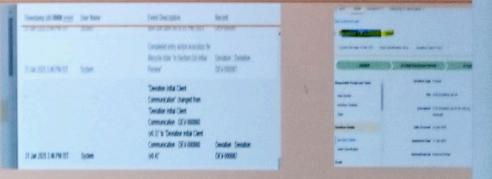
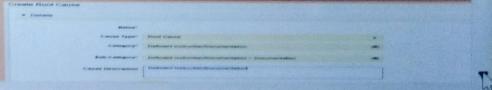


A	B	C
8	7 As escalations are manual out of the Veeva system for critical escalation numbers are generated as per procedure.	field to update the escalation numbers and document the escalation details(personnel escalation notification sent to, outcome decision of the escalation if any) is required
9	8 It appears notification issuance, escalation issuance is automated. But at what stage the escalation triggers. Initial classification? Or final classification? All the sections under Related process are non-editable, and no details were visible even when deviations created for external partner, and critical	to be sorted out and instructions required of usage.
10	9 Further Investigation required : Yes selection becomes mandatory when completing investigation even when technically investigation is completed and closed.	the field option can be removed, or if it related to some other process, the renaming of the field to be considered to avoid confusion.
11	10 Lead investigation cannot be done by section QA	Multiple role by individual user required (with control for no two different activity performed by same user).Ex :quality department/team investigation, review approval are within the QA. The Leadinvestigator in QA department can become a section QA to a CFT.
12	11 There is no section for amendment in the left side pane (like extension, CAPA, etc) under related Processes. The amendment details are entered only during signature in a field. The reason/details are visible only when viewed in workflow timeline.	A section for amendment can be kept under Related processes, along with EC, extensions.
13	12 In the formatted reports all empty fields are also exported.	Empty fields need not be part of report
14	13 Was unable to view the notification details under Related Processes as available in the system. Instead it is appearing in the initial deviation details section automatically, and not sure at what stage is being updated there.	The notification will also be shared with QP in case of EQO apart from the partners. Hence the terminology of client notification to be renamed. (A general term for notification when shared for communication/approval outside the company i.e., with QP/Partner/Client/Supplier)
15	14 In Investigation State No cancellation available	If technically investigation is not initiated, a cancellation with QA approval can be provided.

D17			
A	B	C	
13	Was unable to view the notification details under Related Processes as available in the system. Instead it is appearing in the initial deviation details section automatically, and not sure at what stage is being updated there.	The notofocation will also be shared with QP in case of EQO apart from the partners. Hence the terminology of client notofocation to be renamed. (A general term for notification when shared for communicatio/approval outside the company i.e., with QP/Partner/Client/Supplier)	
14	In Investigation State No cancellation available	If technically investigation is not initiated, a cancellation with QA approval can be provided.	
15	"Responsible People and Tasks"	The section under "Responsible People and Tasks" can be made collapsible, expandable for main section	
16	State of In Intial submission review	The State of In Intial submission review can be made to Section QA review as that activity is done by Section QA, and under Section QA. Current state title is leading to confusion as it appears to be pending with owner for initial review submission.	
17	NA	The role names should be harmonised across the module, activity or states especially for QA terminologies..	
Breakdown/hurdles observed during the record processing			
Sr. No.	Observations /Fields/State	Requirement	ScreenShot/Image of the same
1	Deviation initial and final client notification was generated and	Deviation notification generated correctly	

Breakdown/hurdles observed during the record processing			
Sr. No.	Observations /Fields/State	Requirement	ScreenShot/image of the error
1	Deviation initial and final client notification was generated and came attached in the deviation details automatically for Deviation: DEV-000087. But the notification is of Deviation 000060	Deviation notification report generation manually.	
2	DEV-000060 was rejected at the final approver state, and hence investigation records also re-opened to investigation. Out of two investigations one was modified, and another was not modified/edited, closure was allowed. Deviation: DEV-000077 for this initial ,client notification generated for dev no. 66 but final client deviation is for 77	The appropriate notification should be generated. Also when notifications are generated to be shared with client/partner for approval, a field within the system generated report for client/partner approval comments and signature is required.	
3	Was Unable to change the investigator, section QA at In investigation state	Should be able to change/delegate the investigator/section QA/ Head (All the roles that would be part of the record irrespective of state)	
4	DEV-000077 was processed as critical deviation, but without selecting the Head QA in the team. No where during the process the field was shown as required before completion of activities. Neither the section QA is able to enter the Head QA field during QA final approval. But when tried to approve through section QA prompts the message of Head QA requirement for approval	Section QA/Lead investigator should be able to select Head QA for deviation approval for critical deviations	
5	When creating root cause record at the bottom Deviation type: deviation is displayed which is non editable.	What it is for? If deviation type as in the section of deviation details should be displayed or classification of the deviation..	

Observations

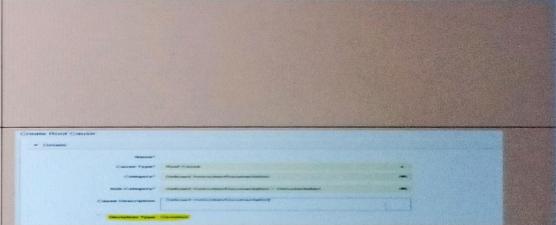
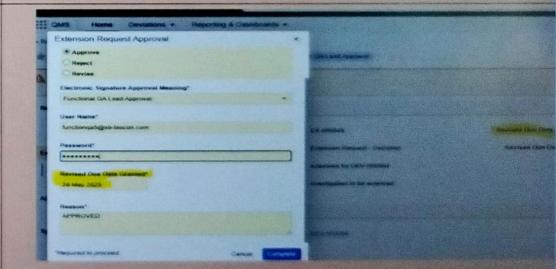
CMO list

+

22°C
Partly cloudy

Search

22:10
18/07/2025

	B	C	D
25	DEV-000077 was processed as critical deviation, but without selecting the Head QA in the team. No where during the process the field was shown as required before completion of activities. Neither the section QA is able to enter the Head QA field during QA final approval. But when tried to approve through section QA prompts the message of Head QA requirement for approval.	Section QA/Lead investigator should be able to select Head QA for deviation approval for critical deviations	
26	When creating root cause record at the bottom Deviation type: deviation is displayed which is non editable.	What it is for? If deviation type as in the section of deviation details should be displayed or classification of the deviation..	
27	Was unable to get the recurrence results even if the multiple record existed with same description and root cause. The recurrence check is working only if the deviation type is related to Environment/Utility Monitoring or OOAL/OOAC value selection when creating the deviation	repeat/recurrence search should return the results at In investigation stage and before investigation completed, with the root cause details filter to match. This will be required for final summary and conclusion/CAPA creation evaluations as recurring deviation might re-categorize the deviation. Or a differentiation for similar deviation and repeat deviation should be provided.	
28 29 30 31	When Initiating extension for the deviation DEV-000060 (due date was 16 Mar 2025) where proposed date was 29 may 2025. during approval Error message displayed: Revised Due Date Granted Field: Revised due date granted should be greater than Parent's due date Deviation due date : 16 Mar 2025 Proposed extension date: 29 May 2025 Selected Approved date : 20 May 2025	If system error to be corrected.	

Observations

CMO list



9 22°C
Partly cloudy



Search



22:12
18/07/2025

A	B	C
11 10	Link multiple deviation open for similar cause within same area to single report integration, only cross link no update in fields	
12 11	Auto alert for any overdue submission without extension approval for user before investigation submission	
13 12	recurrence check shall be only during QA review at submission	
14 13	Based on recurrence check RPI -repeat trend investigation should be auto triggered (similar to TW system is required with due date calculation)	
15 14	Deviation Workflow: Review and finalize the deviation workflow process, ensuring all roles and responsibilities are clearly defined and understood. (Arthur, Vidya)	
16 15	Document Management: Ensure the list of documents from the DMS system is fully uploaded and available for selection in the deviation process. (Kaushik)	
17 16	Deviation Classification: Discuss and finalize the questions for initial classification of deviations to ensure clarity and consistency. (Arthur, Team)	
18 17	Deviation Cancellation: Clarify the process for deviation cancellation, including the roles and responsibilities for approval and rejection. (Arthur, Team)	
19 18	Deviation Product Details: Ensure the ability to manually enter batch numbers for products not configured in SAP during the deviation process. (Arthur, Team)	
20 19	Deviation Impact Assessment: Review and refine the impact assessment questions to ensure they accurately reflect the potential impact on patient safety, data quality, and regulatory compliance. (Arthur, Team)	
21 20	Deviation Attachments: Test the upload speed and functionality for attachments in the deviation process to ensure efficiency. (Arthur, Team)	
22 21	Deviation Notifications: Verify the configuration of email notifications for deviation tasks to ensure all relevant parties are informed promptly. (Arthur, Team)	
23		
24		
25		

A	B
S. No.	Points Raised
1 1	The selection criteria for reoccurrence during the investigation phase (1 year, 2 years, and 3 years) need to be discussed further.
2 2	If the deviation is identified by auditor during audits (It has happened in the past), how do we get the drop down selection of the person? What can be done in that case to select the person identified? This can be discussed with Veeva Vault team/QA team for solution
3 3	BPDR check point from Initiator shall be moved to QA assessor/ review
4 4	Recurrence check shall be limited to QA SOP, 12 months only not to provide additional options
5 5	Scope of Repeat Trend Investigation to be part of Veeva
6 6	How Trackwise and Veeva handshake for reoccurrence check
7 7	CFT child record for investigation shall be part of initial classification rather at investigation phase to avoid conflict of interest
8 8	Investigation field should include Tables and Pictures to complete the investigation within Veeva module itself
9 9	Primary Root cause Category, shall be limit to 6M, sub category to multiple dependent class
10 10	Link multiple deviation open for similar cause within same area to single report integration, only cross link no update in fields
11 11	Auto alert for any overdue submission without extension approval for user before investigation submission
12 12	recurrence check shall be only during QA review at submission
13 13	Based on recurrence check RPI -repeat trend investigation should be auto triggered (similar to TW system is required with due date calculation)
14 14	Deviation Workflow: Review and finalize the deviation workflow process, ensuring all roles and responsibilities are clearly defined and understood. (Arthur, Vidya)
15 15	Document Management: Ensure the list of documents from the DMS system is fully uploaded and available for selection in the deviation process. (Kaushik)
16 16	Deviation Classification: Discuss and finalize the questions for initial classification of deviations to ensure clarity and consistency. (Arthur, Team)
17 17	Deviation Cancellation: Clarify the process for deviation cancellation, including the roles and responsibilities for approval and rejection. (Arthur, Team)
18 18	Deviation Product Details: Ensure the ability to manually enter batch numbers for products not configured in SAP during the deviation process. (Arthur, Team)

E11

▼ ⋮ ✖ ✓ fx ▼

A

B

	Sr No.	Site Name
1	1	Virchow Biotech
2	2	Kemwell Biopharma Pvt Ltd
3	3	Mylan Onco Therapies Limited
4	4	Chemman Labs Pvt. Ltd., (Wyzon)
5	5	Wuxi Biologics
6	6	Lupin Limited , Pune
7	7	Lupin, Mihan
8	8	Stephar B.V.
9	9	SHL Pharma LLC
10	10	Prespack, Sp. Z o.o.ul (Wysogotowo)
11	11	FKB-TERUMO DP
12	12	FKB-KKC DS
13	13	PCI Ireland(Millmount)
14	14	PCI Pharma Services Ltd. (UK) (Andersson Brecon Limited)
15	15	Patheon Manufacturing Services LLC,
16	16	Bioton S. A., Poland
17	17	Clordysis
18	18	PCI, Philadelphia
19	19	PCI, Rockford
20	20	Steripack Medical,

< >

Observations

CMO list

+



22°C

Partly cloudy



Search

- Upgrading deviation classification. Currently by the time deviating is done, the investigation is completed. Re occurrence check to be updated to find exact details.
- g. There should be a notification to management filed to be updated. Currently its either being escalated or not done. We have discussed this taking a report and sending out of VEEVA. The process is fine, but this should be updated in VEEVA to update the escalation was done. Also please consider how to include the FAR notifications in process flow.
 - h. Date due should not be in past.
 - i. In attachment description should be made available and this should be made part of formatted report. Also, the formatted report should not contain the sections that are not applicable to a deviation.
 - j. Notification terminologies should be clear, unambiguous. As discussed currently at multiple steps its tense needs to correct, the statement to be updated like, "further investigation required" etc.

B. Can be Considered.

- a. Through out the deviation, the classification is being done by USER, and if QA is not OKAY, it has authority to send it back. A better way is to Final classification either done by QA or the classification override by QA in stead of sending it back.
- b. The task tab should also provide the clear tree of events like instead of "completing the inv-xxxx", a better option may be completing "inv-xxxx (dev-yyyy)"
- c. A critical deviation closure is being done by site QA, but its extension is approved by Sec QA. These type of process flows to be rationalised.
- d. The term investigator is not the same for GMP and Clinical. Hence this and as applicable the process flow/terminologies should be made unambiguous including currently appearing term GMP deviation in formatted report.

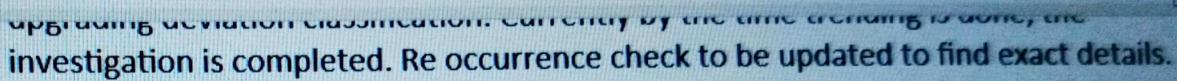
A. Must Consider

- a. Nomenclature for both process and process owners should remain same across all modules and platform with clear responsibilities defined. The expected nomenclature should align to BBL either current or proposed system. For ex, site QA, SEC QA, QA HEAD, Functional QA, etc are confusion and cluster QA can be a deviation is owner require in-depth review and optimisation. And the signature tab refers only Quality.
- b. Data fields (all data fields including asset, document etc.) optimisations needs to be accurate and correct, with option to adding future data seamlessly. Importantly data field selection is also equally important. Repeating a data field process because of single selection is redundant.
- c. There is nomenclature difference between Veeva and BBL, for example, there is no equipment, but everything comes under asset, Hence defining the right nomenclature is significantly improves the process. .
- d. Classification of deviation is extensively discussed, Non GMP (RND, Clinical development) should be considering while defining the criteria. Also combining multiple factors into a single question is leading to ambiguous decision. Along side YES/NO, there should be a option of Potential which should be confirmed at the final stage for closure. The final stage of deviation closure does not consider the impact, it only considered the classification.
- e. We have extensively discussed about action plan for action to be performed during or at the beginning of deviation. Like hold status. Tried but did not found a action of such kind in the current process flow.
- f. The Trending should be done either at the beginning or during the investigation, currently it is being done after the investigation. As repeated trend leads to upgrading deviation classification. Currently by the time trending is done, the investigation is completed. Re occurrence check to be updated to find exact details.
- g. There should be a notification to management filed to be updated. Currently its

- e. We have agreed to adopt the date format DD-MMM-YYYY for all locations. This should happen both on and off-screen display.
- f. Only approved extensions should be considered and counted as number of extensions.
- g. While fields are linked, the links of related fields should be updated at the same instance.
- h. When the deviation is **not submitted**, it can be cancelled by owner itself, without a team and can be cancelled by QA with a team assignment. This should be rationalized. When a deviation is not submitted, it does not matter whether a team id defined or not.

C. Suggestion

- a. While the configuration can be fixed, and scope of feedback is limited. It's suggested to keep the environment open and let the SME /Super SME try, so that if any critical observation (may not be a configuration) found, shall be corrected before going into validation.
- b. The mandatory fields are highlighted only on the initial screen, it should be extended to all screens.
- c. The process flow should be able to show, at which state and with whom the record is pending for how many days.
- d. If we can restrict the formatted out put to simple and plain texts without any BOLD or increase front size. It will remain uniform and contain more information.
- e. In the initial screen the deviation identified by is not a mandatory field, it should be especially when its agreed that not all can initiate deviations. Or at least it can be made mandatory for all internal deviations. And all related fields should be chronologically and sequentially arranged, like, external >> internal >> site >> department >> owner >> deviation. I hope this should be sequence for all QMS process flow in a situation where the same process is being used across sites and department.
- f. A field named "related event" is available. While this can be referred to any quality related events, this field shall be appropriately defined.

1 · 2 · 3 · 4 · 5 · 6 · 7 · 8 · 9 · 10 · 11 · 12 · 13 · 14 · 15 · 

- g. There should be a notification to management filed to be updated. Currently its either being escalated or not done. We have discussed this taking a report and sending out of VEEVA. The process is fine, but this should be updated in VEEVA to update the escalation was done. Also please consider how to include the FAR notifications in process flow.
- h. Date due should not be in past.
- i. In attachment description should be made available and this should be made part of formatted report. Also, the formatted report should not contain the sections that are not applicable to a deviation.
- j. Notification terminologies should be clear, unambiguous. As discussed currently at multiple steps its tense needs to correct, the statement to be updated like, "further investigation required" etc.

B. Can be Considered.

- a. Through out the deviation, the classification is being done by USER, and if QA is not OKAY, it has authority to send it back. A better way is to Final classification either done by QA or the classification override by QA instead of sending it back.
- b. The task tab should also provide the clear tree of events like instead of "completing the inv-xxxx", a better option may be completing "inv-xxxx (dev-yyyy)"
- c. A critical deviation closure is being done by site QA, but its extension is approved by Sec QA. These type of process flows to be rationalised.
- d. The term investigator is not the same for GMP and Clinical. Hence this and as applicable the process flow/terminologies should be made unambiguous including currently appearing term GMP deviation in formatted report.

12	11	Auto alert for any overdue submission without extension approval for user before investigation submission
13	12	recurrence check shall be only during QA review at submission
14	13	Based on recurrence check RPI -repeat trend investigation should be auto triggered (similar to TW system is required with due date calculation)
15	14	Deviation Workflow: Review and finalize the deviation workflow process, ensuring all roles and responsibilities are clearly defined and understood. (Arthur, Vidya)
16	15	Document Management: Ensure the list of documents from the DMS system is fully uploaded and available for selection in the deviation process. (Kaushik)
17	16	Deviation Classification: Discuss and finalize the questions for initial classification of deviations to ensure clarity and consistency. (Arthur, Team)
18	17	Deviation Cancellation: Clarify the process for deviation cancellation, including the roles and responsibilities for approval and rejection. (Arthur, Team)
19	18	Deviation Product Details: Ensure the ability to manually enter batch numbers for products not configured in SAP during the deviation process. (Arthur, Team)
20	19	Deviation Impact Assessment: Review and refine the impact assessment questions to ensure they accurately reflect the potential impact on patient safety, data quality, and regulatory compliance. (Arthur, Team)
21	20	Deviation Attachments: Test the upload speed and functionality for attachments in the deviation process to ensure efficiency. (Arthur, Team)
22	21	Deviation Notifications: Verify the configuration of email notifications for deviation tasks to ensure all relevant parties are informed promptly. (Arthur, Team)
23		
24		

2	1	The selection criteria for reoccurrence during the investigation phase (1 year, 2 years, and 3 years) need to be discussed further.
3	2	If the deviation is identified by auditor during audits (It has happened in the past), how do we get the drop down selection of the person? What can be done in that case to select the person identified? This can be discussed with Veeva Vault team/QA team for solution
4	3	BPDR check point from Initiator shall be moved to QA assessor/ review
5	4	Recurrence check shall be limited to QA SOP, 12 months only not to provide additional options
6	5	Scope of Repeat Trend Investigation to be part of Veeva
7	6	How Trackwise and Veeva handshake for reoccurrence check
8	7	CFT child record for investigation shall be part of initial classification rather at investigation phase to avoid conflict of interest
9	8	Investigation field should include Tables and Pictures to complete the investigation within Veeva module itself
10	9	Primary Root cause Category, shall be limit to 6M, sub category to multiple dependent class
11	10	Link multiple deviation open for similar cause within same area to single report integration, only cross link no update in fields
12	11	Auto alert for any overdue submission without extension approval for user before investigation submission
13	12	recurrence check shall be only during QA review at submission
14	13	Based on recurrence check RPI -repeat trend investigation should be auto triggered (similar to TW system is required with due date calculation)
15	14	Deviation Workflow: Review and finalize the deviation workflow process, ensuring all roles and responsibilities are clearly defined and understood. (Arthur, Vidya)
16	15	Document Management: Ensure the list of documents from the DMS system is fully uploaded and available for selection in the deviation process. (Kaushik)
17	16	Deviation Classification: Discuss and finalize the questions for initial classification of deviations to ensure clarity and consistency. (Arthur, Team)
18	17	Deviation Cancellation: Clarify the process for deviation cancellation, including the roles and responsibilities for approval and rejection. (Arthur, Team)
19	18	Deviation Product Details: Ensure the ability to manually enter batch numbers for products not configured in SAP during the deviation process. (Arthur, Team)

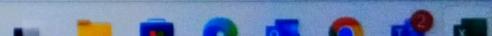
	A	B	C	D	E	F	G	H
1	Subcategory	Type	Type Definition:		Priority	Priority Definition:		
2	Deviation	Issue	Configuration issues identified during testing, Vault issues		Must Have	Requirements that are compulsorily required		
3	Investigation	Observation	Spelling mistakes in PE's		Should Have	Important functionality that should be developed		
4	CAPA	Question	Questions related to Process, Vault, Process Exercise or Lucid		Could Have	Nice to have		
5	Effectiveness Check	Requirement	New requirement, new feature, Renaming of Lifecycle states		Will not Have	Not Required		
6	Extension				NA	Not Applicable		
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19	Veeva Status							
20	New		Item has been raised, but not addressed by the Veeva Team					
21	Analysis		The Veeva Team is currently addressing the item					
22	In Progress							
23	Biocon Review Comments		Pending feedback from Biocon (Changed to by Veeva team)					
24	Veeva Review Comments		Pending feedback from Veeva (Changed to by BI team)					
25	Withdrawn		Item has been withdrawn (Duplicate etc.)					
26	Closed		Item has been addressed, and no further action is required					
27	Ready For Testing		Item has been configured and is ready for Biocon to test					
28	Deferred		Deferred for consideration for the post go live					
29	Biocon Internal		BI to review internally before passing over to Veeva					
30								
31								
32								
33								
34								
35								
36								
37								
38								
39								
40								
41								
42								

Issue Tracker - Deviation

Definitions



Search



A. Must Consider

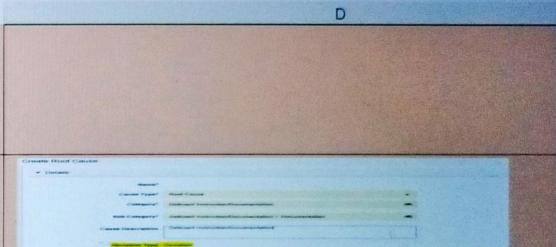
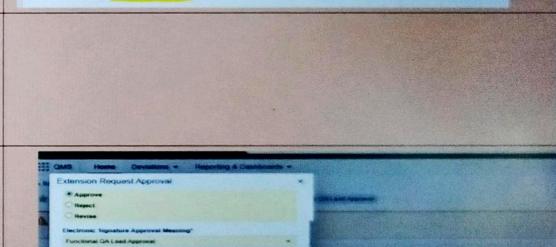
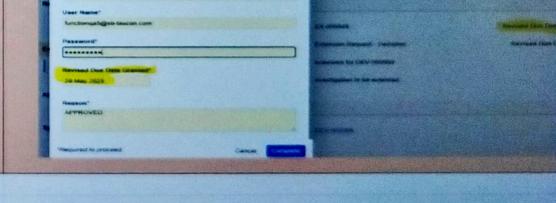
- a. Nomenclature for both process and process owners should remain same across all modules and platform with clear responsibilities defined. The expected nomenclature should align to BBL either current or proposed system. For ex, site QA, SEC QA, QA HEAD, Functional QA, etc are confusion and cluster QA can be a deviation is owner require in-depth review and optimisation. And the signature tab refers only Quality.
- b. Data fields (all data fields including asset, document etc.) optimisations needs to be accurate and correct, with option to adding future data seamlessly. Importantly data field selection is also equally important. Repeating a data field process because of single selection is redundant.
- c. There is nomenclature difference between Veeva and BBL, for example, there is no equipment, but everything comes under asset, Hence defining the right nomenclature is significantly improves the process.
- d. Classification of deviation is extensively discussed, Non GMP (RND, Clinical development) should be considering while defining the criteria. Also combining multiple factors into a single question is leading to ambiguous decision. Along side YES/NO, there should be a option of Potential which should be confirmed at the final stage for closure. The final stage of deviation closure does not consider the impact, it only considered the classification.
- e. We have extensively discussed about action plan for action to be performed during or at the beginning of deviation. Like hold status. Tried but did not found a action of such kind in the current process flow.
- f. The Trending should be done either at the beginning or during the investigation, currently it is being done after the investigation. As repeated trend leads to upgrading deviation classification. Currently by the time trending is done, the investigation is completed. Re occurrence check to be updated to find exact details.
- g. There should be a notification to management filed to be updated. Currently its



A

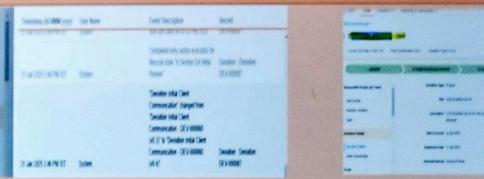
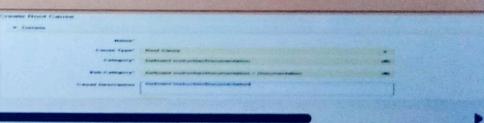
B

	Sr No.	Site Name
1	1	Virchow Biotech
2	2	Kemwell Biopharma Pvt Ltd
3	3	Mylan Onco Therapies Limited
4	4	Chemman Labs Pvt. Ltd., (Wyzon)
5	5	Wuxi Biologics
6	6	Lupin Limited , Pune
7	7	Lupin, Mihan
8	8	Stephar B.V.
9	9	SHL Pharma LLC
10	10	Prespack, Sp. Z. o.o.ul (Wysogotowo)
11	11	FKB-TERUMO DP
12	12	FKB-KKC DS
13	13	PCI Ireland(Millmount)
14	14	PCI Pharma Services Ltd. (UK) (Andersson Brecon Limited)
15	15	Patheon Manufacturing Services LLC,
16	16	Bioton S. A., Poland
17	17	Clordysis
18	18	PCI, Philadelphia
19	19	PCI, Rockford
20	20	Steripack Medical,
21		
22		
23		

	B	C	D
25	DEV-000077 was processed as critical deviation, but without selecting the Head QA in the team. No where during the process the field was shown as required before completion of activities. Neither the section QA is able to enter the Head QA field during QA final approval. But when tried to approve through section QA prompts the message of Head QA requirement for approval	Section QA/Lead investigator should be able to select Head QA for deviation approval for critical deviations	
26	When creating root cause record at the bottom Deviation type: deviation is displayed which is non editable.	What it is for? If deviation type as in the section of deviation details should be displayed or classification of the deviation..	
27	Was unable to get the recurrence results even if the multiple record existed with same description and root cause. The recurrence check is working only if the deviation type is related to Environment/Utility Monitoring or OOAL/OOAC value selection when creating the deviation	repeat/recurrence search should return the results at In investigation stage and before investigation completed, with the root cause details filter to match. This will be required for final summary and conclusion/CAPA creation evaluations as recurring deviation might re-categorize the deviation. Or a differentiation for similar deviation and repeat deviation should be provided.	
28	When Initiating extension for the deviation DEV-000060 (due date was 16 Mar 2025) where proposed date was 29 May 2025. during approval Error message displayed: Revised Due Date Granted Field: Revised due date granted should be greater than Parent's due date Deviation due date : 16 Mar 2025 Proposed extension date: 29 May 2025 Selected Approved date : 20 May 2025	If system error to be corrected.	
29			
30			
31			

Observations CMO list +

Breakdown/hurdles observed during the record processing

Sr. No.	Observations /Fields/State	Requirement	ScreenShot/Image of the error
1	Deviation initial and final client notification was generated and came attached in the deviation details automatically for Deviation: DEV-000087. But the notification is of Deviation 000060	Deviation notification report generation manually.	
2	DEV-000060 was rejected at the final approver state, and hence investigation records also re-opened to in investigation. out of two investigations one was modified, and another was not modified/edited, closure was allowed. Deviation: DEV-000077 for this initial ,client notification generated for dev no. 66 but final client deviation is for 77	The appropriate notification should be generated. Also when notifications are generated to be shared with client/partner for approval, a field within the system generated report for client/partner approval comments and signature is required.	
3	Was Unable to change the investigator, section QA at In investigation state	Should be able to change/delegate the investigator/section QA/ Head (All the roles that would be part of the record irrespective of state)	
4	DEV-000077 was processed as critical deviation, but without selecting the Head QA in the team. No where during the process the field was shown as required before completion of activities. Neither the section QA is able to enter the Head QA field during QA final approval. But when tried to approve through section QA prompts the message of Head QA requirement for approval	Section QA/Lead investigator should be able to select Head QA for deviation approval for critical deviations	
5	When creating root cause record at the bottom Deviation type: deviation is displayed which is non editable.	What it is for? If deviation type as in the section of deviation details should be displayed or classification of the deviation..	

Observations CMO list +

Was unable to view the notification details under Related Processes as available in the system. Instead it is appearing in the initial deviation details section automatically, and not sure at what stage is being updated there.	The notofocation will also be shared with QP in case of EQO apart from the partners. Hence the terminology of client notofocation to be renamed. (A general term for notification when shared for communicatio/approval outside the company i.e., with QP/Partner/Client/Supplier)
In Investigation State No cancellation available	If technically investigation is not initiated, a cancellation with QA approval can be provided.
"Responsible People and Tasks"	The section under "Responsible People and Tasks" can be made collapsible, expandable for main section
State of In Intial submission review	The State of In Intial submission review can be made to Section QA review as that activity is done by Section QA, and under Section QA. Current state title is leading to confusion as it appears to be pending with owner for initial review submission.
NA	The role names should be harmonised across the module, activity or states especially for QA terminologies..

Initiation step by deviation owner

- Deviation type should have something prepopulated for clinical, safety and RND related topics
- Date occurred should have a range of date as from and to
- External should have CRO, CT site, BA site, outsourced vendor
- Owning department should have clinical development instead of clinical research/operations, should have clinical and research quality
- Deviation location does not have any fields related to Clinical/PV/RQA
- Asset impacted? 'Asset' not defined but is mandatory to fill
- Product impacted is mandatory to select Batch No. from drop down which is not the case always

Initial classification by deviation owner

- Impact on all parameters is either a YES or NO. But in clinical this is different as 'YES', 'MIGHT' and "NOT EXPECTED TO" impact
- The hover prompts on each impact criteria should be turned into fixed text for everyone to understand what all it consists of as this is not seen for next processors
- Impacts GXP is a broad term which includes rest of the others too creating more confusion. In such case others should be as sub-criteria
- The logic applied (all yes leading to critical, all yes except subject safety as no leading to major and all no leading to minor) should be made clear here for better judgement; writing in SOP may not help always to refer to

Section QA's review

- Adding Head QA's name should be made inactive in case it's classified as minor/major. It should not allow to put someone's name here without role of Head-QA later
- The workflow shows it's under Section QA review but while signing off the meaning of signature says QA Initial Approval. Both should indicate the same

In Investigation

editions: On

 Accessibility: Good to go

 Focus



department >> owner >> deviation. I hope this should be sequence for all QMS process flow in a situation where the same process is being used across sites and department.

- f. A field named "related event" is available. While this can be referred to any quality event and not only a deviation, the same shall be appropriately defined.
- g. Once the deviation is closed, the tabs "system details and Signature" do not populate all fields, like deviation owner, submitted by etc. it only restricted to investigation details. At least the signature tab should contain all signatories.
- h. It's proposed to use Accepted for all initial Approvals like Initiated >> accepted >> investigated >> Quality approved to remove ambiguity.
- i. Fields which are not mandatory, should not be made mandatory, for example in the batch table, a comment is marked as mandatory.
- j. Signatures should have displayed the meaning screen, like submitting the record for QA acceptance or submitting the investigation for QA approval.

7	As escalations are manual out of the Veeva system for critical escalation numbers are generated as per procedure.	field to update the escalation numbers and document the escalation details (personnel escalation notification sent to, outcome decision of the escalation if any) is required
8	It appears notification issuance, escalation issuance is automated. But at what stage the escalation triggers. Initial classification? Or final classification? All the sections under Related process are non-editable, and no details were visible even when deviations created for external partner, and critical	to be sorted out and instructions required of usage.
9	Further Investigation required : Yes selection becomes mandatory when completing investigation even when technically investigation is completed and closed.	the field option can be removed, or if it related to some other process, the renaming of the field to be considered to avoid confusion.
10	Lead investigation cannot be done by section QA	Multiple role by individual user required (with control for no two different activity performed by same user).Ex : quality department/team investigation, review approval are within the QA. The Leadinvestigator in QA deprtment can become a section QA to a CFT.
11	There is no section for amendment in the left side pane (like extension, CAPA, etc) under related Processes). The amendment details are entered only during signature in a field. The reason/details are visible only when viewed in workflow timeline.	A section for amendment can be kept under Related processes, along with EC, extensions.
12	In the formatted reports all empty fields are also exported.	Empty field need not be part of report
13	Was unable to view the notification details under Related Processes as available in the system. Instead it is appearing in the initial deviation details section automatically, and not sure at what stage is being updated there.	The notification will also be shared with QP in case of EQO apart from the partners. Hence the terminology of client notification to be renamed. (A general term for notification when shared for communication/approval outside the company i.e., with QP/Partner/Client/Supplier)
14	In Investigation State No cancellation available	If technically investigation is not initiated, a cancellation with QA approval can be provided.

In Investigation

- Why again questions like 'further investigation is required', 'CAPA required' etc are being asked while signing off when all this has been already completed on the page before

Terminologies

- To be made uniform and lean for all workflows (Deviation, CC, CAPA, Audit, Vendor) and sub-workflows (CAPA, EC, extensions, escalations/notifications to Management).
- Namely, Site-QA, Section-QA, Function-QA, Lead-QA, Site-QA Head, Cluster Head. These need to be defined and used in the same way in Veeva. Using/showing similar nomenclature in Veeva/Process SOP to be eliminated
- 'Investigator' to be replaced with 'Deviation Assessor' because Investigator means different for CDMA personnel
- Associated documents can be replaced with a better terminology to convey the actual meaning. E.g., deviation to SOP/Guideline/Law

In workflow timeline or status

- Actual 'tense' should reflect. E.g., if review is done then it should show as 'Reviewed' and not only 'Review'

Final report (extract/crystal/formatted)

- Title of the report should not be restricted to only GMP
- Attachments to the deviations currently are not able to be printed

Sr No.	Observations /Fields/State	Requirement
1	1 Owning Facility and Departments (Fields)	External manufacturing (To log the QMS from external sites/facilities occurred at external site/facility) External warehouse ((To log the QMS from external sites/facilities occurred at external site/facility) External Testing Lab ((To log the QMS from external sites/facilities occurred at external site/facility) External Quality Organization (This will be required to handle EQO internal QMS
2	2 Deviation Type(field)	Testing (option for value selection is required, as testing related QMS from external labs are logged by EQO)
3	3 External partner QMS reference No. Field	The free text field required to enter External partner QMS reference No. Field when the deviations related external partner are logged
4	4 Customer Name Field	The field name to be changed to partner as the external sites are not customers for EQO.
5	5 Customer Name Field value list	Refer to the list of CMO list sheet in the excel. In addition the list of testing lab and warehouse is available with CQA as service provider in the system. Same to be considered
6	6 Immediate Action Taken By	The field is value selection (BBL employee names), in case of EQO, immediate actions are taken at sites by site personnel. This field can be made non-mandatory if deviation is related to external partner.
7	7 As escalations are manual out of the Veeva system for critical escalation numbers are generated as per procedure.	field to update the escalation numbers and document the escalation details (personnel escalation notification sent to, outcome decision of the escalation if any) is required
8		

department >> owner >> deviation. I hope this should be sequence for all QMS process flow in a situation where the same process is being used across sites and department.

- f. A field named "related event" is available. While this can be referred to any quality event and not only a deviation, the same shall be appropriately defined.
- g. Once the deviation is closed, the tabs "system details and Signature" do not populate all fields, like deviation owner, submitted by etc. it only restricted to investigation details. At least the signature tab should contain all signatories.
- h. It's proposed to use Accepted for all initial Approvals like Initiated >> accepted >> investigated >> Quality approved to remove ambiguity.
- i. Fields which are not mandatory, should not be made mandatory, for example in the batch table, a comment is marked as mandatory.
- j. Signatures should have displayed the meaning screen, like submitting the record for QA acceptance or submitting the investigation for QA approval.

Initiation step by deviation owner

- Deviation type should have something prepopulated for clinical, safety and RND related topics
- Date occurred should have a range of date as from and to
- External should have CRO, CT site, BA site, outsourced vendor
- Owning department should have clinical development instead of clinical research/operations, should have clinical and research quality
- Deviation location does not have any fields related to Clinical/PV/RQA
- Asset impacted? 'Asset' not defined but is mandatory to fill
- Product impacted is mandatory to select Batch No. from drop down which is not the case always

Initial classification by deviation owner

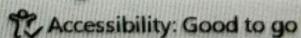
- Impact on all parameters is either a YES or NO. But in clinical this is different as 'YES', 'MIGHT' and "NOT EXPECTED TO" impact
- The hover prompts on each impact criteria should be turned into fixed text for everyone to understand what all it consists of as this is not seen for next processors
- Impacts GXP is a broad term which includes rest of the others too creating more confusion. In such case others should be as sub-criteria
- The logic applied (all yes leading to critical, all yes except subject safety as no leading to major and all no leading to minor) should be made clear here for better judgement; writing in SOP may not help always to refer to

Section QA's review

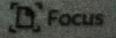
- Adding Head QA's name should be made inactive in case it's classified as minor/major. It should not allow to put someone's name here without role of Head-QA later
- The workflow shows it's under Section QA review but while signing off the meaning of signature says QA Initial Approval. Both should indicate the same

In Investigation

editions: On



Good to go



Initiation step by deviation owner

- Deviation type should have something prepopulated for clinical, safety and RND related topics
- Date occurred should have a range of date as from and to
- External should have CRO, CT site, BA site, outsourced vendor
- Owning department should have clinical development instead of clinical research/operations, should have clinical and research quality
- Deviation location does not have any fields related to Clinical/PV/RQA
- Asset impacted? 'Asset' not defined but is mandatory to fill
- Product impacted is mandatory to select Batch No. from drop down which is not the case always

Initial classification by deviation owner

- Impact on all parameters is either a YES or NO. But in clinical this is different as 'YES', 'MIGHT' and "NOT EXPECTED TO" impact
- The hover prompts on each impact criteria should be turned into fixed text for everyone to understand what all it consists of as this is not seen for next processors
- Impacts GXP is a broad term which includes rest of the others too creating more confusion. In such case others should be as sub-criteria
- The logic applied (all yes leading to critical, all yes except subject safety as no leading to major and all no leading to minor) should be made clear here for better judgement; writing in SOP may not help always to refer to

Section QA's review

- Adding Head QA's name should be made inactive in case it's classified as minor/major. It should not allow to put someone's name here without role of Head-QA later
- The workflow shows it's under Section QA review but while signing off the meaning of signature says QA Initial Approval. Both should indicate the same

In Investigation

editions: On

 Accessibility: Good to go

 Focus



- e. We have agreed to adopt the date format DD-MMM-YYYY for all locations. This should happen both on and off-screen display.
- f. Only approved extensions should be considered and counted as number of extensions.
- g. While fields are linked, the links of related fields should be updated at the same instance.
- h. When the deviation is **not submitted**, it can be cancelled by owner itself, without a team and can be cancelled by QA with a team assignment. This should be rationalized. When a deviation is not submitted, it does not matter whether a team id defined or not.

C. Suggestion

- a. While the configuration can be fixed, and scope of feedback is limited. It's suggested to keep the environment open and let the SME /Super SME try, so that if any critical observation (may not be a configuration) found, shall be corrected before going into validation.
- b. The mandatory fields are highlighted only on the initial screen, it should be extended to all screens.
- c. The process flow should be able to show, at which state and with whom the record is pending for how many days.
- d. If we can restrict the formatted out put to simple and plain texts without any BOLD or increase front size. It will remain uniform and contain more information.
- e. In the initial screen the deviation identified by is not a mandatory field, it should be especially when its agreed that not all can initiate deviations. Or at least it can be made mandatory for all internal deviations. And all related fields should be chronologically and sequentially arranged, like, external >> internal >> site >> department >> owner >> deviation. I hope this should be sequence for all QMS process flow in a situation where the same process is being used across sites and department.
- f. A field named "related event" is available. While this can be referred to any quality

department >> owner >> deviation. I hope this should be sequence for all QMS process flow in a situation where the same process is being used across sites and department.

- f. A field named "related event" is available. While this can be referred to any quality event and not only a deviation, the same shall be appropriately defined.
- g. Once the deviation is closed, the tabs "system details and Signature" do not populate all fields, like deviation owner, submitted by etc. it only restricted to investigation details. At least the signature tab should contain all signatories.
- h. It's proposed to use Accepted for all initial Approvals like Initiated >> accepted >> investigated >> Quality approved to remove ambiguity.
- i. Fields which are not mandatory, should not be made mandatory, for example in the batch table, a comment is marked as mandatory.
- j. Signatures should have displayed the meaning screen, like submitting the record for QA acceptance or submitting the investigation for QA approval.

Sr No.	Observations /Fields/State	Requirement
1	Owning Facility and Departments (Fields)	<p>External manufacturing (To log the QMS from external sites/facilities occurred at external site/facility)</p> <p>External warehouse ((To log the QMS from external sites/facilities occurred at external site/facility))</p> <p>External Testing Lab ((To log the QMS from external sites/facilities occurred at external site/facility))</p> <p>External Quality Organization (This will be required to handle EQO internal QMS elements)</p>
2	Deviation Type(field)	Testing (option for value selection is required, as testing related QMS from external labs are logged by EQO)
3	External partner QMS reference No. Field	The free text field required to enter External partner QMS reference No. Field when the deviations related external partner are logged
4		

7	As escalations are manual out of the Veeva system for critical escalation numbers are generated as per procedure.	field to update the escalation numbers and document the escalation details (personnel escalation notification sent to, outcome decision of the escalation if any) is required
8	It appears notification issuance, escalation issuance is automated. But at what stage the escalation triggers. Initial classification? Or final classification? All the sections under Related process are non-editable, and no details were visible even when deviations created for external partner, and critical	to be sorted out and instructions required of usage.
9	Further Investigation required : Yes selection becomes mandatory when completing investigation even when technically investigation is completed and closed.	the field option can be removed, or if it related to some other process, the renaming of the field to be considered to avoid confusion.
10	Lead investigation cannot be done by section QA	Multiple role by individual user required (with control for no two different activity performed by same user).Ex : quality department/team investigation, review approval are within the QA. The Leadinvestigator in QA deprtment can become a section QA to a CFT.
11	There is no section for amendment in the left side pane (like extension, CAPA, etc) under related Processes). The amendment details are entered only during signature in a field. The reason/details are visible only when viewed in workflow timeline.	A section for amendment can be kept under Related processes, along with EC, extensions.
12	In the formatted reports all empty fields are also exported.	Empty field need not be part of report
13	Was unable to view the notification details under Related Processes as available in the system. Instead it is appearing in the initial deviation details section automatically, and not sure at what stage is being updated there.	The notification will also be shared with QP in case of EQO apart from the partners. Hence the terminology of client notification to be renamed. (A general term for notification when shared for communication/approval outside the company i.e., with QP/Partner/Client/Supplier)
14	In Investigation State No cancellation available	If technically investigation is not initiated, a cancellation with QA approval can be provided.

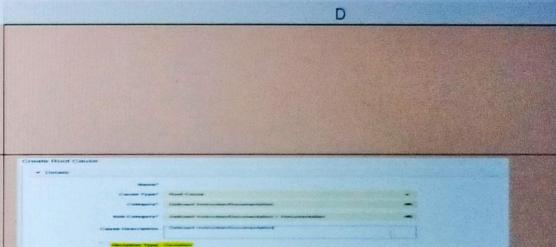
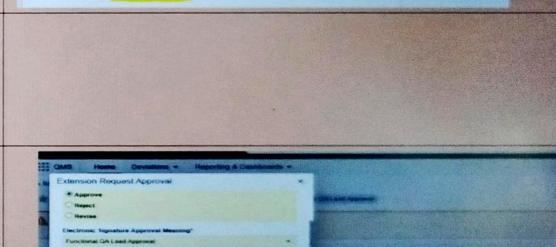
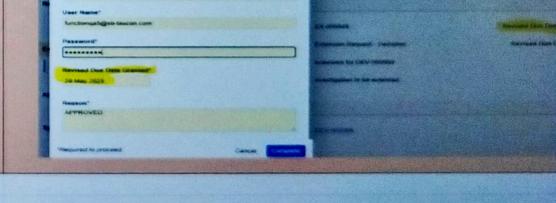
Was unable to view the notification details under Related Processes as available in the system. Instead it is appearing in the initial deviation details section automatically, and not sure at what stage is being updated there.	The notofocation will also be shared with QP in case of EQO apart from the partners. Hence the terminology of client notofocation to be renamed. (A general term for notification when shared for communicatio/approval outside the company i.e., with QP/Partner/Client/Supplier)
In Investigation State No cancellation available	If technically investigation is not initiated, a cancellation with QA approval can be provided.
"Responsible People and Tasks"	The section under "Responsible People and Tasks" can be made collapsible, expandable for main section
State of In Intial submission review	The State of In Intial submission review can be made to Section QA review as that activity is done by Section QA, and under Section QA. Current state title is leading to confusion as it appears to be pending with owner for initial review submission.
NA	The role names should be harmonised across the module, activity or states especially for QA terminologies..

12	11	Auto alert for any overdue submission without extension approval for user before investigation submission
13	12	recurrence check shall be only during QA review at submission
14	13	Based on recurrence check RPI -repeat trend investigation should be auto triggered (similar to TW system is required with due date calculation)
15	14	Deviation Workflow: Review and finalize the deviation workflow process, ensuring all roles and responsibilities are clearly defined and understood. (Arthur, Vidya)
16	15	Document Management: Ensure the list of documents from the DMS system is fully uploaded and available for selection in the deviation process. (Kaushik)
17	16	Deviation Classification: Discuss and finalize the questions for initial classification of deviations to ensure clarity and consistency. (Arthur, Team)
18	17	Deviation Cancellation: Clarify the process for deviation cancellation, including the roles and responsibilities for approval and rejection. (Arthur, Team)
19	18	Deviation Product Details: Ensure the ability to manually enter batch numbers for products not configured in SAP during the deviation process. (Arthur, Team)
20	19	Deviation Impact Assessment: Review and refine the impact assessment questions to ensure they accurately reflect the potential impact on patient safety, data quality, and regulatory compliance. (Arthur, Team)
21	20	Deviation Attachments: Test the upload speed and functionality for attachments in the deviation process to ensure efficiency. (Arthur, Team)
22	21	Deviation Notifications: Verify the configuration of email notifications for deviation tasks to ensure all relevant parties are informed promptly. (Arthur, Team)
23		
24		

A

B

	Sr No.	Site Name
1	1	Virchow Biotech
2	2	Kemwell Biopharma Pvt Ltd
3	3	Mylan Onco Therapies Limited
4	4	Chemman Labs Pvt. Ltd., (Wyzon)
5	5	Wuxi Biologics
6	6	Lupin Limited , Pune
7	7	Lupin, Mihan
8	8	Stephar B.V.
9	9	SHL Pharma LLC
10	10	Prespack, Sp. Z. o.o.ul (Wysogotowo)
11	11	FKB-TERUMO DP
12	12	FKB-KKC DS
13	13	PCI Ireland(Millmount)
14	14	PCI Pharma Services Ltd. (UK) (Andersson Brecon Limited)
15	15	Patheon Manufacturing Services LLC,
16	16	Bioton S. A., Poland
17	17	Clordysis
18	18	PCI, Philadelphia
19	19	PCI, Rockford
20	20	Steripack Medical,
21		
22		
23		

	B	C	D
25	DEV-000077 was processed as critical deviation, but without selecting the Head QA in the team. No where during the process the field was shown as required before completion of activities. Neither the section QA is able to enter the Head QA field during QA final approval. But when tried to approve through section QA prompts the message of Head QA requirement for approval	Section QA/Lead investigator should be able to select Head QA for deviation approval for critical deviations	
26	When creating root cause record at the bottom Deviation type: deviation is displayed which is non editable.	What it is for? If deviation type as in the section of deviation details should be displayed or classification of the deviation..	
27	Was unable to get the recurrence results even if the multiple record existed with same description and root cause. The recurrence check is working only if the deviation type is related to Environment/Utility Monitoring or OOAL/OOAC value selection when creating the deviation	repeat/recurrence search should return the results at In investigation stage and before investigation completed, with the root cause details filter to match. This will be required for final summary and conclusion/CAPA creation evaluations as recurring deviation might re-categorize the deviation. Or a differentiation for similar deviation and repeat deviation should be provided.	
28	When Initiating extension for the deviation DEV-000060 (due date was 16 Mar 2025) where proposed date was 29 May 2025. during approval Error message displayed: Revised Due Date Granted Field: Revised due date granted should be greater than Parent's due date Deviation due date : 16 Mar 2025 Proposed extension date: 29 May 2025 Selected Approved date : 20 May 2025	If system error to be corrected.	
29			
30			
31			
	Observations	CMO list	+

2	1	The selection criteria for reoccurrence during the investigation phase (1 year, 2 years, and 3 years) need to be discussed further.
3	2	If the deviation is identified by auditor during audits (It has happened in the past), how do we get the drop down selection of the person? What can be done in that case to select the person identified? This can be discussed with Veeva Vault team/QA team for solution
4	3	BPDR check point from Initiator shall be moved to QA assessor/ review
5	4	Recurrence check shall be limited to QA SOP, 12 months only not to provide additional options
6	5	Scope of Repeat Trend Investigation to be part of Veeva
7	6	How Trackwise and Veeva handshake for reoccurrence check
8	7	CFT child record for investigation shall be part of initial classification rather at investigation phase to avoid conflict of interest
9	8	Investigation field should include Tables and Pictures to complete the investigation within Veeva module itself
10	9	Primary Root cause Category, shall be limit to 6M, sub category to multiple dependent class
11	10	Link multiple deviation open for similar cause within same area to single report integration, only cross link no update in fields
12	11	Auto alert for any overdue submission without extension approval for user before investigation submission
13	12	recurrence check shall be only during QA review at submission
14	13	Based on recurrence check RPI -repeat trend investigation should be auto triggered (similar to TW system is required with due date calculation)
15	14	Deviation Workflow: Review and finalize the deviation workflow process, ensuring all roles and responsibilities are clearly defined and understood. (Arthur, Vidya)
16	15	Document Management: Ensure the list of documents from the DMS system is fully uploaded and available for selection in the deviation process. (Kaushik)
17	16	Deviation Classification: Discuss and finalize the questions for initial classification of deviations to ensure clarity and consistency. (Arthur, Team)
18	17	Deviation Cancellation: Clarify the process for deviation cancellation, including the roles and responsibilities for approval and rejection. (Arthur, Team)
19	18	Deviation Product Details: Ensure the ability to manually enter batch numbers for products not configured in SAP during the deviation process. (Arthur, Team)

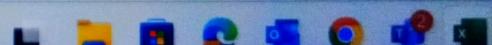
	A	B	C	D	E	F	G	H
1	Subcategory	Type	Type Definition:		Priority	Priority Definition:		
2	Deviation	Issue	Configuration issues identified during testing, Vault issues		Must Have	Requirements that are compulsorily required		
3	Investigation	Observation	Spelling mistakes in PE's		Should Have	Important functionality that should be developed		
4	CAPA	Question	Questions related to Process, Vault, Process Exercise or Lucid		Could Have	Nice to have		
5	Effectiveness Check	Requirement	New requirement, new feature, Renaming of Lifecycle states		Will not Have	Not Required		
6	Extension				NA	Not Applicable		
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19	Veeva Status							
20	New		Item has been raised, but not addressed by the Veeva Team					
21	Analysis		The Veeva Team is currently addressing the item					
22	In Progress							
23	Biocon Review Comments		Pending feedback from Biocon (Changed to by Veeva team)					
24	Veeva Review Comments		Pending feedback from Veeva (Changed to by BI team)					
25	Withdrawn		Item has been withdrawn (Duplicate etc.)					
26	Closed		Item has been addressed, and no further action is required					
27	Ready For Testing		Item has been configured and is ready for Biocon to test					
28	Deferred		Deferred for consideration for the post go live					
29	Biocon Internal		BI to review internally before passing over to Veeva					
30								
31								
32								
33								
34								
35								
36								
37								
38								
39								
40								
41								
42								

Issue Tracker - Deviation

Definitions



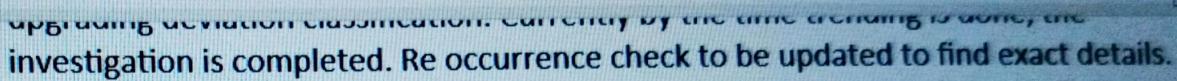
Search



A. Must Consider

- a. Nomenclature for both process and process owners should remain same across all modules and platform with clear responsibilities defined. The expected nomenclature should align to BBL either current or proposed system. For ex, site QA, SEC QA, QA HEAD, Functional QA, etc are confusion and cluster QA can be a deviation is owner require in-depth review and optimisation. And the signature tab refers only Quality.
- b. Data fields (all data fields including asset, document etc.) optimisations needs to be accurate and correct, with option to adding future data seamlessly. Importantly data field selection is also equally important. Repeating a data field process because of single selection is redundant.
- c. There is nomenclature difference between Veeva and BBL, for example, there is no equipment, but everything comes under asset, Hence defining the right nomenclature is significantly improves the process.
- d. Classification of deviation is extensively discussed, Non GMP (RND, Clinical development) should be considering while defining the criteria. Also combining multiple factors into a single question is leading to ambiguous decision. Along side YES/NO, there should be a option of Potential which should be confirmed at the final stage for closure. The final stage of deviation closure does not consider the impact, it only considered the classification.
- e. We have extensively discussed about action plan for action to be performed during or at the beginning of deviation. Like hold status. Tried but did not found a action of such kind in the current process flow.
- f. The Trending should be done either at the beginning or during the investigation, currently it is being done after the investigation. As repeated trend leads to upgrading deviation classification. Currently by the time trending is done, the investigation is completed. Re occurrence check to be updated to find exact details.
- g. There should be a notification to management filed to be updated. Currently its



1 · 2 · 3 · 4 · 5 · 6 · 7 · 8 · 9 · 10 · 11 · 12 · 13 · 14 · 15 · 

- g. There should be a notification to management filed to be updated. Currently its either being escalated or not done. We have discussed this taking a report and sending out of VEEVA. The process is fine, but this should be updated in VEEVA to update the escalation was done. Also please consider how to include the FAR notifications in process flow.
- h. Date due should not be in past.
- i. In attachment description should be made available and this should be made part of formatted report. Also, the formatted report should not contain the sections that are not applicable to a deviation.
- j. Notification terminologies should be clear, unambiguous. As discussed currently at multiple steps its tense needs to correct, the statement to be updated like, "further investigation required" etc.

B. Can be Considered.

- a. Through out the deviation, the classification is being done by USER, and if QA is not OKAY, it has authority to send it back. A better way is to Final classification either done by QA or the classification override by QA instead of sending it back.
- b. The task tab should also provide the clear tree of events like instead of "completing the inv-xxxx", a better option may be completing "inv-xxxx (dev-yyyy)"
- c. A critical deviation closure is being done by site QA, but its extension is approved by Sec QA. These type of process flows to be rationalised.
- d. The term investigator is not the same for GMP and Clinical. Hence this and as applicable the process flow/terminologies should be made unambiguous including currently appearing term GMP deviation in formatted report.

department >> owner >> deviation. I hope this should be sequence for all QMS process flow in a situation where the same process is being used across sites and department.

- f. A field named "related event" is available. While this can be referred to any quality event and not only a deviation, the same shall be appropriately defined.
- g. Once the deviation is closed, the tabs "system details and Signature" do not populate all fields, like deviation owner, submitted by etc. it only restricted to investigation details. At least the signature tab should contain all signatories.
- h. It's proposed to use Accepted for all initial Approvals like Initiated >> accepted >> investigated >> Quality approved to remove ambiguity.
- i. Fields which are not mandatory, should not be made mandatory, for example in the batch table, a comment is marked as mandatory.
- j. Signatures should have displayed the meaning screen, like submitting the record for QA acceptance or submitting the investigation for QA approval.

Initiation step by deviation owner

- Deviation type should have something prepopulated for clinical, safety and RND related topics
- Date occurred should have a range of date as from and to
- External should have CRO, CT site, BA site, outsourced vendor
- Owning department should have clinical development instead of clinical research/operations, should have clinical and research quality
- Deviation location does not have any fields related to Clinical/PV/RQA
- Asset impacted? 'Asset' not defined but is mandatory to fill
- Product impacted is mandatory to select Batch No. from drop down which is not the case always

Initial classification by deviation owner

- Impact on all parameters is either a YES or NO. But in clinical this is different as 'YES', 'MIGHT' and "NOT EXPECTED TO" impact
- The hover prompts on each impact criteria should be turned into fixed text for everyone to understand what all it consists of as this is not seen for next processors
- Impacts GXP is a broad term which includes rest of the others too creating more confusion. In such case others should be as sub-criteria
- The logic applied (all yes leading to critical, all yes except subject safety as no leading to major and all no leading to minor) should be made clear here for better judgement; writing in SOP may not help always to refer to

Section QA's review

- Adding Head QA's name should be made inactive in case it's classified as minor/major. It should not allow to put someone's name here without role of Head-QA later
- The workflow shows it's under Section QA review but while signing off the meaning of signature says QA Initial Approval. Both should indicate the same

In Investigation

editions: On

 Accessibility: Good to go

 Focus



- e. We have agreed to adopt the date format DD-MMM-YYYY for all locations. This should happen both on and off-screen display.
- f. Only approved extensions should be considered and counted as number of extensions.
- g. While fields are linked, the links of related fields should be updated at the same instance.
- h. When the deviation is **not submitted**, it can be cancelled by owner itself, without a team and can be cancelled by QA with a team assignment. This should be rationalized. When a deviation is not submitted, it does not matter whether a team id defined or not.

C. Suggestion

- a. While the configuration can be fixed, and scope of feedback is limited. It's suggested to keep the environment open and let the SME /Super SME try, so that if any critical observation (may not be a configuration) found, shall be corrected before going into validation.
- b. The mandatory fields are highlighted only on the initial screen, it should be extended to all screens.
- c. The process flow should be able to show, at which state and with whom the record is pending for how many days.
- d. If we can restrict the formatted out put to simple and plain texts without any BOLD or increase front size. It will remain uniform and contain more information.
- e. In the initial screen the deviation identified by is not a mandatory field, it should be especially when its agreed that not all can initiate deviations. Or at least it can be made mandatory for all internal deviations. And all related fields should be chronologically and sequentially arranged, like, external >> internal >> site >> department >> owner >> deviation. I hope this should be sequence for all QMS process flow in a situation where the same process is being used across sites and department.
- f. A field named "related event" is available. While this can be referred to any quality

- Upgrading deviation classification. Currently by the time deviating is done, the investigation is completed. Re occurrence check to be updated to find exact details.
- g. There should be a notification to management filed to be updated. Currently its either being escalated or not done. We have discussed this taking a report and sending out of VEEVA. The process is fine, but this should be updated in VEEVA to update the escalation was done. Also please consider how to include the FAR notifications in process flow.
 - h. Date due should not be in past.
 - i. In attachment description should be made available and this should be made part of formatted report. Also, the formatted report should not contain the sections that are not applicable to a deviation.
 - j. Notification terminologies should be clear, unambiguous. As discussed currently at multiple steps its tense needs to correct, the statement to be updated like, "further investigation required" etc.

B. Can be Considered.

- a. Through out the deviation, the classification is being done by USER, and if QA is not OKAY, it has authority to send it back. A better way is to Final classification either done by QA or the classification override by QA in stead of sending it back.
- b. The task tab should also provide the clear tree of events like instead of "completing the inv-xxxx", a better option may be completing "inv-xxxx (dev-yyyy)"
- c. A critical deviation closure is being done by site QA, but its extension is approved by Sec QA. These type of process flows to be rationalised.
- d. The term investigator is not the same for GMP and Clinical. Hence this and as applicable the process flow/terminologies should be made unambiguous including currently appearing term GMP deviation in formatted report.

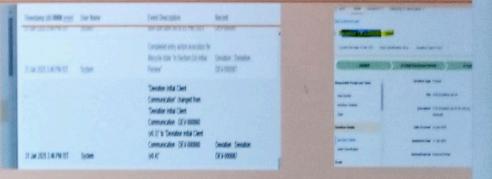
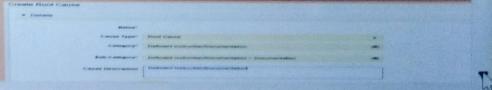
- e. We have agreed to adopt the date format DD-MMM-YYYY for all locations. This should happen both on and off-screen display.
- f. Only approved extensions should be considered and counted as number of extensions.
- g. While fields are linked, the links of related fields should be updated at the same instance.
- h. When the deviation is **not submitted**, it can be cancelled by owner itself, without a team and can be cancelled by QA with a team assignment. This should be rationalized. When a deviation is not submitted, it does not matter whether a team id defined or not.

C. Suggestion

- a. While the configuration can be fixed, and scope of feedback is limited. It's suggested to keep the environment open and let the SME /Super SME try, so that if any critical observation (may not be a configuration) found, shall be corrected before going into validation.
- b. The mandatory fields are highlighted only on the initial screen, it should be extended to all screens.
- c. The process flow should be able to show, at which state and with whom the record is pending for how many days.
- d. If we can restrict the formatted out put to simple and plain texts without any BOLD or increase front size. It will remain uniform and contain more information.
- e. In the initial screen the deviation identified by is not a mandatory field, it should be especially when its agreed that not all can initiate deviations. Or at least it can be made mandatory for all internal deviations. And all related fields should be chronologically and sequentially arranged, like, external >> internal >> site >> department >> owner >> deviation. I hope this should be sequence for all QMS process flow in a situation where the same process is being used across sites and department.
- f. A field named "related event" is available. While this can be referred to any quality system, this field shall be appropriately defined.

A	B	C
11 10	Link multiple deviation open for similar cause within same area to single report integration, only cross link no update in fields	
12 11	Auto alert for any overdue submission without extension approval for user before investigation submission	
13 12	recurrence check shall be only during QA review at submission	
14 13	Based on recurrence check RPI -repeat trend investigation should be auto triggered (similar to TW system is required with due date calculation)	
15 14	Deviation Workflow: Review and finalize the deviation workflow process, ensuring all roles and responsibilities are clearly defined and understood. (Arthur, Vidya)	
16 15	Document Management: Ensure the list of documents from the DMS system is fully uploaded and available for selection in the deviation process. (Kaushik)	
17 16	Deviation Classification: Discuss and finalize the questions for initial classification of deviations to ensure clarity and consistency. (Arthur, Team)	
18 17	Deviation Cancellation: Clarify the process for deviation cancellation, including the roles and responsibilities for approval and rejection. (Arthur, Team)	
19 18	Deviation Product Details: Ensure the ability to manually enter batch numbers for products not configured in SAP during the deviation process. (Arthur, Team)	
20 19	Deviation Impact Assessment: Review and refine the impact assessment questions to ensure they accurately reflect the potential impact on patient safety, data quality, and regulatory compliance. (Arthur, Team)	
21 20	Deviation Attachments: Test the upload speed and functionality for attachments in the deviation process to ensure efficiency. (Arthur, Team)	
22 21	Deviation Notifications: Verify the configuration of email notifications for deviation tasks to ensure all relevant parties are informed promptly. (Arthur, Team)	
23		
24		
25		

A	B
S. No.	Points Raised
1 1	The selection criteria for reoccurrence during the investigation phase (1 year, 2 years, and 3 years) need to be discussed further.
2 2	If the deviation is identified by auditor during audits (It has happened in the past), how do we get the drop down selection of the person? What can be done in that case to select the person identified? This can be discussed with Veeva Vault team/QA team for solution
3 3	BPDR check point from Initiator shall be moved to QA assessor/ review
4 4	Recurrence check shall be limited to QA SOP, 12 months only not to provide additional options
5 5	Scope of Repeat Trend Investigation to be part of Veeva
6 6	How Trackwise and Veeva handshake for reoccurrence check
7 7	CFT child record for investigation shall be part of initial classification rather at investigation phase to avoid conflict of interest
8 8	Investigation field should include Tables and Pictures to complete the investigation within Veeva module itself
9 9	Primary Root cause Category, shall be limit to 6M, sub category to multiple dependent class
10 10	Link multiple deviation open for similar cause within same area to single report integration, only cross link no update in fields
11 11	Auto alert for any overdue submission without extension approval for user before investigation submission
12 12	recurrence check shall be only during QA review at submission
13 13	Based on recurrence check RPI -repeat trend investigation should be auto triggered (similar to TW system is required with due date calculation)
14 14	Deviation Workflow: Review and finalize the deviation workflow process, ensuring all roles and responsibilities are clearly defined and understood. (Arthur, Vidya)
15 15	Document Management: Ensure the list of documents from the DMS system is fully uploaded and available for selection in the deviation process. (Kaushik)
16 16	Deviation Classification: Discuss and finalize the questions for initial classification of deviations to ensure clarity and consistency. (Arthur, Team)
17 17	Deviation Cancellation: Clarify the process for deviation cancellation, including the roles and responsibilities for approval and rejection. (Arthur, Team)
18 18	Deviation Product Details: Ensure the ability to manually enter batch numbers for products not configured in SAP during the deviation process. (Arthur, Team)

Breakdown/hurdles observed during the record processing			
Sr. No.	Observations /Fields/State	Requirement	ScreenShot/image of the error
1	Deviation initial and final client notification was generated and came attached in the deviation details automatically for Deviation: DEV-000087. But the notification is of Deviation 000060	Deviation notification report generation manually.	
2	DEV-000060 was rejected at the final approver state, and hence investigation records also re-opened to investigation. Out of two investigations one was modified, and another was not modified/edited, closure was allowed. Deviation: DEV-000077 for this initial ,client notification generated for dev no. 66 but final client deviation is for 77	The appropriate notification should be generated. Also when notifications are generated to be shared with client/partner for approval, a field within the system generated report for client/partner approval comments and signature is required.	
3	Was Unable to change the investigator, section QA at In investigation state	Should be able to change/delegate the investigator/section QA/ Head (All the roles that would be part of the record irrespective of state)	
4	DEV-000077 was processed as critical deviation, but without selecting the Head QA in the team. No where during the process the field was shown as required before completion of activities. Neither the section QA is able to enter the Head QA field during QA final approval. But when tried to approve through section QA prompts the message of Head QA requirement for approval	Section QA/Lead investigator should be able to select Head QA for deviation approval for critical deviations	
5	When creating root cause record at the bottom Deviation type: deviation is displayed which is non editable.	What it is for? If deviation type as in the section of deviation details should be displayed or classification of the deviation..	

Observations

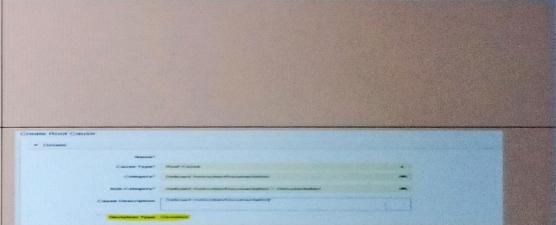
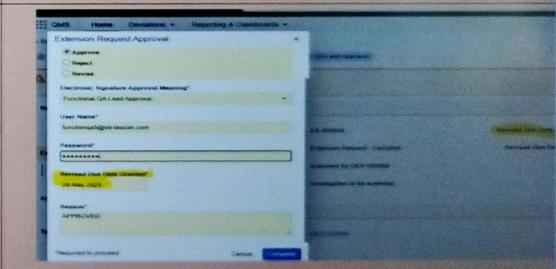
CMO list

+

22°C
Partly cloudy

Search

22:10
18/07/2025

	B	C	D
25	DEV-000077 was processed as critical deviation, but without selecting the Head QA in the team. No where during the process the field was shown as required before completion of activities. Neither the section QA is able to enter the Head QA field during QA final approval. But when tried to approve through section QA prompts the message of Head QA requirement for approval.	Section QA/Lead investigator should be able to select Head QA for deviation approval for critical deviations	
26	When creating root cause record at the bottom Deviation type: deviation is displayed which is non editable.	What it is for? If deviation type as in the section of deviation details should be displayed or classification of the deviation..	
27	Was unable to get the recurrence results even if the multiple record existed with same description and root cause. The recurrence check is working only if the deviation type is related to Environment/Utility Monitoring or OOAL/OOAC value selection when creating the deviation	repeat/recurrence search should return the results at In investigation stage and before investigation completed, with the root cause details filter to match. This will be required for final summary and conclusion/CAPA creation evaluations as recurring deviation might re-categorize the deviation. Or a differentiation for similar deviation and repeat deviation should be provided.	
28	When Initiating extension for the deviation DEV-000060 (due date was 16 Mar 2025) where proposed date was 29 may 2025. during approval Error message displayed: Revised Due Date Granted Field: Revised due date granted should be greater than Parent's due date Deviation due date : 16 Mar 2025 Proposed extension date: 29 May 2025 Selected Approved date : 20 May 2025	If system error to be corrected.	
29			
30			
31			
	Observations CMO list +		
	9 22°C Partly cloudy	Search	22:12 18/07/2025

E11

▼ ⋮ ✖ ✓ fx ▼

A

B

	Sr No.	Site Name
1	1	Virchow Biotech
2	2	Kemwell Biopharma Pvt Ltd
3	3	Mylan Onco Therapies Limited
4	4	Chemman Labs Pvt. Ltd., (Wyzon)
5	5	Wuxi Biologics
6	6	Lupin Limited , Pune
7	7	Lupin, Mihan
8	8	Stephar B.V.
9	9	SHL Pharma LLC
10	10	Prespack, Sp. Z o.o.ul (Wysogotowo)
11	11	FKB-TERUMO DP
12	12	FKB-KKC DS
13	13	PCI Ireland(Millmount)
14	14	PCI Pharma Services Ltd. (UK) (Andersson Brecon Limited)
15	15	Patheon Manufacturing Services LLC,
16	16	Bioton S. A., Poland
17	17	Clordysis
18	18	PCI, Philadelphia
19	19	PCI, Rockford
20	20	Steripack Medical,

< >

Observations

CMO list

+



22°C

Partly cloudy



Search

D17			
A	B	C	
13	Was unable to view the notification details under Related Processes as available in the system. Instead it is appearing in the initial deviation details section automatically, and not sure at what stage is being updated there.	The notofocation will also be shared with QP in case of EQO apart from the partners. Hence the terminology of client notofocation to be renamed. (A general term for notification when shared for communicatio/approval outside the company i.e., with QP/Partner/Client/Supplier)	
14	In Investigation State No cancellation available	If technically investigation is not initiated, a cancellation with QA approval can be provided.	
15	"Responsible People and Tasks"	The section under "Responsible People and Tasks" can be made collapsible, expandable for main section	
16	State of In Intial submission review	The State of In Intial submission review can be made to Section QA review as that activity is done by Section QA, and under Section QA. Current state title is leading to confusion as it appears to be pending with owner for initial review submission.	
17	NA	The role names should be harmonised across the module, activity or states especially for QA terminologies..	
Breakdown/hurdles observed during the record processing			
Sr. No.	Observations /Fields/State	Requirement	ScreenShot/Image of the same
1	Deviation initial and final client notification was generated and	Deviation notification generated correctly	

A	B	C
8	7 As escalations are manual out of the Veeva system for critical escalation numbers are generated as per procedure.	field to update the escalation numbers and document the escalation details(personnel escalation notification sent to, outcome decision of the escalation if any) is required
9	8 It appears notification issuance, escalation issuance is automated. But at what stage the escalation triggers. Initial classification? Or final classification? All the sections under Related process are non-editable, and no details were visible even when deviations created for external partner, and critical	to be sorted out and instructions required of usage.
10	9 Further Investigation required : Yes selection becomes mandatory when completing investigation even when technically investigation is completed and closed.	the field option can be removed, or if it related to some other process, the renaming of the field to be considered to avoid confusion.
11	10 Lead investigation cannot be done by section QA	Multiple role by individual user required (with control for no two different activity performed by same user).Ex :quality department/team investigation, review approval are within the QA. The Leadinvestigator in QA department can become a section QA to a CFT.
12	11 There is no section for amendment in the left side pane (like extension, CAPA, etc) under related Processes. The amendment details are entered only during signature in a field. The reason/details are visible only when viewed in workflow timeline.	A section for amendment can be kept under Related processes, along with EC, extensions.
13	12 In the formatted reports all empty fields are also exported.	Empty fields need not be part of report
14	13 Was unable to view the notification details under Related Processes as available in the system. Instead it is appearing in the initial deviation details section automatically, and not sure at what stage is being updated there.	The notification will also be shared with QP in case of EQO apart from the partners. Hence the terminology of client notification to be renamed. (A general term for notification when shared for communication/approval outside the company i.e., with QP/Partner/Client/Supplier)
15	14 In Investigation State No cancellation available	If technically investigation is not initiated, a cancellation with QA approval can be provided.

Sr No.	Observations /Fields/State	Requirement
1	1 Owning Facility and Departments (Fields)	External manufacturing (To log the QMS from external sites/facilities occurred at external site/facility) External warehouse ((To log the QMS from external sites/facilities occurred at external site/facility) External Testing Lab ((To log the QMS from external sites/facilities occurred at external site/facility) External Quality Organization (This will be required to handle EQO internal QMS
2	2 Deviation Type(field)	Testing (option for value selection is required, as testing related QMS from external labs are logged by EQO)
3	3 External partner QMS reference No. Field	The free text field required to enter External partner QMS reference No. Field when the deviations related external partner are logged
4	4 Customer Name Field	The field name to be changed to partner as the external sites are not customers for EQO.
5	5 Customer Name Field value list	Refer to the list of CMO list sheet in the excel. In addition the list of testing lab and warehouse is available with CQA as service provider in the system. Same to be considered
6	6 Immediate Action Taken By	The field is value selection (BBL employee names), in case of EQO, immediate actions are taken at sites by site personnel. This field can be made non-mandatory if deviation is related to external partner.
7	7 As escalations are manual out of the Veeva system for critical escalation numbers are generated as per procedure.	field to update the escalation numbers and document the escalation details (personnel escalation notification sent to, outcome decision of the escalation if any) is required
8		

A. Must Consider

- a. Nomenclature for both process and process owners should remain same across all modules and platform with clear responsibilities defined. The expected nomenclature should align to BBL either current or proposed system. For ex, site QA, SEC QA, QA HEAD, Functional QA, etc are confusion and cluster QA can be a deviation is owner require in-depth review and optimisation. And the signature tab refers only Quality.
- b. Data fields (all data fields including asset, document etc.) optimisations needs to be accurate and correct, with option to adding future data seamlessly. Importantly data field selection is also equality important. Repeating a data field process because of single selection is redundant.
- c. There is nomenclature difference between Veeva and BBL, for example, there is no equipment, but everything comes under asset, Hence defining the right nomenclature is significantly improves the process. .
- d. Classification of deviation is extensively discussed, Non GMP (RND, Clinical development) should be considering while defining the criteria. Also combining multiple factors into a single question is leading to ambiguous decision. Along side YES/NO, there should be a option of Potential which should be confirmed at the final stage for closure. The final stage of deviation closure does not consider the impact, it only considered the classification.
- e. We have extensively discussed about action plan for action to be performed during or at the beginning of deviation. Like hold status. Tried but did not found a action of such kind in the current process flow.
- f. The Trending should be done either at the beginning or during the investigation, currently it is being done after the investigation. As repeated trend leads to upgrading deviation classification. Currently by the time trending is done, the investigation is completed. Re occurrence check to be updated to find exact details.
- g. There should be a notification to management filed to be updated. Currently its