

Instructions for GXP Change Management steps and GXP Related CIs

Article ID: KB0038342

Created: 2024-12-16 20:50:06

Updated: 2025-01-08 15:47:39

Author: {'link':

'https://fmcnadev.service-now.com/api/now/table/sys_user/c39a6bc26fb9860070404a950d3ee41e',

'value': 'c39a6bc26fb9860070404a950d3ee41e'}

Category: {'link':

'https://fmcnadev.service-now.com/api/now/table/kb_category/fc7d1a0987177494e3f297d83cbb3570',

'value': 'fc7d1a0987177494e3f297d83cbb3570'}

What must follow the requirements for GXP in Change Management

The Service Offerings listed below are GXP relevant. If one of those listed is affected by the change being implemented (Normal, Emergency and Non-Production) then the steps listed below must be followed.

PFMEEPHAP003

PFMEETLAPP001\PFMES17ETL

qfmeephap002

TFMEHD3AP8002

PFMEEPHAP004

pfmeptcdb001a

QFMEMAQAP001

TFMEHD3DB8001

PFMEEPHCS002

pfmetblap1002

TFMEETLAPP001\TFMES17ETL

tfmetblap1002

pfmeephdb002

PFMEETLAPP001

PFMEHD2AP001

PFMEHD2AP002

pfmeptcdb001b

PFMEHD2DB001

PFMEMAQAP001

pfmetblap1003

pfmetblap1002

PFMES16DB002

TFMEETLAPP001

wffmc01

tfmetblap1003

TFMES16DB002

Additional steps for implementation for the Non-production change

Prepare the GXP approval document (see attachment in this knowledge article) for this change. Communicate to the GXP approvers for this change in the test environment along with the GXP approval document and receive their electronic signature approval for implementation to the test environment. In the change record set the field GXP Relevant to "Yes".

Add a Review task to the change record with the Short Description "GXP approval post implementation" and assign it to the team owning the change.

When the change record moves to an Authorize state, the GXP approvals will be added to the Approvals tab.

Once one of them approves the change in the change record, the change coordinator (Assigned to field) will then be added as approver.

After implementation, request the GXP approvers for this change to verify the implementation and give signoff on the approval document. Add the email and document of their signoff to the task "GXP approval post implementation".

Additional steps for implementation for the Production change

Update the GXP approval document for this change. Communicate to the GXP approvers for this change in the test environment along with the GXP approval document and receive their electronic signature approval for implementation to the test environment. In the change record set the field GXP Relevant to "Yes".

Relate the test change record to this change record (if there is one). Add a Review task to the change record with the Short Description "GXP approval post implementation" and assign it to the team owning the change.

When the change record moves to an Authorize state, the GXP approvals will be added to the Approvals tab.

Once one of them approves the change in the change record, the change coordinator (Assigned to field) will then be added as approver.

After implementation, request the GXP approvers for this change to verify the implementation and give signoff in the approval document. Add the email and document of their signoff to the task "GXP approval post implementation".