VIAMED

zztest not real file

Carried out by Derek Lamb
16 / 10 / 18

VIAMED

- Stock References Review

- Supplier Review

- Sales Review

- Countries Review

- Returns Review

- Design Changes Review

- User Instructions Review

- Labels Review

- Document Updates Review

- Internal Issues Review

- Clinical / FDA Incidents online search

Stock References Review

Stock Reference	Description
testitem	

Comments on Stock references review:

Supplier Review

Comments on Suppliers:

Sales Information

Stock Reference	Description	2012	2013	2014	2015	2016	2017	2018
testitem								

Comments on Sales Information:

Countries Review

Comments on Sales to Countries:

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2012	2013	2014	2015	2016	2017	2018
testitem	Needs Evaluating						1	
testitem	new fault with test							1
testitem	test had error 1						1	
testitem	test had error 2						1	

Comments on Returns:

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

Comments on Risks with Design Changes:

User Instructions Review

Comments on User Instructions:

Comments on Risks User Instructions:

Labels Review

Comments on Labels:

Comments on Risks Labels:

Documentation Updates / Changes

Comments on Document Changes:

Comments on Risks with Document Changes:

Internal Issues Review
Number of Issues reviewed: 8

Issue ID	Subject
106861	Office Meeting Post Market Surveilance File 38 zztest not real file Risk File Updated
106859	Office Meeting Post Market Surveilance File 38 zztest not real file Risk File Updated
124350	Office Meeting VIAMED Management Meeting Software Validation Document Control (802)
118617	Office Meeting VIAMED Management Meeting Software Validation Document Control (802)
112844	Office Meeting VIAMED Management Meeting Software Validation Document Control (802)
130316	Office Meeting VIAMED Management Meeting Software Validation Non Conformance Product Risk Feedback Loop (789)
106801	Office Meeting Non Conformance Issues TESTITEM test Non Conformance
106806	Office Meeting Production Problems we havew a problem

Comments on Issues:

Comments on Risks with Issues:

VIAMED Sales And Marketing - Post Market Surveilance
File 38 zztest not real file Risk File Updated
Issue ID #106861
Date Created 30/Oct/2017
Issued To: Derek Lamb
Completed Status: 30 Oct 2017
Stock Ref: testitem

Notes:
Risk file has changed, VM3COP27.12 Needs reviewing for 38 zztest not real file as the Risk assesment has
changed
_____
30 Oct 2017 Derek Lamb

_____
Issues:106861

VIAMED Sales And Marketing - Post Market Surveilance
File 38 zztest not real file Risk File Updated
Issue ID #106859
Date Created 30/Oct/2017
Issued To: Derek Lamb
Completed Status: 30 Oct 2017
Stock Ref: testitem

Notes:
Risk file has changed, VM3COP27.12 Needs reviewing for 38 zztest not real file as the Risk assesment has changed

_____

30 Oct 2017 Derek Lamb

_____

Issues:106859

VIAMED Management Meeting - VIAMED Management Meeting
Software Validation Document Control (802)
Issue ID #124350
Date Created 20/Jul/2018
Issued To: Derek Lamb
Completed Status: 25 Jul 2018

Notes:
System Generated
Task To be Completed To test document control is working as intended.

Search Stock Item testitem
search for linked documents,

should be a test document in the attached documents bring up the document,

Check document is on the out of date documents list

download the work doc,

update the word file with current date,produce pdf of new fileupload ontop of the old file.

update the expiry date of the new document,
Document should no longer be on the out of date document list
_____
 20 Jul 2018 Derek Lamb
  working as intended,
changing the rolling issue to 6 monthly
_____
Issues:124350

VIAMED Management Meeting - VIAMED Management Meeting
Software Validation Document Control (802)
Issue ID #118617
Date Created 20/Apr/2018
Issued To: Derek Lamb
Completed Status: 10 May 2018

Notes:
System Generated
Task To be Completed To test document control is working as intended.

Search Stock Item testitem
search for linked documents,

should be a test document in the attached documents bring up the document,

Check document is on the out of date documents list

download the work doc,

update the word file with current date,produce pdf of new fileupload ontop of the old file.

update the expiry date of the new document,
Document should no longer be on the out of date document list
_____
 04 May 2018 Derek Lamb
 dobne
_____

Issues:118617

VIAMED Management Meeting - VIAMED Management Meeting
Software Validation Document Control (802)
Issue ID #112844
Date Created 22/Jan/2018
Issued To: Derek Lamb
Completed Status: 23 Jan 2018

Notes:
    System Generated
    Task To be Completed To test document control is working as intended.

    Search Stock Item testitem
    search for linked documents,

    should be a test document in the attached documents bring up the document,

    Check document is on the out of date documents list

    download the work doc,

    update the word file with current date,produce pdf of new fileupload ontop of the old file.

    update the expiry date of the new document,
    Document should no longer be on the out of date document list
    _____
    22 Jan 2018 Derek Lamb
     all done and works ok

    _____

Issues:112844

VIAMED Management Meeting - VIAMED Management Meeting
Software Validation Non Conformance Product Risk Feedback Loop (789)
Issue ID #130316
Date Created 16/Oct/2018
Issued To: Derek Lamb
Completed Status: Still Outstanding

Notes:
  System Generated
   Task To be Completed

  testitem

  Create a Non Conformance from this Issue.

  then review the Post Market Surveillance against the Test Technical file zztest not real file.

  Scroll down to the Issues section, the Non conformance issue and this Issue Should be present
  _____
  16 Oct 2018 Derek Lamb
  Created Related Issue #130334
  Added by Derek Lamb sent to Derek Lamb
  test non conformance issue only
  _____
  Issues:130316

Non Conformance Issues - Non Conformance Issues
TESTITEM test Non Conformance
Issue ID #106801
Date Created 30/Oct/2017
Issued To: Derek Lamb
Completed Status: 02 Nov 2017

Notes:
   Added by Derek Lamb sent to Derek Lamb
   raised non conformance

_____
  31 Oct 2017 Derek Lamb

_____
  Issues:106801

Production - Production Problems
we havew a problem
Issue ID #106806
Date Created 30/Oct/2017
Issued To: Auditor
Completed Status: 31 Oct 2017

Notes:
Added by Auditor sent to Auditor
with testitem

_____
31 Oct 2017 Auditor

_____
31 Oct 2017 Auditor

_____
Issues:106806

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem   :
Do any of the Results indicate outdated Technology   :
Comments on Clinical Search :

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem :
Do any of the Results indicate outdated Technology :
Comments on Clinical Search :