

SQA Metric Items From FPA Spreadsheet - June 2018

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Abstract

Evaluation of various potential metrics, performance indicators from the Excel workbook that Software Quality Assurance collected called First Pass Acceptance. This will only be run for the month of January 2018. ¹

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¹Date Ran: Wednesday 1st August, 2018 at 10:42

1 Introduction

The data is processed using R², Version 3.5.1 named “Feather Spray”. The only extension (package or library) utilized is lubridate (version 1.7.4) to provide key functionality in the processing of dates.

The data is read into R from a comma seperated value (csv) file which is derived (saved) from the spreadsheet without modification. Additional values are computed as needed.

This report is prepared in the R enviroment using a collection of packages know as Sweave that included knitr which in turn feeds the package into L^AT_EX 2_ε a typesetting program to produce a PDF file. L^AT_EX 2_ε is implmented in MiT_EX. L^AT_EX 2_ε is utilizing the folowing packages to control style and formating:

- datetime and
- multitoc

This will only show a point in time summary and no trends.

2 Data and Calculations

2.1 Data

A seperate data dictionary will be prepared to for both the source data and computed values stored in R.

2.2 Calculations

All calculations presented here have not been implemented in R as formulas.

3 Work Yet to be Completed

3.1 Formula

Some calculations would be better implemented as formulas. The calculations need to be evulated and the formulas developed where needed.

3.2 Trending

Eventually the “System” will be updated to select the data on a for a calander month. After processing the resulots will be stored in a seperate file. This will allow for longer term trending of this data.

3.2.1 Graphs

When “trending” is implmented graphs of the trends will also be added.

²RStudio is utilized as an IDE

4 Quantity Metrics

4.1 Application supported

This is a list of all application support this period.

Note: Alphabetize the list

- [1] "GS Reports"
- [2] "DARA Filler DHM and RU"
- [3] "CMSNext"
- [4] "EP Evaluator"
- [5] "TrendReader"
- [6] "CMSnext"
- [7] "GDSN/GS1"
- [8] "Alinity S Non-LIMS spreadsheets"
- [9] "WWLIMS"
- [10] "DFCS"
- [11] "IRIS"
- [12] "Pulse"
- [13] "Knowledge Management"
- [14] "ADD Shop Floor Paper (SFP) Report System"
- [15] "eNovator"

4.2 Number of Projects

The total number of projects worked on in this period. This may differ from the application list because some applications may have more than one project in the period.

- [1] 28

4.3 Number of Reviews

This is the number of items reviewed, a document will be counted more than once if it is reviewed more than once.

- [1] 176

4.4 Number of Items Reviewed

This is the number of unique items reviewed, each item is only counted once regardless of how many times it is reviewed.

Note: This is reporting low due to certain items having no way to discriminate between such as multiple executions of the same test script or results from an IIVP run on different computers within the same project.

- [1] 134

4.5 Number of Projects Started

The point at which a project is started is when version 1 of the *Software Change Request* is approved.

Note: This now counts ML type projects (Metrics Library and GS Reports) using the Project Plan as the point that a project starts.

[1] 8

4.6 Projects Completed

The point at which a project is considered completed is when version 1 of the *System Certification Summary* is approved.

Note: now counts GS (Global Service) Reports Move to Production as the end of project.

[1] 7

4.7 Number Of Deliverables by Type

This is unique for each deliverable. It only counts each document once so a deliverable that is disapproved and then approved is only counted once.

Cancellation	CII
2	10
Decommissioning Report	Design Documentation
0	0
Design Verification	ERES
4	1
FRS	IDP
1	5
IIVP	IIVP results
10	21
IIVP Results	ISSD
0	2
Maintenance Plan	Move to Production
2	4
Other	Project Plan
1	6
Release Notes	Risk Assessment
0	1
Software Change Request	Software Compliance Assessment
8	1
System Certification Summary	Test Protocol
5	17
Test Protocol Results	Traceability
14	9

	URS	URS/FRS
	3	0
User Acceptance Protocol	User Acceptance Protocol	results
	1	4
Validation Plan		
	2	

4.8 Number of Deliverable by Application

This is the number of unique deliverables that each application submitted. It only counts each document once, regardless of the status.

Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	1
AFMS	0
Alinity S Non-LIMS spreadsheets	3
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	1
CMSNext	40
DARA Filler DHM and RU	7
DaVinci	0
DFCS	9
DPW	0
EDMS	0

eNovator	
	1
EP Evaluator	
	1
GDSN/GS1	
	3
Groninger	
	0
GS Reports	
	8
ideaPoint	
	0
IRIS	
	2
Knowledge Management	
	2
Metrics Library	
	0
Navigator	
	0
PCN/SCN	
	0
PEAR	
	0
Power BI	
	0
Print on Demand	
	0
Pulse	
	7
QIMS	
	0
Reliasoft Xfmea	
	0
RSLMS	
	0
SAS	
	0
TestComplete	
	0
TODS	
	0
TrendReader	
	13
WWLIMS	
	36

4.9 Number of Approvals, Disapprovals, and First Pass Approvals

A	A-FP	D
33	100	43

4.10 Table of Deliverables by Application

	Cancellation	CII
Abbott Transfusion Medicine	0	0
ADD Shop Floor Paper (SFP) Report System	0	0
AFMS	0	0
Alinity S Non-LIMS spreadsheets	0	0
Alinity Source Verifier	0	0
AMM	0	0
AP 24 CIP	0	0
Apollo/PHM	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CMSnext	0	0
CMSNext	1	3
DARA Filler DHM and RU	0	2
DaVinci	0	0
DFCS	0	0
DPW	0	0
EDMS	0	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	0
Groninger	0	0
GS Reports	0	0
ideaPoint	0	0
IRIS	0	0
Knowledge Management	0	0
Metrics Library	0	0
Navigator	0	0
PCN/SCN	0	0
PEAR	0	0
Power BI	0	0
Print on Demand	0	0
Pulse	0	0
QIMS	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0

TODS	0	0
TrendReader	1	1
WWLIMS	0	4

Decommissioning Report

Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	0

	Design Documentation
Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	0

	Design Verification	ERES	FRS	IDP
Abbott Transfusion Medicine	0	0	0	0
ADD Shop Floor Paper (SFP) Report System	0	0	0	0
AFMS	0	0	0	0

Alinity S Non-LIMS spreadsheets	0	0	0	0
Alinity Source Verifier	0	0	0	0
AMM	0	0	0	0
AP 24 CIP	0	0	0	0
Apollo/PHM	0	0	0	0
Assay File Database	0	0	0	0
BioCommand Batch Control Plus	0	0	0	0
CMSnext	0	0	0	1
CMSNext	2	0	0	1
DARA Filler DHM and RU	0	0	0	1
DaVinci	0	0	0	0
DFCS	0	0	0	0
DPW	0	0	0	0
EDMS	0	0	0	0
eNovator	0	0	0	1
EP Evaluator	0	1	0	0
GDSN/GS1	0	0	1	0
Groninger	0	0	0	0
GS Reports	0	0	0	0
ideaPoint	0	0	0	0
IRIS	0	0	0	0
Knowledge Management	0	0	0	0
Metrics Library	0	0	0	0
Navigator	0	0	0	0
PCN/SCN	0	0	0	0
PEAR	0	0	0	0
Power BI	0	0	0	0
Print on Demand	0	0	0	0
Pulse	0	0	0	0
QIMS	0	0	0	0
Reliasoft Xfmea	0	0	0	0
RSLMS	0	0	0	0
SAS	0	0	0	0
TestComplete	0	0	0	0
TODS	0	0	0	0
TrendReader	0	0	0	0
WVLIMS	2	0	0	1

	IIVP	IIVP results	IIVP Results	ISSD
Abbott Transfusion Medicine	0	0	0	0
ADD Shop Floor Paper (SFP) Report System	1	0	0	0
AFMS	0	0	0	0
Alinity S Non-LIMS spreadsheets	0	0	0	0
Alinity Source Verifier	0	0	0	0
AMM	0	0	0	0
AP 24 CIP	0	0	0	0

Apollo/PHM	0	0	0	0
Assay File Database	0	0	0	0
BioCommand Batch Control Plus	0	0	0	0
CMSnext	0	0	0	0
CMSNext	1	5	0	1
DARA Filler DHM and RU	2	2	0	0
DaVinci	0	0	0	0
DFCS	0	0	0	0
DPW	0	0	0	0
EDMS	0	0	0	0
eNovator	0	0	0	0
EP Evaluator	0	0	0	0
GDSN/GS1	0	0	0	0
Groninger	0	0	0	0
GS Reports	0	0	0	0
ideaPoint	0	0	0	0
IRIS	2	0	0	0
Knowledge Management	0	0	0	1
Metrics Library	0	0	0	0
Navigator	0	0	0	0
PCN/SCN	0	0	0	0
PEAR	0	0	0	0
Power BI	0	0	0	0
Print on Demand	0	0	0	0
Pulse	0	0	0	0
QIMS	0	0	0	0
Reliasoft Xfmea	0	0	0	0
RSLMS	0	0	0	0
SAS	0	0	0	0
TestComplete	0	0	0	0
TODS	0	0	0	0
TrendReader	1	3	0	0
WVLIMS	3	11	0	0

Maintenance Plan Move to Production

Abbott Transfusion Medicine	0	0
ADD Shop Floor Paper (SFP) Report System	0	0
AFMS	0	0
Alinity S Non-LIMS spreadsheets	0	0
Alinity Source Verifier	0	0
AMM	0	0
AP 24 CIP	0	0
Apollo/PHM	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CMSnext	0	0

CMSNext	1	0
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	0	0
DPW	0	0
EDMS	0	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	0
Groninger	0	0
GS Reports	0	4
ideaPoint	0	0
IRIS	0	0
Knowledge Management	0	0
Metrics Library	0	0
Navigator	0	0
PCN/SCN	0	0
PEAR	0	0
Power BI	0	0
Print on Demand	0	0
Pulse	0	0
QIMS	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	1	0
WVLIMS	0	0

	Other Project Plan Release Notes		
Abbott Transfusion Medicine	0	0	0
ADD Shop Floor Paper (SFP) Report System	0	0	0
AFMS	0	0	0
Alinity S Non-LIMS spreadsheets	0	0	0
Alinity Source Verifier	0	0	0
AMM	0	0	0
AP 24 CIP	0	0	0
Apollo/PHM	0	0	0
Assay File Database	0	0	0
BioCommand Batch Control Plus	0	0	0
CMSnext	0	0	0
CMSNext	1	0	0
DARA Filler DHM and RU	0	0	0
DaVinci	0	0	0
DFCS	0	2	0

DPW	0	0	0
EDMS	0	0	0
eNovator	0	0	0
EP Evaluator	0	0	0
GDSN/GS1	0	0	0
Groninger	0	0	0
GS Reports	0	4	0
ideaPoint	0	0	0
IRIS	0	0	0
Knowledge Management	0	0	0
Metrics Library	0	0	0
Navigator	0	0	0
PCN/SCN	0	0	0
PEAR	0	0	0
Power BI	0	0	0
Print on Demand	0	0	0
Pulse	0	0	0
QIMS	0	0	0
Reliasoft Xfmea	0	0	0
RSLMS	0	0	0
SAS	0	0	0
TestComplete	0	0	0
TODS	0	0	0
TrendReader	0	0	0
WVLIMS	0	0	0

Risk Assessment

Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0

GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	1
WWLIMS	0

Software Change Request

Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	1
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	1
DARA Filler DHM and RU	0
DaVinci	0
DFCS	2
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0

IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	1
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	2
WVLIMS	1

Software Compliance Assessment

Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0

PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	1

System Certification Summary

Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	2
DARA Filler DHM and RU	0
DaVinci	0
DFCS	1
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	1
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0

Pulse	0
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	1

	Test Protocol	Test Protocol Results
Abbott Transfusion Medicine	0	0
ADD Shop Floor Paper (SFP) Report System	0	0
AFMS	0	0
Alinity S Non-LIMS spreadsheets	1	0
Alinity Source Verifier	0	0
AMM	0	0
AP 24 CIP	0	0
Apollo/PHM	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CMSnext	0	0
CMSNext	10	9
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	0	0
DPW	0	0
EDMS	0	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	0
Groninger	0	0
GS Reports	0	0
ideaPoint	0	0
IRIS	0	0
Knowledge Management	0	0
Metrics Library	0	0
Navigator	0	0
PCN/SCN	0	0
PEAR	0	0
Power BI	0	0
Print on Demand	0	0
Pulse	2	0
QIMS	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0

SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	2	0
WVLIMS	2	5

	Traceability	URS	URS/FRS
Abbott Transfusion Medicine	0	0	0
ADD Shop Floor Paper (SFP) Report System	0	0	0
AFMS	0	0	0
Alinity S Non-LIMS spreadsheets	0	1	0
Alinity Source Verifier	0	0	0
AMM	0	0	0
AP 24 CIP	0	0	0
Apollo/PHM	0	0	0
Assay File Database	0	0	0
BioCommand Batch Control Plus	0	0	0
CMSnext	0	0	0
CMSNext	2	0	0
DARA Filler DHM and RU	0	0	0
DaVinci	0	0	0
DFCS	0	0	0
DPW	0	0	0
EDMS	0	0	0
eNovator	0	0	0
EP Evaluator	0	0	0
GDSN/GS1	1	0	0
Groninger	0	0	0
GS Reports	0	0	0
ideaPoint	0	0	0
IRIS	0	0	0
Knowledge Management	0	0	0
Metrics Library	0	0	0
Navigator	0	0	0
PCN/SCN	0	0	0
PEAR	0	0	0
Power BI	0	0	0
Print on Demand	0	0	0
Pulse	4	0	0
QIMS	0	0	0
Reliasoft Xfmea	0	0	0
RSLMS	0	0	0
SAS	0	0	0
TestComplete	0	0	0
TODS	0	0	0
TrendReader	0	1	0

WWLIMS	2	1	0
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	User Acceptance Protocol		
Abbott Transfusion Medicine			0
ADD Shop Floor Paper (SFP) Report System			0
AFMS			0
Alinity S Non-LIMS spreadsheets			0
Alinity Source Verifier			0
AMM			0
AP 24 CIP			0
Apollo/PHM			0
Assay File Database			0
BioCommand Batch Control Plus			0
CMSnext			0
CMSNext			0
DARA Filler DHM and RU			0
DaVinci			0
DFCS			1
DPW			0
EDMS			0
eNovator			0
EP Evaluator			0
GDSN/GS1			0
Groninger			0
GS Reports			0
ideaPoint			0
IRIS			0
Knowledge Management			0
Metrics Library			0
Navigator			0
PCN/SCN			0
PEAR			0
Power BI			0
Print on Demand			0
Pulse			0
QIMS			0
Reliasoft Xfmea			0
RSLMS			0
SAS			0
TestComplete			0
TODS			0
TrendReader			0
WWLIMS			0

	User Acceptance Protocol results		
Abbott Transfusion Medicine			0

ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	3
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	1

	Validation Plan
Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0

AMM	0
AP 24 CIP	0
Apollo/PHM	0
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	1
Groninger	0
GS Reports	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	1

4.11 Table of Rejection Reasons

Inaccurate information	Incorrect scope
21	0
Insufficient testing	Insufficient traceability
1	4
N/A	Not compliant with procedure
2	8
Not following configuration management	Not following document version control
0	1

Not using template	Other
2	3
Requirement deficiency	
0	

4.12 Defects Verses Application

	Inaccurate information	Incorrect scope
Alinity S Non-LIMS spreadsheets	0	0
CMSnext	1	0
CMSNext	9	0
DFCS	1	0
eNovator	0	0
GDSN/GS1	2	0
Knowledge Management	0	0
Pulse	3	0
TrendReader	1	0
WWLIMS	4	0

	Insufficient testing
Alinity S Non-LIMS spreadsheets	0
CMSnext	0
CMSNext	1
DFCS	0
eNovator	0
GDSN/GS1	0
Knowledge Management	0
Pulse	0
TrendReader	0
WWLIMS	0

	Insufficient traceability N/A	
Alinity S Non-LIMS spreadsheets	1	0
CMSnext	0	0
CMSNext	3	2
DFCS	0	0
eNovator	0	0
GDSN/GS1	0	0
Knowledge Management	0	0
Pulse	0	0
TrendReader	0	0
WWLIMS	0	0

	Not compliant with procedure
Alinity S Non-LIMS spreadsheets	1
CMSnext	0

CMSNext	5
DFCS	0
eNovator	0
GDSN/GS1	1
Knowledge Management	1
Pulse	0
TrendReader	0
WWLIMS	0

Not following configuration management

Alinity S Non-LIMS spreadsheets	0
CMSnext	0
CMSNext	0
DFCS	0
eNovator	0
GDSN/GS1	0
Knowledge Management	0
Pulse	0
TrendReader	0
WWLIMS	0

Not following document version control

Alinity S Non-LIMS spreadsheets	0
CMSnext	0
CMSNext	0
DFCS	0
eNovator	1
GDSN/GS1	0
Knowledge Management	0
Pulse	0
TrendReader	0
WWLIMS	0

Not using template Other

Alinity S Non-LIMS spreadsheets	0	1
CMSnext	0	0
CMSNext	0	2
DFCS	0	0
eNovator	0	0
GDSN/GS1	0	0
Knowledge Management	0	0
Pulse	0	0
TrendReader	2	0
WWLIMS	0	0

Requirement deficiency

Alinity S Non-LIMS spreadsheets	0
CMSnext	0
CMSNext	0
DFCS	0
eNovator	0
GDSN/GS1	0
Knowledge Management	0
Pulse	0
TrendReader	0
WWLIMS	0

4.13 Defects Verses Deliverable

```
> table(as.character(subset(FPA, subset = (status == "D"))$deliverable),
+       subset(FPA, subset = (status == "D"))$reason)
```

	Inaccurate information	Incorrect scope
CII	0	0
Design Verification	0	0
IDP	1	0
IIVP results	1	0
ISSD	0	0
Maintenance Plan	0	0
Other	0	0
Project Plan	1	0
Software Change Request	5	0
Software Compliance Assessment	1	0
System Certification Summary	5	0
Test Protocol	3	0
Test Protocol Results	1	0
Traceability	0	0
URS	0	0
Validation Plan	3	0

	Insufficient testing	Insufficient traceability
CII	0	0
Design Verification	0	0
IDP	0	0
IIVP results	0	0
ISSD	0	0
Maintenance Plan	0	0
Other	0	0
Project Plan	0	0
Software Change Request	0	0
Software Compliance Assessment	0	0
System Certification Summary	0	0

Test Protocol	1	2
Test Protocol Results	0	0
Traceability	0	2
URS	0	0
Validation Plan	0	0

N/A Not compliant with procedure

CII	0	0
Design Verification	0	2
IDP	0	1
IIVP results	0	0
ISSD	0	0
Maintenance Plan	0	1
Other	0	1
Project Plan	0	0
Software Change Request	1	0
Software Compliance Assessment	0	0
System Certification Summary	1	1
Test Protocol	0	0
Test Protocol Results	0	0
Traceability	0	1
URS	0	1
Validation Plan	0	0

Not following configuration management

CII	0
Design Verification	0
IDP	0
IIVP results	0
ISSD	0
Maintenance Plan	0
Other	0
Project Plan	0
Software Change Request	0
Software Compliance Assessment	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0
Validation Plan	0

Not following document version control

CII	0
Design Verification	0
IDP	1

IIVP results	0
ISSD	0
Maintenance Plan	0
Other	0
Project Plan	0
Software Change Request	0
Software Compliance Assessment	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0
Validation Plan	0

	Not using template	Other
CII	1	0
Design Verification	0	0
IDP	0	0
IIVP results	0	0
ISSD	0	1
Maintenance Plan	1	0
Other	0	0
Project Plan	0	0
Software Change Request	0	0
Software Compliance Assessment	0	0
System Certification Summary	0	0
Test Protocol	0	2
Test Protocol Results	0	0
Traceability	0	0
URS	0	0
Validation Plan	0	0

	Requirement deficiency
CII	0
Design Verification	0
IDP	0
IIVP results	0
ISSD	0
Maintenance Plan	0
Other	0
Project Plan	0
Software Change Request	0
Software Compliance Assessment	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0

Traceability	0
URS	0
Validation Plan	0

4.14 Rejection Reason by Deliverable

CII	Design Verification
1	2
IDP	IIVP results
3	1
ISSD	Maintenance Plan
1	2
Other	Project Plan
1	1
Software Change Request	Software Compliance Assessment
7	1
System Certification Summary	Test Protocol
7	8
Test Protocol Results	Traceability
1	3
URS	Validation Plan
1	3

4.15 Number of Rejections by Project

Alinity S Non-LIMS spreadsheets	CMSnext
3	1
CMSNext	DFCS
22	1
eNovator	GDSN/GS1
1	3
Knowledge Management	Pulse
1	3
TrendReader	WWLIMS
4	4

5 Rate Metrics

5.1 Document Approval Rate

This is portion of documents that are approved upon review.

It is computed by counting the number of approvals divided that by the total number of reviews.

[1] 0.7556818

5.2 First Pass Acceptance

this is the portion of documents that are approved on the first review conducted by SQA.

It is computed by counting the number of first pass approvals divided by the number of reviews.

[1] 0.5681818