

SQA Metric Items From FPA Spreadsheet - November 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 November 2018.

¹

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¹Date Ran: Monday 3rd December, 2018 at 11:03

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
- multtoc

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] "WWLIMS"
- [2] "MQA Protocol"
- [3] "EDMS"
- [4] "ADD Shop Floor Paper (SFP) Report System"
- [5] "Assay File Database"
- [6] "Pulse"
- [7] "Clinical Chemistry Excel Spreadsheet for Digital Printing"
- [8] "R&D Data Management Dashboard"
- [9] "PEAR"
- [10] "DFCS"
- [11] "IRIS"
- [12] "GDSN/GS1"
- [13] "QIMS"
- [14] "Power BI"
- [15] "GS Reports"
- [16] "AFMS"
- [17] "DaVinci"
- [18] "CHaRM"
- [19] "Helios"
- [20] "eNovator"
- [21] "Metrics Library"
- [22] "Helios Global Contact Center"

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] 38

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] 138

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 descramate between such as multiple executions of the same test script or results from an IIVP run on different computers within the same project.

[1] 96

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] 9

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] 10

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
0	4
Data Migration Plan	Data Privacy Plan
1	1
Decommissioning Report	Design Documentation
0	3
Design Verification	ERES
1	3
FRS	IDP
9	3
IIVP	IIVP results
3	3
IIVP Results	ISSD
2	2

Maintenance Plan	1	Move to Production	7
Other	0	Project Plan	9
Release Notes	0	Risk Assessment	2
Software Change Request	7	Software Compliance Assessment	2
System Certification Summary	7	Test protocol	0
Test Protocol	5	Test Protocol Results	8
Traceability	4	URS	5
URS/FRS	1	User Acceptance Protocol	0
User Acceptance Protocol results	0	Validation Plan	3

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	7
AFMS	2
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	2
BioCommand Batch Control Plus	0

	CHaRM	
		4
Clinical Chemistry Excel Spreadsheet for Digital Printing		13
	CMSnext	0
	CMSNext	0
DARA Filler DHM and RU		0
	DaVinci	10
	DFCS	4
	DPW	0
	EDMS	2
	eNovator	1
EP Evaluator		0
	GDSN/GS1	8
	Groninger	0
	GS Reports	9
	Helios	2
Helios Global Contact Center		1
	ideaPoint	0
	IRIS	1
Knowledge Management		0
	Metrics Library	2
	MQA Protocol	11
	Navigator	0
	PCN/SCN	0

PEAR	
1	
Power BI	
2	
Print on Demand	
0	
Pulse	
1	
QIMS	
2	
QPI	
0	
R&D Data Management Dashboard	
2	
Reliasoft Xfmea	
0	
RSLMS	
0	
SAS	
0	
TestComplete	
0	
TODS	
0	
TrendReader	
0	
WWLIMS	
9	

4.9 Number of Approvals, Disapprovals, and First Pass Approvals

A	A-FP	D
34	61	43

4.10 Table of Deliverables by Application

	Cancellation	CII
Abbott Transfusion Medicine	0	0
ADD Shop Floor Paper (SFP) Report System	0	1
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

ASPG	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CHaRM	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	0
CMSnext	0	0
CMSNext	0	0
DARA Filler DHM and RU	0	0
DaVinci	0	1
DFCS	0	0
DPW	0	0
EDMS	0	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	1
Groninger	0	0
GS Reports	0	0
Helios	0	0
Helios Global Contact Center	0	0
ideaPoint	0	0
IRIS	0	0
Knowledge Management	0	0
Metrics Library	0	0
MQA Protocol	0	1
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
QPI	0	0
R&D Data Management Dashboard	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	0	0
WWLIMS	0	0

Data Migration 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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	1
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

Data Privacy 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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	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
Helios	0
Helios Global Contact Center	1
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0

TrendReader	0
WVLIMS	0
	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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0

RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	2
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0

QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	0

Design Verification

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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0

PEAR	1
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

	ERES	FRS	IDP	IIVP
Abbott Transfusion Medicine	0	0	0	0
ADD Shop Floor Paper (SFP) Report System	0	0	1	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
ASPG	0	0	0	0
Assay File Database	0	0	0	0
BioCommand Batch Control Plus	0	0	0	0
CHaRM	1	0	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1	1	0	1
CMSnext	0	0	0	0
CMSNext	0	0	0	0
DARA Filler DHM and RU	0	0	0	0
DaVinci	0	0	1	1
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	1
Groninger	0	0	0	0
GS Reports	0	0	0	0
Helios	0	1	0	0
Helios Global Contact Center	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
MQA Protocol	1	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
QPI	0	0	0	0
R&D Data Management Dashboard	0	1	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
WWLIMS	0	6	1	0

IIVP 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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	1
DPW	0
EDMS	1
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0

Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	1
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

	IIVP Results	ISSD
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
ASPG	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CHaRM	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	1
CMSnext	0	0
CMSNext	0	0
DARA Filler DHM and RU	0	0
DaVinci	1	0
DFCS	0	0
DPW	0	0
EDMS	0	0
eNovator	1	0
EP Evaluator	0	0

GDSN/GS1	0	0
Groninger	0	0
GS Reports	0	0
Helios	0	0
Helios Global Contact Center	0	0
ideaPoint	0	0
IRIS	0	0
Knowledge Management	0	0
Metrics Library	0	0
MQA Protocol	0	1
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
QPI	0	0
R&D Data Management Dashboard	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	0	0
WVLIMS	0	0

Maintenance 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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0
Move to Production	
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
ASPG	0
Assay File Database	2
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0

CMSNext	0
DARA Filler DHM and RU	0
DaVinci	1
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	4
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

	Other Project Plan	
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
ASPG	0	0
Assay File Database	0	0

BioCommand Batch Control Plus	0	0
CHaRM	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	2
CMSnext	0	0
CMSNext	0	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	5
Helios	0	0
Helios Global Contact Center	0	0
ideaPoint	0	0
IRIS	0	0
Knowledge Management	0	0
Metrics Library	0	0
MQA Protocol	0	0
Navigator	0	0
PCN/SCN	0	0
PEAR	0	0
Power BI	0	2
Print on Demand	0	0
Pulse	0	0
QIMS	0	0
QPI	0	0
R&D Data Management Dashboard	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	0	0
WVLIMS	0	0

Release Notes

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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

	Software Change Request
Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	1
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	1
Clinical Chemistry Excel Spreadsheet for Digital Printing	2
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	1
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	1
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	1
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0

TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	1
Clinical Chemistry Excel Spreadsheet for Digital Printing	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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	1
QPI	0

R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

System Certification Summary

Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	1
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	1
DFCS	1
DPW	0
EDMS	1
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	2
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0

Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	1

	Test 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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0

Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

	Test 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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	1
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	1
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
ideaPoint	0

IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	3
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

	Test Protocol Results
Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	3
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	1
DFCS	1
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	3
Groninger	0

GS Reports	0
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	0

	Traceability	URS
Abbott Transfusion Medicine	0	0
ADD Shop Floor Paper (SFP) Report System	1	0
AFMS	0	1
Alinity S Non-LIMS spreadsheets	0	0
Alinity Source Verifier	0	0
AMM	0	0
AP 24 CIP	0	0
Apollo/PHM	0	0
ASPG	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CHaRM	0	1
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	1
CMSnext	0	0
CMSNext	0	0
DARA Filler DHM and RU	0	0
DaVinci	1	0
DFCS	1	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
Helios	0	1
Helios Global Contact Center	0	0
ideaPoint	0	0
IRIS	0	0
Knowledge Management	0	0
Metrics Library	0	0
MQA Protocol	1	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
QPI	0	0
R&D Data Management Dashboard	0	1
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	0	0
WWLIMS	0	0

	URS/FRS
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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	0

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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0

Clinical Chemistry Excel Spreadsheet for Digital Printing	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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	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

ASPG
 Assay File Database
 BioCommand Batch Control Plus
 CHaRM
 Clinical Chemistry Excel Spreadsheet for Digital Printing
 CMSnext
 CMSNext
 DARA Filler DHM and RU
 DaVinci
 DFCS
 DPW
 EDMS
 eNovator
 EP Evaluator
 GDSN/GS1
 Groninger
 GS Reports
 Helios
 Helios Global Contact Center
 ideaPoint
 IRIS
 Knowledge Management
 Metrics Library
 MQA Protocol
 Navigator
 PCN/SCN
 PEAR
 Power BI
 Print on Demand
 Pulse
 QIMS
 QPI
 R&D Data Management Dashboard
 Reliasoft Xfmea
 RSLMS
 SAS
 TestComplete
 TODS
 TrendReader
 WWLIMS

	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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	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
Helios	0
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	2
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	1

4.11 Table of Rejection Reasons

Inaccurate information	Incorrect Approvers
27	1
Incorrect scope	Insufficient testing
1	1
Insufficient traceability	N/A
2	0
Not compliant with procedure	Not following configuration management
5	0
Not following document version control	Not using template
1	0
Other	Requirement deficiency
2	1

4.12 Defects Verses Application

	Inaccurate information
ADD Shop Floor Paper (SFP) Report System	4
AFMS	1
Assay File Database	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	7
DaVinci	0
EDMS	0
GDSN/GS1	4
Helios	0
IRIS	2
MQA Protocol	6
QIMS	2
WVLIMS	1
	Incorrect Approvers
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Assay File Database	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DaVinci	0
EDMS	1
GDSN/GS1	0
Helios	0
IRIS	0
MQA Protocol	0
QIMS	0
WVLIMS	0

	Incorrect scope
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Assay File Database	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DaVinci	0
EDMS	0
GDSN/GS1	1
Helios	0
IRIS	0
MQA Protocol	0
QIMS	0
WWLIMS	0

	Insufficient testing
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Assay File Database	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
DaVinci	0
EDMS	0
GDSN/GS1	0
Helios	0
IRIS	0
MQA Protocol	0
QIMS	0
WWLIMS	0

	Insufficient traceability
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Assay File Database	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	2
DaVinci	0
EDMS	0
GDSN/GS1	0
Helios	0
IRIS	0
MQA Protocol	0
QIMS	0
WWLIMS	0

	N/A
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Assay File Database	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DaVinci	0
EDMS	0
GDSN/GS1	0
Helios	0
IRIS	0
MQA Protocol	0
QIMS	0
WWLIMS	0

	Not compliant with procedure
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Assay File Database	1
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
DaVinci	0
EDMS	0
GDSN/GS1	1
Helios	2
IRIS	0
MQA Protocol	0
QIMS	0
WWLIMS	0

	Not following configuration mana
ADD Shop Floor Paper (SFP) Report System	
AFMS	
Assay File Database	
CHaRM	
Clinical Chemistry Excel Spreadsheet for Digital Printing	
DaVinci	
EDMS	
GDSN/GS1	
Helios	
IRIS	
MQA Protocol	
QIMS	
WWLIMS	

Not following document version c

ADD Shop Floor Paper (SFP) Report System
 AFMS
 Assay File Database
 CHaRM
 Clinical Chemistry Excel Spreadsheet for Digital Printing
 DaVinci
 EDMS
 GDSN/GS1
 Helios
 IRIS
 MQA Protocol
 QIMS
 WVLIMS

Not using template

ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Assay File Database	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DaVinci	0
EDMS	0
GDSN/GS1	0
Helios	0
IRIS	0
MQA Protocol	0
QIMS	0
WVLIMS	0

Other

ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Assay File Database	0
CHaRM	1
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DaVinci	1
EDMS	0
GDSN/GS1	0
Helios	0
IRIS	0
MQA Protocol	0
QIMS	0
WVLIMS	0

Requirement deficiency

ADD Shop Floor Paper (SFP) Report System	0
--	---

AFMS	0
Assay File Database	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
DaVinci	0
EDMS	0
GDSN/GS1	0
Helios	0
IRIS	0
MQA Protocol	0
QIMS	0
WVLIMS	0

4.13 Defects Verses Deliverable

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

	Inaccurate information	Incorrect Approvers
CII	5	0
Data Migration Plan	2	0
ERES	1	0
FRS	1	0
IIVP	1	0
IIVP results	0	1
ISSD	1	0
Maintenance Plan	0	0
Move to Production	0	0
Project Plan	1	0
Software Change Request	4	0
System Certification Summary	1	0
Test Protocol	4	0
Test Protocol Results	0	0
Traceability	1	0
URS	3	0
URS/FRS	1	0
Validation Plan	1	0

	Incorrect scope	Insufficient testing
CII	0	0
Data Migration Plan	0	0
ERES	0	0
FRS	0	0
IIVP	1	0
IIVP results	0	0
ISSD	0	0

Maintenance Plan	0	0
Move to Production	0	0
Project Plan	0	0
Software Change Request	0	0
System Certification Summary	0	0
Test Protocol	0	0
Test Protocol Results	0	0
Traceability	0	0
URS	0	0
URS/FRS	0	1
Validation Plan	0	0

Insufficient traceability N/A

CII	0	0
Data Migration Plan	0	0
ERES	0	0
FRS	1	0
IIVP	0	0
IIVP results	0	0
ISSD	0	0
Maintenance Plan	0	0
Move to Production	0	0
Project Plan	0	0
Software Change Request	0	0
System Certification Summary	0	0
Test Protocol	0	0
Test Protocol Results	0	0
Traceability	0	0
URS	0	0
URS/FRS	1	0
Validation Plan	0	0

Not compliant with procedure

CII	0
Data Migration Plan	0
ERES	0
FRS	1
IIVP	0
IIVP results	0
ISSD	0
Maintenance Plan	0
Move to Production	1
Project Plan	1
Software Change Request	0
System Certification Summary	0
Test Protocol	0

Test Protocol Results	1
Traceability	0
URS	1
URS/FRS	0
Validation Plan	0

Not following configuration management

CII	0
Data Migration Plan	0
ERES	0
FRS	0
IIVP	0
IIVP results	0
ISSD	0
Maintenance Plan	0
Move to Production	0
Project Plan	0
Software Change Request	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0
URS/FRS	0
Validation Plan	0

Not following document version control

CII	0
Data Migration Plan	0
ERES	0
FRS	0
IIVP	0
IIVP results	0
ISSD	0
Maintenance Plan	0
Move to Production	0
Project Plan	0
Software Change Request	0
System Certification Summary	0
Test Protocol	1
Test Protocol Results	0
Traceability	0
URS	0
URS/FRS	0
Validation Plan	0

	Not using template	Other Requirement deficiency
CII	0	0
Data Migration Plan	0	0
ERES	0	0
FRS	0	0
IIVP	0	0
IIVP results	0	0
ISSD	0	0
Maintenance Plan	0	0
Move to Production	0	0
Project Plan	0	0
Software Change Request	0	0
System Certification Summary	0	0
Test Protocol	0	1
Test Protocol Results	0	0
Traceability	0	0
URS	0	1
URS/FRS	0	0
Validation Plan	0	0

4.14 Rejection Reason by Deliverable

CII	Data Migration Plan
5	2
ERES	FRS
1	4
IIVP	IIVP results
2	1
ISSD	Maintenance Plan
1	1
Move to Production	Project Plan
1	2
Software Change Request	System Certification Summary
4	2
Test Protocol	Test Protocol Results
6	1
Traceability	URS
1	5
URS/FRS	Validation Plan
3	1

4.15 Number of Rejections by Project

ADD Shop Floor Paper (SFP) Report System
5
AFMS

	1
Assay File Database	1
	1
CHARM	1
Clinical Chemistry Excel Spreadsheet for Digital Printing	13
	1
DaVinci	1
	1
EDMS	1
GDSN/GS1	7
	2
Helios	2
	2
IRIS	2
	6
MQA Protocol	2
	2
QIMS	2
	1
WWLIMS	1

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] 0.6884058

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] 0.442029