

SQA Metric Items From FPA Spreadsheet - December 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 December 2018.

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¹Date Ran: Wednesday 2nd January, 2019 at 10:52

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] "R&D Data Management Dashboard"
- [2] "WWLIMS"
- [3] "QIMS"
- [4] "DFCS"
- [5] "Clinical Chemistry Excel Spreadsheet for Digital Printing"
- [6] "Pulse"
- [7] "BioXpert"
- [8] "PEAR"
- [9] "Acceptance Sampling Plan Generator (ASPG)"
- [10] "GDSN/GS1"
- [11] "eNovator"
- [12] "GS Reports"
- [13] "IDA Reporting"
- [14] "Metrics Library"
- [15] "TODS"
- [16] "AFMS"
- [17] "TrendReader"

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] 27

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] 193

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] 148

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] 4

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] 4

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	3
Data Migration Plan	Data Privacy Plan
0	0
Decommissioning Report	Design Documentation
0	2
Design Verification	ERES
28	2
FRS	IDP
6	1
IIVP	IIVP results
9	6
IIVP Results	ISSD
9	1
Maintenance Plan	Move to Production
2	2
Other	Project Plan
0	3
Release Notes	Risk Assessment
0	2
Software Change Request	Software Compliance Assessment
5	0
System Certification Summary	Test protocol
2	0

Test Protocol	Test Protocol Results
33	21
Traceability	URS
7	3
URS/FRS	User Acceptance Protocol
1	0
User Acceptance Protocol results	Validation Plan
0	0

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
Acceptance Sampling Plan Generator (ASPG)	2
ADD Shop Floor Paper (SFP) Report System	0
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	0
BioCommand Batch Control Plus	0
BioXpert	3
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	8
CMSnext	0

	CMSNext	
		0
DARA Filler DHM and RU		0
	DaVinci	0
	DFCS	9
	DPW	0
	EDMS	0
	eNovator	24
EP Evaluator		0
	GDSN/GS1	5
	Groninger	0
GS Reports		4
	Helios	0
Helios Global Contact Center		0
	IDA Reporting	2
	ideaPoint	0
	IRIS	0
Knowledge Management		0
Metrics Library		1
	MQA Protocol	0
	Navigator	0
	PCN/SCN	0
	PEAR	5
	Power BI	0

Print on Demand	0
Pulse	1
QIMS	42
QPI	0
R&D Data Management Dashboard	4
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	16
TrendReader	4
WWLIMS	16

4.9 Number of Approvals, Disapprovals, and First Pass Approvals

A	A-FP	D
62	77	54

4.10 Table of Deliverables by Application

	Cancellation	CII
Abbott Transfusion Medicine	0	0
Acceptance Sampling Plan Generator (ASPG)	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

BioXpert	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	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
Helios	0	0
Helios Global Contact Center	0	0
IDA Reporting	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	1
Power BI	0	0
Print on Demand	0	0
Pulse	0	0
QIMS	0	2
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

Data Migration Plan

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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
IDA Reporting	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

	Data Privacy Plan
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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
IDA Reporting	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

	Decommissioning Report
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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
IDA Reporting	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
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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
IDA Reporting	0

ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	1
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	1
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

Design Verification

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	9
DPW	0
EDMS	0
eNovator	0

EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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	1
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	16
TrendReader	0
WVLIMS	1

	ERES	FRS	IDP	IIVP
Abbott Transfusion Medicine	0	0	0	0
Acceptance Sampling Plan Generator (ASPG)	0	0	0	0
ADD Shop Floor Paper (SFP) Report System	0	0	0	0
AFMS	0	1	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
BioXpert	1	0	0	0
CHaRM	0	0	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	0	0	2
CMSnext	0	0	0	0

CMSNext	0	0	0	0
DARA Filler DHM and RU	0	0	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	3
EP Evaluator	0	0	0	0
GDSN/GS1	0	0	1	0
Groninger	0	0	0	0
GS Reports	0	0	0	0
Helios	0	0	0	0
Helios Global Contact Center	0	0	0	0
IDA Reporting	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	0	0	0	0
Navigator	0	0	0	0
PCN/SCN	0	0	0	0
PEAR	0	0	0	1
Power BI	0	0	0	0
Print on Demand	0	0	0	0
Pulse	0	0	0	0
QIMS	0	1	0	3
QPI	0	0	0	0
R&D Data Management Dashboard	1	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	0	4	0	0

IIVP results

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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	
BioXpert	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	
IDA Reporting	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	4	
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
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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	0
DFCS	0	0
DPW	0	0
EDMS	0	0
eNovator	4	0
EP Evaluator	0	0
GDSN/GS1	1	1
Groninger	0	0
GS Reports	0	0
Helios	0	0
Helios Global Contact Center	0	0
IDA Reporting	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	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	4	0
WVLIMS	0	0

Maintenance Plan

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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	1
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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

Move to Production

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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	2
Helios	0
Helios Global Contact Center	0
IDA Reporting	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
Acceptance Sampling Plan Generator (ASPG)	0	1
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
BioXpert	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	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	1

Helios	0	0
Helios Global Contact Center	0	0
IDA Reporting	0	1
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	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

	Release Notes
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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
IDA Reporting	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
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	1

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
IDA Reporting	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
Software Change Request	
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	1
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	2
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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
IDA Reporting	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

	System Certification Summary
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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	2
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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
IDA Reporting	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
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	2
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	4
EP Evaluator	0

GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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	15
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	11

Test Protocol Results	
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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	6
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	1
Helios	0
Helios Global Contact Center	0
IDA Reporting	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	13
QPI	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	0

	Traceability	URS
Abbott Transfusion Medicine	0	0
Acceptance Sampling Plan Generator (ASPG)	0	1
ADD Shop Floor Paper (SFP) Report System	0	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
BioXpert	0	0
CHaRM	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1	0
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	2	0
EP Evaluator	0	0
GDSN/GS1	1	1
Groninger	0	0
GS Reports	0	0
Helios	0	0
Helios Global Contact Center	0	0
IDA Reporting	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	0
Print on Demand	0	0
Pulse	0	0
QIMS	3	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

URS/FRS

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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
IDA Reporting	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	1
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0

TrendReader	0
WVLIMS	0

	User Acceptance Protocol
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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
IDA Reporting	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

User Acceptance Protocol results

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

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

	Validation Plan
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
BioXpert	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
IDA Reporting	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

4.11 Table of Rejection Reasons

Inaccurate information	Incorrect Approvers
15	6
Incorrect Objective Evidence	Incorrect scope
6	1
Insufficient testing	Insufficient traceability
1	0
N/A	Not compliant with procedure
1	5
Not following configuration management	Not following document version control
0	0
Not using template	other
2	1
Other	Requirement deficiency
11	1

4.12 Defects Verses Application

	Inaccurate information
Acceptance Sampling Plan Generator (ASPG)	0
AFMS	0

BioXpert	1
Clinical Chemistry Excel Spreadsheet for Digital Printing	4
DFCS	0
eNovator	4
GDSN/GS1	1
QIMS	4
R&D Data Management Dashboard	0
TODS	0
WWLIMS	0

Incorrect Approvers

Acceptance Sampling Plan Generator (ASPG)	2
AFMS	0
BioXpert	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
DFCS	0
eNovator	0
GDSN/GS1	0
QIMS	3
R&D Data Management Dashboard	0
TODS	0
WWLIMS	0

Incorrect Objective Evidence

Acceptance Sampling Plan Generator (ASPG)	0
AFMS	0
BioXpert	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
eNovator	0
GDSN/GS1	0
QIMS	6
R&D Data Management Dashboard	0
TODS	0
WWLIMS	0

Incorrect scope

Acceptance Sampling Plan Generator (ASPG)	0
AFMS	0
BioXpert	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
eNovator	1
GDSN/GS1	0
QIMS	0
R&D Data Management Dashboard	0

TODS	0
WVLIMS	0
	Insufficient testing
Acceptance Sampling Plan Generator (ASPG)	0
AFMS	0
BioXpert	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
DFCS	0
eNovator	0
GDSN/GS1	0
QIMS	0
R&D Data Management Dashboard	0
TODS	0
WVLIMS	0
	Insufficient traceability
Acceptance Sampling Plan Generator (ASPG)	0
AFMS	0
BioXpert	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
eNovator	0
GDSN/GS1	0
QIMS	0
R&D Data Management Dashboard	0
TODS	0
WVLIMS	0
	N/A
Acceptance Sampling Plan Generator (ASPG)	0
AFMS	0
BioXpert	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
eNovator	0
GDSN/GS1	0
QIMS	1
R&D Data Management Dashboard	0
TODS	0
WVLIMS	0
	Not compliant with procedure
Acceptance Sampling Plan Generator (ASPG)	0
AFMS	0
BioXpert	0

Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
eNovator	4
GDSN/GS1	0
QIMS	0
R&D Data Management Dashboard	1
TODS	0
WWLIMS	0

Not following configuration mana

Acceptance Sampling Plan Generator (ASPG)

AFMS

BioXpert

Clinical Chemistry Excel Spreadsheet for Digital Printing

DFCS

eNovator

GDSN/GS1

QIMS

R&D Data Management Dashboard

TODS

WWLIMS

Not following document version c

Acceptance Sampling Plan Generator (ASPG)

AFMS

BioXpert

Clinical Chemistry Excel Spreadsheet for Digital Printing

DFCS

eNovator

GDSN/GS1

QIMS

R&D Data Management Dashboard

TODS

WWLIMS

Not using template

Acceptance Sampling Plan Generator (ASPG)	0
AFMS	0
BioXpert	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
eNovator	0
GDSN/GS1	0
QIMS	2
R&D Data Management Dashboard	0
TODS	0

WVLIMS

0

	other	Other
Acceptance Sampling Plan Generator (ASPG)	0	0
AFMS	0	0
BioXpert	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	0
DFCS	0	1
eNovator	1	2
GDSN/GS1	0	0
QIMS	0	0
R&D Data Management Dashboard	0	0
TODS	0	8
WVLIMS	0	0

	Requirement deficiency
Acceptance Sampling Plan Generator (ASPG)	0
AFMS	1
BioXpert	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
eNovator	0
GDSN/GS1	0
QIMS	0
R&D Data Management Dashboard	0
TODS	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
Design Verification	0	0
FRS	0	1
IIVP	3	0
IIVP results	0	1
ISSD	1	0
Project Plan	0	1
Software Change Request	2	1
System Certification Summary	0	0
Test Protocol	4	0
Test Protocol Results	1	1
Traceability	3	0
URS	0	1

	Incorrect Objective Evidence	Incorrect scope
Design Verification	0	0
FRS	0	0
IIVP	0	0
IIVP results	0	0
ISSD	0	0
Project Plan	0	0
Software Change Request	0	1
System Certification Summary	0	0
Test Protocol	0	0
Test Protocol Results	6	0
Traceability	0	0
URS	0	0

	Insufficient testing	Insufficient traceability
Design Verification	0	0
FRS	0	0
IIVP	0	0
IIVP results	0	0
ISSD	0	0
Project Plan	0	0
Software Change Request	0	0
System Certification Summary	0	0
Test Protocol	1	0
Test Protocol Results	0	0
Traceability	0	0
URS	0	0

	N/A	Not compliant with procedure
Design Verification	0	1
FRS	0	0
IIVP	0	0
IIVP results	0	0
ISSD	0	0
Project Plan	0	0
Software Change Request	0	4
System Certification Summary	0	0
Test Protocol	0	0
Test Protocol Results	1	0
Traceability	0	0
URS	0	0

	Not following configuration management
Design Verification	0
FRS	0

IIVP	0
IIVP results	0
ISSD	0
Project Plan	0
Software Change Request	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0

Not following document version control

Design Verification	0
FRS	0
IIVP	0
IIVP results	0
ISSD	0
Project Plan	0
Software Change Request	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0

Not using template other Other

Design Verification	0	0	9
FRS	0	0	0
IIVP	0	0	1
IIVP results	0	0	0
ISSD	0	0	0
Project Plan	0	0	0
Software Change Request	0	0	0
System Certification Summary	0	1	0
Test Protocol	1	0	0
Test Protocol Results	1	0	0
Traceability	0	0	1
URS	0	0	0

Requirement deficiency

Design Verification	0
FRS	1
IIVP	0
IIVP results	0
ISSD	0
Project Plan	0

Software Change Request	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0

4.14 Rejection Reason by Deliverable

Design Verification	FRS
10	2
IIVP	IIVP results
4	1
ISSD	Project Plan
1	1
Software Change Request	System Certification Summary
9	2
Test Protocol	Test Protocol Results
8	11
Traceability	URS
4	1

4.15 Number of Rejections by Project

Acceptance Sampling Plan Generator (ASPG)	2
	AFMS
	1
	BioXpert
	1
Clinical Chemistry Excel Spreadsheet for Digital Printing	6
	DFCS
	1
	eNovator
	15
	GDSN/GS1
	1
	QIMS
	17
R&D Data Management Dashboard	1
	TODS
	8
	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] 0.7098446

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] 0.3989637