

# SQA Metric Items From FPA Spreadsheet - October 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 October 2018. <sup>1</sup>

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<sup>1</sup>Date Ran: Monday 3<sup>rd</sup> December, 2018 at 11:05

# 1 Introduction

The data is processed using R<sup>2</sup>, 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<sup>A</sup>T<sub>E</sub>X 2<sub>ε</sub> a typesetting program to produce a PDF file. L<sup>A</sup>T<sub>E</sub>X 2<sub>ε</sub> is implmented in MiT<sub>E</sub>X. L<sup>A</sup>T<sub>E</sub>X 2<sub>ε</sub> 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.

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<sup>2</sup>RStudio 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] "Pulse"
- [2] "DFCS"
- [3] "EDMS"
- [4] "MQA Protocol"
- [5] "ASPG"
- [6] "WWLIMS"
- [7] "ADD Shop Floor Paper (SFP) Report System"
- [8] "Apollo/PHM"
- [9] "CMSNext"
- [10] "QPI"
- [11] "GS Reports"
- [12] "Helios"
- [13] "GDSN/GS1"
- [14] "AFMS"
- [15] "Metrics Library"
- [16] "CHaRM"
- [17] "R&D Data Management Dashboard"

### 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] 43

### 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] 278

### 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] 188

## 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] 18

## 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] 14

## 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	8
Data Migration Plan	Data Privacy Plan
0	0
Decommissioning Report	Design Documentation
0	1
Design Verification	ERES
7	3
FRS	IDP
4	5
IIVP	IIVP results
8	6
IIVP Results	ISSD
11	4
Maintenance Plan	Move to Production
2	7
Other	Project Plan
1	7
Release Notes	Risk Assessment
1	0
Software Change Request	Software Compliance Assessment
15	10
System Certification Summary	Test protocol
8	0

Test Protocol	Test Protocol Results
25	32
Traceability	URS
9	5
URS/FRS	User Acceptance Protocol
0	1
User Acceptance Protocol results	Validation Plan
3	5

#### 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	10
AFMS	2
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	28
ASPG	3
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	2
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	13
DARA Filler DHM and RU	0

DaVinci	0
DFCS	31
DPW	0
EDMS	8
eNovator	0
EP Evaluator	0
GDSN/GS1	13
Groninger	0
GS Reports	13
Helios	2
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	3
MQA Protocol	3
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	26
QIMS	0

	QPI
	23
R&D Data Management Dashboard	
	2
Reliasoft Xfmea	
	0
RSLMS	
	0
SAS	
	0
TestComplete	
	0
TODS	
	0
TrendReader	
	0
WWLIMS	
	6

#### 4.9 Number of Approvals, Disapprovals, and First Pass Approvals

A	A-FP	D
69	128	81

#### 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	1
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	0
DFCS	0	2

DPW	0	0
EDMS	0	1
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	0
Navigator	0	0
PCN/SCN	0	0
PEAR	0	0
Power BI	0	0
Print on Demand	0	0
Pulse	0	2
QIMS	0	0
QPI	0	1
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
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

#### 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	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
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	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	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	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	2
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	1
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	3
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	1	0	0	1
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	2	1
ASPG	1	0	0	0
Assay File Database	0	0	0	0
BioCommand Batch Control Plus	0	0	0	0
CHaRM	0	0	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	0	0	0
CMSnext	0	0	0	0
CMSNext	0	1	1	0
DARA Filler DHM and RU	0	0	0	0
DaVinci	0	0	0	0
DFCS	0	0	1	1
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	2
Groninger	0	0	0	0
GS Reports	0	0	0	0
Helios	0	0	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	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	1	0	1
QIMS	0	0	0	0
QPI	0	0	1	2

R&D Data Management Dashboard	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	1	2	0	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	1
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	2
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	2
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	1	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	5	1
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	1	0
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	0	1
DPW	0	0
EDMS	0	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	1	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	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	3	1
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	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	0
DFCS	0
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	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	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	7
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	1	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	0
DFCS	0	1
DPW	0	0
EDMS	0	0

eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	0
Groninger	0	0
GS Reports	0	6
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	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
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	1
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	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
Software Change Request	
Abbott Transfusion Medicine	0
ADD Shop Floor Paper (SFP) Report System	1
AFMS	1
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	1

ASPG	1
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	1
Clinical Chemistry Excel Spreadsheet for Digital Printing	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
Helios	1
Helios Global Contact Center	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	1
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	3
QIMS	0
QPI	0
R&D Data Management Dashboard	1
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WVLIMS	1
Software Compliance Assessment	
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	1
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	2
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	1
MQA Protocol	1
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	1
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	2
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	1
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	2
QIMS	0
QPI	1
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	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	1
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	1
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	2
DARA Filler DHM and RU	0
DaVinci	0
DFCS	6
DPW	0
EDMS	2
eNovator	0
EP Evaluator	0
GDSN/GS1	7
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	2

QIMS	0
QPI	4
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	1
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	10
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	5
DARA Filler DHM and RU	0
DaVinci	0
DFCS	1
DPW	0
EDMS	1
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	6
QIMS	0
QPI	7
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
ADD Shop Floor Paper (SFP) Report System	0	1
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	2	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	1	0
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	2	1
DPW	0	0
EDMS	0	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	1	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	0	0
Navigator	0	0
PCN/SCN	0	0
PEAR	0	0
Power BI	0	0
Print on Demand	0	0
Pulse	2	1
QIMS	0	0
QPI	1	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

	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	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

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	1
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	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	3



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	2
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	1
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	1
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
60	0
Incorrect scope	Insufficient testing
0	4
Insufficient traceability	N/A
1	1
Not compliant with procedure	Not following configuration management
7	0
Not following document version control	Not using template

0	0
Other	Requirement deficiency
7	0

## 4.12 Defects Verses Application

	Inaccurate information
ADD Shop Floor Paper (SFP) Report System	4
AFMS	2
Apollo/PHM	14
CHaRM	0
CMSNext	1
DFCS	14
EDMS	2
GDSN/GS1	2
MQA Protocol	3
Pulse	5
QPI	8
R&D Data Management Dashboard	1
WWLIMS	4

	Incorrect Approvers	Incorrect scope
ADD Shop Floor Paper (SFP) Report System	0	0
AFMS	0	0
Apollo/PHM	0	0
CHaRM	0	0
CMSNext	0	0
DFCS	0	0
EDMS	0	0
GDSN/GS1	0	0
MQA Protocol	0	0
Pulse	0	0
QPI	0	0
R&D Data Management Dashboard	0	0
WWLIMS	0	0

	Insufficient testing
ADD Shop Floor Paper (SFP) Report System	3
AFMS	0
Apollo/PHM	1
CHaRM	0
CMSNext	0
DFCS	0
EDMS	0
GDSN/GS1	0
MQA Protocol	0

Pulse	0
QPI	0
R&D Data Management Dashboard	0
WWLIMS	0

#### Insufficient traceability N/A

ADD Shop Floor Paper (SFP) Report System	0	0
AFMS	0	0
Apollo/PHM	0	1
CHaRM	0	0
CMSNext	0	0
DFCS	1	0
EDMS	0	0
GDSN/GS1	0	0
MQA Protocol	0	0
Pulse	0	0
QPI	0	0
R&D Data Management Dashboard	0	0
WWLIMS	0	0

#### Not compliant with procedure

ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Apollo/PHM	0
CHaRM	3
CMSNext	0
DFCS	1
EDMS	0
GDSN/GS1	1
MQA Protocol	1
Pulse	0
QPI	1
R&D Data Management Dashboard	0
WWLIMS	0

#### Not following configuration management

ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Apollo/PHM	0
CHaRM	0
CMSNext	0
DFCS	0
EDMS	0
GDSN/GS1	0
MQA Protocol	0
Pulse	0

QPI	0
R&D Data Management Dashboard	0
WWLIMS	0

	Not following document version control
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Apollo/PHM	0
CHaRM	0
CMSNext	0
DFCS	0
EDMS	0
GDSN/GS1	0
MQA Protocol	0
Pulse	0
QPI	0
R&D Data Management Dashboard	0
WWLIMS	0

	Not using template	Other
ADD Shop Floor Paper (SFP) Report System	0	1
AFMS	0	1
Apollo/PHM	0	4
CHaRM	0	0
CMSNext	0	1
DFCS	0	0
EDMS	0	0
GDSN/GS1	0	0
MQA Protocol	0	0
Pulse	0	0
QPI	0	0
R&D Data Management Dashboard	0	0
WWLIMS	0	0

	Requirement deficiency
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Apollo/PHM	0
CHaRM	0
CMSNext	0
DFCS	0
EDMS	0
GDSN/GS1	0
MQA Protocol	0
Pulse	0
QPI	0

R&D Data Management Dashboard	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	1	0
Design Verification	2	0
FRS	2	0
IDP	4	0
IIVP	0	0
IIVP results	3	0
IIVP Results	6	0
ISSD	3	0
Maintenance Plan	1	0
Other	1	0
Project Plan	2	0
Release Notes	1	0
Software Change Request	12	0
Software Compliance Assessment	1	0
System Certification Summary	6	0
Test Protocol	5	0
Test Protocol Results	6	0
URS	1	0
Validation Plan	3	0

	Incorrect scope	Insufficient testing
CII	0	0
Design Verification	0	0
FRS	0	0
IDP	0	0
IIVP	0	0
IIVP results	0	0
IIVP Results	0	0
ISSD	0	0
Maintenance Plan	0	0
Other	0	0
Project Plan	0	0
Release Notes	0	0
Software Change Request	0	0
Software Compliance Assessment	0	0
System Certification Summary	0	0
Test Protocol	0	4

Test Protocol Results	0	0
URS	0	0
Validation Plan	0	0

Insufficient traceability N/A

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

Not compliant with procedure

CII	0
Design Verification	0
FRS	0
IDP	0
IIVP	0
IIVP results	0
IIVP Results	1
ISSD	0
Maintenance Plan	0
Other	0
Project Plan	0
Release Notes	0
Software Change Request	2
Software Compliance Assessment	3
System Certification Summary	0
Test Protocol	0
Test Protocol Results	1
URS	0
Validation Plan	0

	Not following configuration management	
CII		0
Design Verification		0
FRS		0
IDP		0
IIVP		0
IIVP results		0
IIVP Results		0
ISSD		0
Maintenance Plan		0
Other		0
Project Plan		0
Release Notes		0
Software Change Request		0
Software Compliance Assessment		0
System Certification Summary		0
Test Protocol		0
Test Protocol Results		0
URS		0
Validation Plan		0

	Not following document version control	
CII		0
Design Verification		0
FRS		0
IDP		0
IIVP		0
IIVP results		0
IIVP Results		0
ISSD		0
Maintenance Plan		0
Other		0
Project Plan		0
Release Notes		0
Software Change Request		0
Software Compliance Assessment		0
System Certification Summary		0
Test Protocol		0
Test Protocol Results		0
URS		0
Validation Plan		0

	Not using template	Other
CII	0	0
Design Verification	0	0
FRS	0	0



IDP	0	0
IIVP	0	0
IIVP results	0	0
IIVP Results	0	0
ISSD	0	0
Maintenance Plan	0	0
Other	0	0
Project Plan	0	0
Release Notes	0	0
Software Change Request	0	2
Software Compliance Assessment	0	0
System Certification Summary	0	0
Test Protocol	0	0
Test Protocol Results	0	4
URS	0	1
Validation Plan	0	0

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

#### 4.14 Rejection Reason by Deliverable

CII	Design Verification	
2		2
FRS		IDP
2		4
IIVP	IIVP results	
1		3

IIVP Results	ISSD
7	3
Maintenance Plan	Other
1	1
Project Plan	Release Notes
2	1
Software Change Request	Software Compliance Assessment
16	5
System Certification Summary	Test Protocol
6	9
Test Protocol Results	URS
11	2
Validation Plan	
3	

#### 4.15 Number of Rejections by Project

ADD Shop Floor Paper (SFP) Report System
8
AFMS
3
Apollo/PHM
21
CHaRM
3
CMSNext
2
DFCS
16
EDMS
2
GDSN/GS1
3
MQA Protocol
4
Pulse
5
QPI
9
R&D Data Management Dashboard
1
WWLIMS
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] 0.6726619

### 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] 0.4352518