SQA Metric Items From FPA Spreadsheet - October 2018

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Abstract

Evaulation of various potential matrics, 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. [1]

Contents

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[1]Date Ran: Thursday 1st November, 2018 at 09:27

1 Introduction

The data is processed using R[2], 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 LaTeX 2_ε a typeseting program to produce a PDF file. LaTeX 2_ε in implented in MiTEX. LaTeX 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 implented graphs of the trends will also be added.

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[2]RStudio is utilized as an IDE

4 Quanity Metrics

4.1 Application supported

This is a list of all application support this period.

Note: Alphabatize 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 periond.

```
[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 certian items having no way to descrimate 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
  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.
Itonly 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
                                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
                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
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

7

Helios	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
WWLIMS	0	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
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
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

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

EDMS	1	0	0	0
eNovator	0	0	0	0
EP Evaluator	0	0	0	0
GDSN/GS1	0	0	0	0
Groninger	0	0	0	0
GS Reports	0	0	0	0
Helios	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	3	0	1	0
QIMS	0	0	0	0
QPI	0	0	0	1
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
WWLIMS	0	1	2	0

	IIVP	IIVP results	IIVP Results	ISSD
Abbott Transfusion Medicine	0	0	0	0
ADD Shop Floor Paper (SFP) Report System	1	0	1	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	1	1	5	1
ASPG	0	0	0	0
Assay File Database	0	0	0	0
BioCommand Batch Control Plus	0	0	0	0
CHaRM	0	0	0	0
CMSnext	0	0	0	0
CMSNext	0	0	1	0
DARA Filler DHM and RU	0	0	0	0
DaVinci	0	0	0	0

DFCS	1	2	0	1
DPW	0	0	0	0
EDMS	0	1	0	0
eNovator	0	0	0	0
EP Evaluator	0	0	0	0
GDSN/GS1	2	0	1	0
Groninger	0	0	0	0
GS Reports	0	0	0	0
Helios	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	1	2	0	0
QIMS	0	0	0	0
QPI	2	0	3	1
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
WWLIMS	0	0	0	0

	Maintenance Plan	Move to Production
Abbott Transfusion Medicine	0	0
ADD Shop Floor Paper (SFP) Report System	1	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
CMSnext	0	0
CMSNext	0	0

DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	0	0
DPW	0	0
EDMS	1	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	0
Groninger	0	0
GS Reports	0	7
Helios	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
WWLIMS	0	0

	Other	Project Plan	Release Notes
Abbott Transfusion Medicine	0	0	0
ADD Shop Floor Paper (SFP) Report System	0	0	0
AFMS	0	0	0
Alinity S Non-LIMS spreadsheets	0	0	0
Alinity Source Verifier	0	0	0
AMM	0	0	0
AP 24 CIP	0	0	0
Apollo/PHM	1	0	0
ASPG	0	0	0
Assay File Database	0	0	0
BioCommand Batch Control Plus	0	0	0
CHaRM	0	0	0

CMSnext	0	0	0
CMSNext	0	0	0
DARA Filler DHM and RU	0	0	0
DaVinci	0	0	0
DFCS	0	1	0
DPW	0	0	0
EDMS	0	0	0
eNovator	0	0	0
EP Evaluator	0	0	0
GDSN/GS1	0	0	0
Groninger	0	0	0
GS Reports	0	6	0
Helios	0	0	0
ideaPoint	0	0	0
IRIS	0	0	0
Knowledge Management	0	0	0
Metrics Library	0	0	0
MQA Protocol	0	0	0
Navigator	0	0	0
PCN/SCN	0	0	0
PEAR	0	0	0
Power BI	0	0	0
Print on Demand	0	0	0
Pulse	0	0	0
QIMS	0	0	0
QPI	0	0	1
R&D Data Management Dashboard	0	0	0
Reliasoft Xfmea	0	0	0
RSLMS	0	0	0
SAS	0	0	0
TestComplete	0	0	0
TODS	0	0	0
TrendReader	0	0	0
WWLIMS	0	0	0

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

BioCommand Batch Control Plus	0
CHaRM	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
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

	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
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
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
WWLIMS	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
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
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
WWLIMS                                                      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
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
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
WWLIMS	0

	Test protocol	Test Protocol
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	1
ASPG	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CHaRM	0	0
CMSnext	0	0
CMSNext	0	2
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	0	6
DPW	0	0
EDMS	0	2
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	7
Groninger	0	0
GS Reports	0	0
Helios	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	4
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

Test Protocol Results Traceability

Abbott Transfusion Medicine	0	0
ADD Shop Floor Paper (SFP) Report System	1	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	10	2
ASPG	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CHaRM	0	0
CMSnext	0	0
CMSNext	5	1
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	1	2
DPW	0	0
EDMS	1	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	1	1
Groninger	0	0
GS Reports	0	0
Helios	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	6	2
QIMS	0	0
QPI	7	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
WWLIMS	0	0

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

TrendReader	0	0	0
WWLIMS	0	0	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
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	3
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	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

	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
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
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
WWLIMS                                       1
```

4.11   Table of Rejection Reasons

```
                Inaccurate information                      Incorrect scope
                                    60                                    0
                  Insufficient testing            Insufficient traceability
                                     4                                    1
                                   N/A          Not compliant with procedure
                                     1                                    7
Not following configuration management Not following document version control
                                     0                                    0
                    Not using template                                Other
                                     0                                    7
                Requirement deficiency
                                     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 scope Insufficient testing
ADD Shop Floor Paper (SFP) Report System               0                    3
AFMS                                                   0                    0
Apollo/PHM                                             0                    1
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 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
WWLIMS                                                   0
```

4.13   Defects Verses Deliverable

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

	Inaccurate information	Incorrect scope
CII	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

	Insufficient testing	Insufficient traceability
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                          1
System Certification Summary                      0                          0
Test Protocol                                     4                          0
Test Protocol Results                             0                          0
URS                                               0                          0
Validation Plan                                   0                          0
```

	N/A	Not compliant with procedure
CII	1	0
Design Verification	0	0
FRS	0	0
IDP	0	0
IIVP	0	0
IIVP results	0	0
IIVP Results	0	1
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	3
System Certification Summary	0	0
Test Protocol	0	0
Test Protocol Results	0	1
URS	0	0
Validation Plan	0	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 devided 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 devided by the number of reviews.

```
[1] 0.4352518
```