SQA Metric Items From FPA Spreadsheet - September 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 September 2018. [1]

Contents

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[1] Date Ran: Monday 1$^\text{st}$ October, 2018 at 10:40

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 $\text{\LaTeX}\,2_\varepsilon$ a typeseting program to produce a PDF file. $\text{\LaTeX}\,2_\varepsilon$ in implented in MiTEX. $\text{\LaTeX}\,2_\varepsilon$ 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] "GS Reports"
 [2] "DFCS"
 [3] "IRIS"
 [4] "Apollo/PHM"
 [5] "Helios"
 [6] "GDSN/GS1"
 [7] "RSLMS"
 [8] "EDMS"
 [9] "WWLIMS"
[10] "MQA Protocol"
[11] "Pulse"
[12] "CMSNext"
[13] "ADD Shop Floor Paper (SFP) Report System"
[14] "Power BI"
[15] "QPI"
[16] "Metrics Library"
[17] "AFMS"
[18] "Print on Demand"
```

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] 28
```

4.3 Number of Reviews

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

```
[1] 224
```

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] 161
```

4.5   Number of Projects Started

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

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

```
[1] 9
```

4.6   Projects Completed

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

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

```
[1] 5
```

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
                            6                                       1
                          FRS                                     IDP
                            9                                       2
                         IIVP                             IIVP results
                           13                                       9
                 IIVP Results                                    ISSD
                            7                                       1
             Maintenance Plan                       Move to Production
                            0                                       3
                        Other                            Project Plan
                            2                                       4
                Release Notes                         Risk Assessment
                            0                                       0
      Software Change Request     Software Compliance Assessment
                           14                                       3
  System Certification Summary                           Test protocol
                            4                                       8
```

4

```
            Test Protocol                   Test Protocol Results
                       30                                       21
            Traceability                                      URS
                        6                                        5
                  URS/FRS            User Acceptance Protocol
                        0                                        3
User Acceptance Protocol results                    Validation Plan
                        0                                        1
```

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
                                      4
                                   AFMS
                                      1
        Alinity S Non-LIMS spreadsheets
                                      0
                Alinity Source Verifier
                                      0
                                    AMM
                                      0
                              AP 24 CIP
                                      0
                             Apollo/PHM
                                     51
                    Assay File Database
                                      0
           BioCommand Batch Control Plus
                                      0
                                CMSnext
                                      0
                                CMSNext
                                     25
                  DARA Filler DHM and RU
                                      0
                                 DaVinci
                                      0
                                   DFCS
                                      9
                                    DPW
                                      0
```

```
            EDMS
               4
        eNovator
               0
    EP Evaluator
               0
        GDSN/GS1
               4
       Groninger
               0
      GS Reports
               6
          Helios
               2
       ideaPoint
               0
            IRIS
               4
Knowledge Management
               0
 Metrics Library
               1
    MQA Protocol
               1
       Navigator
               0
         PCN/SCN
               0
            PEAR
               0
        Power BI
               1
 Print on Demand
               1
           Pulse
              20
            QIMS
               0
             QPI
               4
Reliasoft Xfmea
               0
           RSLMS
              10
             SAS
               0
```

```
                     TestComplete
                               0
                            TODS
                               0
                     TrendReader
                               0
                          WWLIMS
                              13
```

4.9   Number of Approvals, Disapprovals, and First Pass Approvals

```
  A A-FP     D
 71   80    73
```

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
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CMSnext	0	0
CMSNext	0	3
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	0	0
DPW	0	0
EDMS	0	1
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	0
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	0
Reliasoft Xfmea	0	0
RSLMS	0	1
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
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
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
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
WWLIMS	0

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

	Design Verification	ERES	FRS	IDP
Abbott Transfusion Medicine	0	0	0	0
ADD Shop Floor Paper (SFP) Report System	0	0	0	0
AFMS	0	0	0	0
Alinity S Non-LIMS spreadsheets	0	0	0	0
Alinity Source Verifier	0	0	0	0
AMM	0	0	0	0
AP 24 CIP	0	0	0	0
Apollo/PHM	0	0	1	0
Assay File Database	0	0	0	0
BioCommand Batch Control Plus	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	0	0	1	1
DPW	0	0	0	0
EDMS	2	0	0	0
eNovator	0	0	0	0
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
ideaPoint	0	0	0	0
IRIS	0	0	1	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	2	0	2	0
QIMS	0	0	0	0
QPI	1	0	2	0
Reliasoft Xfmea	0	0	0	0
RSLMS	1	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	0	0

	IIVP	IIVP results	IIVP Results	ISSD
Abbott Transfusion Medicine	0	0	0	0
ADD Shop Floor Paper (SFP) Report System	2	0	2	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	3	2	1	0
Assay File Database	0	0	0	0
BioCommand Batch Control Plus	0	0	0	0
CMSnext	0	0	0	0
CMSNext	3	1	4	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	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	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	1	0	0
QIMS	0	0	0	0
QPI	0	0	0	0
Reliasoft Xfmea	0	0	0	0
RSLMS	1	3	0	0
SAS	0	0	0	0
TestComplete	0	0	0	0
TODS	0	0	0	0
TrendReader	0	0	0	0
WWLIMS	2	2	0	1

	Maintenance Plan	Move to Production
Abbott Transfusion Medicine	0	0
ADD Shop Floor Paper (SFP) Report System	0	0
AFMS	0	0
Alinity S Non-LIMS spreadsheets	0	0
Alinity Source Verifier	0	0
AMM	0	0
AP 24 CIP	0	0
Apollo/PHM	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CMSnext	0	0
CMSNext	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	3
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
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
Assay File Database	0	0	0
BioCommand Batch Control Plus	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	0	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	3	0
Helios	0	0	0
ideaPoint	0	0	0
IRIS	0	0	0
Knowledge Management	0	0	0
Metrics Library	0	1	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          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                                        1          0          0


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

```
Reliasoft Xfmea                                              0
RSLMS                                                        1
SAS                                                          0
TestComplete                                                 0
TODS                                                         0
TrendReader                                                  0
WWLIMS                                                       1


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

SAS		0
TestComplete		0
TODS		0
TrendReader		0
WWLIMS		2

	Test protocol	Test Protocol
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	8	19
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CMSnext	0	0
CMSNext	0	5
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
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	1
Pulse	0	4
QIMS	0	0
QPI	0	0
Reliasoft Xfmea	0	0
RSLMS	0	1
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	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	14	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
CMSnext	0	0
CMSNext	2	1
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	1	1
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
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	1	0
Print on Demand	0	0
Pulse	1	4
QIMS	0	0
QPI	0	0
Reliasoft Xfmea	0	0
RSLMS	1	0
SAS	0	0
TestComplete	0	0

TODS	0	0
TrendReader	0	0
WWLIMS	1	0

	URS	URS/FRS	User Acceptance Protocol
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
Assay File Database	0	0	0
BioCommand Batch Control Plus	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	0	3
DPW	0	0	0
EDMS	0	0	0
eNovator	0	0	0
EP Evaluator	0	0	0
GDSN/GS1	1	0	0
Groninger	0	0	0
GS Reports	0	0	0
Helios	0	0	0
ideaPoint	0	0	0
IRIS	1	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	2	0	0
QIMS	0	0	0
QPI	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
Assay File Database	0
BioCommand Batch Control Plus	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
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
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
        Assay File Database                         0
        BioCommand Batch Control Plus               0
        CMSnext                                     0
        CMSNext                                     0
        DARA Filler DHM and RU                      0
        DaVinci                                     0
        DFCS                                        0
        DPW                                         0
        EDMS                                        0
        eNovator                                    0
        EP Evaluator                                0
        GDSN/GS1                                    0
        Groninger                                   0
        GS Reports                                  0
        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                                         1
        Reliasoft Xfmea                             0
        RSLMS                                       0
        SAS                                         0
        TestComplete                                0
        TODS                                        0
        TrendReader                                 0
        WWLIMS                                      0
```

4.11   Table of Rejection Reasons

Inaccurate information	Incorrect scope
47	0
Insufficient testing	Insufficient traceability
1	3
N/A	Not compliant with procedure
1	1
Not following configuration management	Not following document version control
1	3
Not using template	Other
0	14
Requirement deficiency	
0	

4.12   Defects Verses Application

	Inaccurate information	Incorrect scope	Insufficient testing
AFMS	1	0	0
Apollo/PHM	8	0	0
CMSNext	5	0	1
DFCS	4	0	0
EDMS	1	0	0
GDSN/GS1	0	0	0
Helios	1	0	0
IRIS	6	0	0
MQA Protocol	3	0	0
Print on Demand	0	0	0
Pulse	8	0	0
QPI	2	0	0
RSLMS	3	0	0
WWLIMS	5	0	0

	Insufficient traceability	N/A	Not compliant with procedure
AFMS	0	0	0
Apollo/PHM	3	0	0
CMSNext	0	1	0
DFCS	0	0	0
EDMS	0	0	0
GDSN/GS1	0	0	0
Helios	0	0	0
IRIS	0	0	0
MQA Protocol	0	0	0
Print on Demand	0	0	1
Pulse	0	0	0
QPI	0	0	0

```
RSLMS                                        0   0                                    0
WWLIMS                                       0   0                                    0


                Not following configuration management
AFMS                                                    0
Apollo/PHM                                              0
CMSNext                                                 0
DFCS                                                    0
EDMS                                                    0
GDSN/GS1                                                1
Helios                                                  0
IRIS                                                    0
MQA Protocol                                            0
Print on Demand                                         0
Pulse                                                   0
QPI                                                     0
RSLMS                                                   0
WWLIMS                                                  0


                Not following document version control Not using template
AFMS                                                    0                  0
Apollo/PHM                                              0                  0
CMSNext                                                 2                  0
DFCS                                                    0                  0
EDMS                                                    0                  0
GDSN/GS1                                                0                  0
Helios                                                  0                  0
IRIS                                                    0                  0
MQA Protocol                                            0                  0
Print on Demand                                         0                  0
Pulse                                                   0                  0
QPI                                                     1                  0
RSLMS                                                   0                  0
WWLIMS                                                  0                  0


                Other Requirement deficiency
AFMS            0                        0
Apollo/PHM      8                        0
CMSNext         5                        0
DFCS            0                        0
EDMS            0                        0
GDSN/GS1        0                        0
Helios          0                        0
IRIS            0                        0
MQA Protocol    0                        0
Print on Demand 0                        0
```

```
Pulse              0                    0
QPI                1                    0
RSLMS              0                    0
WWLIMS             0                    0
```

4.13   Defects Verses Deliverable

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

	Inaccurate information	Incorrect scope
CII	0	0
Design Documentation	1	0
Design Verification	2	0
FRS	3	0
IDP	1	0
IIVP	3	0
IIVP results	2	0
IIVP Results	1	0
Other	0	0
Software Change Request	14	0
System Certification Summary	4	0
Test protocol	3	0
Test Protocol	5	0
Test Protocol Results	1	0
Traceability	3	0
URS	2	0
Validation Plan	2	0

	Insufficient testing	Insufficient traceability
CII	0	0
Design Documentation	0	0
Design Verification	0	0
FRS	0	0
IDP	0	0
IIVP	0	0
IIVP results	0	0
IIVP Results	0	0
Other	0	0
Software Change Request	0	0
System Certification Summary	0	0
Test protocol	0	3
Test Protocol	1	0
Test Protocol Results	0	0
Traceability	0	0
URS	0	0

```

| | | |
|---|---|---|
| Validation Plan | 0 | 0 |

| | N/A | Not compliant with procedure |
|---|---|---|
| CII | 0 | 0 |
| Design Documentation | 0 | 0 |
| Design Verification | 0 | 0 |
| FRS | 0 | 0 |
| IDP | 1 | 0 |
| IIVP | 0 | 0 |
| IIVP results | 0 | 0 |
| IIVP Results | 0 | 0 |
| Other | 0 | 0 |
| Software Change Request | 0 | 0 |
| System Certification Summary | 0 | 0 |
| Test protocol | 0 | 0 |
| Test Protocol | 0 | 1 |
| Test Protocol Results | 0 | 0 |
| Traceability | 0 | 0 |
| URS | 0 | 0 |
| Validation Plan | 0 | 0 |

| | Not following configuration management |
|---|---|
| CII | 0 |
| Design Documentation | 0 |
| Design Verification | 0 |
| FRS | 1 |
| IDP | 0 |
| IIVP | 0 |
| IIVP results | 0 |
| IIVP Results | 0 |
| Other | 0 |
| Software Change Request | 0 |
| System Certification Summary | 0 |
| Test protocol | 0 |
| Test Protocol | 0 |
| Test Protocol Results | 0 |
| Traceability | 0 |
| URS | 0 |
| Validation Plan | 0 |

| | Not following document version control |
|---|---|
| CII | 1 |
| Design Documentation | 0 |
| Design Verification | 0 |
| FRS | 1 |
| IDP | 0 |

```
IIVP   0
IIVP results   0
IIVP Results   0
Other   0
Software Change Request   0
System Certification Summary   0
Test protocol   0
Test Protocol   0
Test Protocol Results   0
Traceability   1
URS   0
Validation Plan   0
```

| | Not using template | Other | Requirement deficiency |
|---|---|---|---|
| CII | 0 | 0 | 0 |
| Design Documentation | 0 | 0 | 0 |
| Design Verification | 0 | 1 | 0 |
| FRS | 0 | 1 | 0 |
| IDP | 0 | 0 | 0 |
| IIVP | 0 | 2 | 0 |
| IIVP results | 0 | 1 | 0 |
| IIVP Results | 0 | 1 | 0 |
| Other | 0 | 2 | 0 |
| Software Change Request | 0 | 0 | 0 |
| System Certification Summary | 0 | 0 | 0 |
| Test protocol | 0 | 0 | 0 |
| Test Protocol | 0 | 0 | 0 |
| Test Protocol Results | 0 | 5 | 0 |
| Traceability | 0 | 1 | 0 |
| URS | 0 | 0 | 0 |
| Validation Plan | 0 | 0 | 0 |

## 4.14   Rejection Reason by Deliverable

| CII | Design Documentation |
|---|---|
| 2 | 1 |
| Design Verification | FRS |
| 3 | 6 |
| IDP | IIVP |
| 2 | 5 |
| IIVP results | IIVP Results |
| 4 | 2 |
| Other | Software Change Request |
| 2 | 14 |
| System Certification Summary | Test protocol |
| 4 | 6 |

```
        Test Protocol      Test Protocol Results
                   7                          6
        Traceability                        URS
                   5                          2
     Validation Plan
                   2
```

4.15 Number of Rejections by Project

```
     AFMS      Apollo/PHM        CMSNext            DFCS            EDMS
        1              20             15               4               1
 GDSN/GS1          Helios           IRIS    MQA Protocol Print on Demand
        1               1              6               3               1
    Pulse             QPI          RSLMS          WWLIMS
        8               4              3               5
```

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] 0.6651786
```

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] 0.3571429
```