# SQA Metric Items From FPA Spreadsheet - August 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 August 2018.  $^{\rm 1}$ 

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|   | Started   | 3   3   3             | 5 |              | e Metrics Document Approval Rate First Pass Acceptance .                      | 25<br>25<br>25       |

<sup>&</sup>lt;sup>1</sup>Date Ran: Wednesday 5<sup>th</sup> September, 2018 at 14:12

#### 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 environment using a collection of packages know as Sweave that included knitr which in turn feeds the package into LATEX  $2_{\varepsilon}$  a typeseting program to produce a PDF file. LATEX  $2_{\varepsilon}$  in implented in MiTeX. LATEX  $2_{\varepsilon}$  is utilizing the following 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.

 $<sup>^2\</sup>mathrm{RS}$ tudio is utilized as an IDE

### **Quanity Metrics**

#### Application supported

This is a list of all application support this period.

Note: Alphabatize the list

- [1] "Pulse" [2] "WWLIMS" [3] "DFCS" [4] "EDMS" [5] "DARA Filler DHM and RU" [6] "EP Evaluator" [7] "GS Reports" [8] "Apollo/PHM" [9] "RSLMS" [10] "TrendReader"
- [11] "ADD Shop Floor Paper (SFP) Report System"

#### 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] 19

#### **Number of Reviews** 4.3

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

[1] 110

#### Number of Items Reviewed 4.4

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] 81

#### 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] 5

#### 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] 8

#### 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                 |
|--------------------------------|------------------------------|
| 0                              | 0                            |
| CII                            | Decommissioning Report       |
| 5                              | 0                            |
| Design Documentation           | Design Verification          |
| 0                              | 4                            |
| ERES                           | FRS                          |
| 1                              | 2                            |
| IDP                            | IIVP                         |
| 1                              | 3                            |
| IIVP results                   | IIVP Results                 |
| 16                             | 0                            |
| ISSD                           | Maintenance Plan             |
| 0                              | 0                            |
| Move to Production             | Other                        |
| 3                              | 0                            |
| Project Plan                   | Release Notes                |
| 4                              | 1                            |
| Risk Assessment                | Software Change Request      |
| 0                              | 4                            |
| Software Compliance Assessment | System Certification Summary |
| 4                              | 5                            |
| Test Protocol                  | Test Protocol Results        |
| 6                              |                              |

| URS                      | Traceability                     |
|--------------------------|----------------------------------|
| 2                        | 7                                |
| User Acceptance Protocol | URS/FRS                          |
| 0                        | 0                                |
| Validation Plan          | User Acceptance Protocol results |
| 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
ADD Shop Floor Paper (SFP) Report System
                                         2
                                      AFMS
                                         0
         Alinity S Non-LIMS spreadsheets
                                         0
                 Alinity Source Verifier
                                         0
                                       AMM
                                         0
                                 AP 24 CIP
                                         0
                               Apollo/PHM
                      Assay File Database
           BioCommand Batch Control Plus
                                         0
                                   {\tt CMSnext}
                                         0
                                   CMSNext
                                         0
                   DARA Filler DHM and RU
                                  DaVinci
                                         0
                                      DFCS
                                        13
                                       DPW
                                         0
                                      EDMS
```

```
2
            eNovator
        EP Evaluator
            GDSN/GS1
           Groninger
          GS Reports
           ideaPoint
                IRIS
Knowledge Management
     Metrics Library
           Navigator
             PCN/SCN
                  0
                PEAR
                  0
            Power BI
     Print on Demand
               Pulse
                QIMS
     Reliasoft Xfmea
               RSLMS
                  14
                 SAS
        TestComplete
                TODS
         TrendReader
                 3
              WWLIMS
```

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

A A-FP D
0 26 60 24

## 4.10 Table of Deliverables by Application

|  |   | Cancellation | CII |
|--|---|--------------|-----|
|  | 0 | 0            | 0   |
| 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                               | 0 | 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            | 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   |
| ideaPoint                                | 0 | 0            | 0   |
| IRIS                                     | 0 | 0            | 0   |
| Knowledge Management                     | 0 | 0            | 0   |
| Metrics Library                          | 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            | 1   |
| QIMS                                     | 0 | 0            | 0   |
| Reliasoft Xfmea                          | 0 | 0            | 0   |

| RSLMS        | 0 | 0 | 1 |
|--------------|---|---|---|
| SAS          | 0 | 0 | 0 |
| TestComplete | 0 | 0 | 0 |
| TODS         | 0 | 0 | 0 |
| TrendReader  | 0 | 0 | 0 |
| WWLIMS       | 0 | 0 | 2 |
|              |   |   |   |

## Decommissioning Report 0

|   | U |
|---|---|
| Abbott Transfusion Medicine                   | 0 |
| ADD Shop Floor Paper (SFP) Report System 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 |
| ideaPoint                                     | 0 |
| IRIS  | 0 |
| Knowledge Management                          | 0 |
| Metrics Library                               | 0 |
| Navigator                                     | 0 |
| PCN/SCN                                       | 0 |
| PEAR  | 0 |
| Power BI                                      | 0 |
| Print on Demand                               | 0 |
| Pulse   | 0 |
| QIMS  | 0 |
| Reliasoft Xfmea                               | 0 |
| RSLMS   | 0 |
| SAS   | 0 |
| TestComplete                                  | 0 |

| TODS                                     |        |               | 0 |
|--|--------|---------------|---|
| TrendReader                              |        |               | 0 |
| WWLIMS                                   |        |               | 0 |
|  |        |               | · |
|  | Design | Documentation |   |
|  | DCBIGH | 0             |   |
| Abbott Transfusion Medicine              |        | 0             |   |
| ADD Shop Floor Paper (SFP) Report System |        | 0             |   |
| AFMS 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             |   |
| ideaPoint                                |        | 0             |   |
| IRIS                                     |        | 0             |   |
| Knowledge Management                     |        | 0             |   |
| Metrics Library                          |        | 0             |   |
| Navigator                                |        | 0             |   |
| PCN/SCN                                  |        | 0             |   |
| PEAR                                     |        | 0             |   |
| Power BI                                 |        | 0             |   |
| Print on Demand                          |        | 0             |   |
| Pulse                                    |        | 0             |   |
| QIMS                                     |        | 0             |   |
| Reliasoft Xfmea                          |        | 0             |   |
| RSLMS                                    |        | 0             |   |
| SAS                                      |        | 0             |   |
|  |        | 0             |   |
| TestComplete                             |        |               |   |
| TODS                                     |        | 0             |   |
| TrendReader                              |        | 0             |   |
| WWLIMS                                   |        | 0             |   |

|  | Design | Verification   | FRFS | FRS | TDP |
|--|--------|----------------|------|-----|-----|
|  | Design | Verification 0 | 0    | 0   | 0   |
| Abbott Transfusion Medicine              |        | 0              | 0    | 0   | 0   |
| ADD Shop Floor Paper (SFP) Report System |        | 0              | 0    | 0   | 0   |
| AFMS                                     |        | 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    | 0   | 0   |
| DARA Filler DHM and RU                   |        | 0              | 0    | 0   | 0   |
| DaVinci                                  |        | 0              | 0    | 0   | 0   |
| DFCS                                     |        | 2              | 0    | 0   | 0   |
| DPW                                      |        | 0              | 0    | 0   | 0   |
| EDMS                                     |        | 0              | 0    | 0   | 0   |
| eNovator                                 |        | 0              | 0    | 0   | 0   |
| EP Evaluator                             |        | 0              | 0    | 0   | 0   |
| GDSN/GS1                                 |        | 0              | 0    | 0   | 0   |
| Groninger                                |        | 0              | 0    | 0   | 0   |
| GS Reports                               |        | 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   |
| 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              | 0    | 0   | 0   |
| QIMS                                     |        | 0              | 0    | 0   | 0   |
| Reliasoft Xfmea                          |        | 0              | 0    | 0   | 0   |
| RSLMS                                    |        | 1              | 0    | 1   | 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   | 1   |

IIVP IIVP results IIVP Results ISSD 0 0 0

| Abbott Transfusion Medicine              | 0           | 0           | 0          | 0   |
|--|-------------|-------------|------------|-----|
| ADD Shop Floor Paper (SFP) Report System | 1           | 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          | 0   |
| Assay File Database                      | 0           | 0           | 0          | 0   |
| BioCommand Batch Control Plus            | 0           | 0           | 0          | 0   |
| CMSnext                                  | 0           | 0           | 0          | 0   |
| CMSNext                                  | 0           | 0           | 0          | 0   |
| DARA Filler DHM and RU                   | 0           | 1           | 0          | 0   |
| DaVinci                                  | 0           | 0           | 0          | 0   |
| DFCS                                     | 1           | 1           | 0          | 0   |
| DPW                                      | 0           | 0           | 0          | 0   |
| EDMS                                     | 0           | 0           | 0          | 0   |
| eNovator                                 | 0           | 0           | 0          | 0   |
| EP Evaluator                             | 0           | 0           | 0          | 0   |
| GDSN/GS1                                 | 0           | 0           | 0          | 0   |
| Groninger                                | 0           | 0           | 0          | 0   |
| GS Reports                               | 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   |
| 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           | 2           | 0          | 0   |
| QIMS                                     | 0           | 0           | 0          | 0   |
| Reliasoft Xfmea                          | 0           | 0           | 0          | 0   |
| RSLMS                                    | 1           | 1           | 0          | 0   |
| SAS                                      | 0           | 0           | 0          | 0   |
| TestComplete                             | 0           | 0           | 0          | 0   |
| TODS                                     | 0           | 0           | 0          | 0   |
| TrendReader                              | 0           | 0           | 0          | 0   |
| WWLIMS                                   | 0           | 10          | 0          | 0   |
|  | Maintenance | Plan Move t | o Product: | ion |
|  |             | 0           |            | 0   |
| Abbott Transfusion Medicine              |             | 0           |            | 0   |
| ADD Shop Floor Paper (SFP) Report System |             | 0           |            | 0   |
| ATMO                                     |             | ^           |            | ^   |

AFMS

| 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 |
| ideaPoint                                | 0                                | 0 |
| IRIS                                     | 0                                | 0 |
| Knowledge Management                     | 0                                | 0 |
| Metrics Library                          | 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 |
| Reliasoft Xfmea                          | 0                                | 0 |
| RSLMS                                    | 0                                | 0 |
| SAS                                      | 0                                | 0 |
| TestComplete                             | 0                                | 0 |
| TODS                                     | 0                                | 0 |
| TrendReader                              | 0                                | 0 |
| WWLIMS                                   | 0                                | 0 |
|  | · ·                              | ŭ |
|  | Other Project Plan Release Notes |   |
|  | 0 0 0                            |   |
| Abbott Transfusion Medicine              | 0 0 0                            |   |
| ADD Shop Floor Paper (SFP) Report System |                                  |   |
| AFMS                                     | 0 0 0                            |   |
| Alinity S Non-LIMS spreadsheets          | 0 0 0                            |   |
| Alinity Source Verifier                  | 0 0 0                            |   |
| AMM                                      | 0 0 0                            |   |
| APIT                                     | 0 0                              |   |

| AP 24 CIP                     | 0 | 0 | 0 |
|-------------------------------|---|---|---|
| Apollo/PHM                    | 0 | 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 | 4 | 0 |
| ideaPoint                     | 0 | 0 | 0 |
| IRIS                          | 0 | 0 | 0 |
| Knowledge Management          | 0 | 0 | 0 |
| Metrics Library               | 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 |
| Reliasoft Xfmea               | 0 | 0 | 0 |
| RSLMS                         | 0 | 0 | 0 |
| SAS                           | 0 | 0 | 0 |
| TestComplete                  | 0 | 0 | 0 |
| TODS                          | 0 | 0 | 0 |
| TrendReader                   | 0 | 0 | 1 |
| WWLIMS                        | 0 | 0 | 0 |
|                               |   |   |   |

#### Risk Assessment 0 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 0 Assay File Database

| 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 |
| ideaPoint                     | 0 |
| IRIS                          | 0 |
| Knowledge Management          | 0 |
| Metrics Library               | 0 |
| Navigator                     | 0 |
| PCN/SCN                       | 0 |
| PEAR                          | 0 |
| Power BI                      | 0 |
| Print on Demand               | 0 |
| Pulse                         | 0 |
| QIMS                          | 0 |
| Reliasoft Xfmea               | 0 |
| RSLMS                         | 0 |
| SAS                           | 0 |
| TestComplete                  | 0 |
| TODS                          | 0 |
| TrendReader                   | 0 |
| WWLIMS                        | 0 |

#### Software Change Request

0 Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System 0 0 Alinity S Non-LIMS spreadsheets 0 Alinity Source Verifier 0  $\mathsf{MMA}$ 0 AP 24 CIP 0 Apollo/PHM 1 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                                     |          |                    | 1         |   |
| eNovator                                 |          |                    | 0         |   |
| EP Evaluator                             |          |                    | 0         |   |
| GDSN/GS1                                 |          |                    | 0         |   |
| Groninger                                |          |                    | 0         |   |
| GS Reports                               |          |                    | 0         |   |
| ideaPoint                                |          |                    | 0         |   |
| IRIS                                     |          |                    | 0         |   |
| Knowledge Management                     |          |                    | 0         |   |
| Metrics Library                          |          |                    | 0         |   |
| Navigator                                |          |                    | 0         |   |
| PCN/SCN                                  |          |                    | 0         |   |
| PEAR                                     |          |                    | 0         |   |
| Power BI                                 |          |                    | 0         |   |
| Print on Demand                          |          |                    | 0         |   |
| Pulse                                    |          |                    | 0         |   |
| QIMS                                     |          |                    | 0         |   |
| Reliasoft Xfmea                          |          |                    | 0         |   |
| RSLMS                                    |          |                    | 1         |   |
| SAS                                      |          |                    | 0         |   |
| TestComplete                             |          |                    | 0         |   |
| TODS                                     |          |                    | 0         |   |
| TrendReader                              |          |                    | 0         |   |
| WWLIMS                                   |          |                    | 1         |   |
|  |          |                    |           |   |
|  | Software | ${\tt Compliance}$ | Assessmen | t |
|  |          |                    |           | 0 |
| 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 |
| Assay File Database                      |          |                    |           | 0 |
| BioCommand Batch Control Plus            |          |                    |           | 0 |
| CMSnext                                  |          |                    |           | 0 |
| CMSNext                                  |          |                    |           | 0 |
| DADA E DIW 1 DII                         |          |                    |           | _ |

DARA Filler DHM and RU

DaVinci

DFCS

0

0

1

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

| EP Evaluator         | 1 |
|----------------------|---|
| GDSN/GS1             | 0 |
| Groninger            | 0 |
| GS Reports           | 0 |
| ideaPoint            | 0 |
| IRIS                 | 0 |
| Knowledge Management | 0 |
| Metrics Library      | 0 |
| Navigator            | 0 |
| PCN/SCN              | 0 |
| PEAR                 | 0 |
| Power BI             | 0 |
| Print on Demand      | 0 |
| Pulse                | 1 |
| QIMS                 | 0 |
| Reliasoft Xfmea      | 0 |
| RSLMS                | 1 |
| SAS                  | 0 |
| TestComplete         | 0 |
| TODS                 | 0 |
| TrendReader          | 1 |
| WWLIMS               | 1 |
|                      |   |

|  | Test | ${\tt Protocol}$ | Test | ${\tt Protocol}$ | Results |
|--|------|------------------|------|------------------|---------|
|  |      | 0                |      |                  | 0       |
| 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                                     |      | 4                |      |                  | 3       |
| DPW                                      |      | 0                |      |                  | 0       |
| EDMS                                     |      | 0                |      |                  | 0       |
| eNovator                                 |      | 0                |      |                  | 0       |
| EP Evaluator                             |      | 0                |      |                  | 0       |
| GDSN/GS1                                 |      | 0                |      |                  | 0       |
| Groninger                                |      | 0                |      |                  | 0       |

| GS Reports           | 0 | 0 |
|----------------------|---|---|
| ideaPoint            | 0 | 0 |
| IRIS                 | 0 | 0 |
| Knowledge Management | 0 | 0 |
| Metrics Library      | 0 | 0 |
| Navigator            | 0 | 0 |
| PCN/SCN              | 0 | 0 |
| PEAR                 | 0 | 0 |
| Power BI             | 0 | 0 |
| Print on Demand      | 0 | 0 |
| Pulse                | 0 | 1 |
| QIMS                 | 0 | 0 |
| Reliasoft Xfmea      | 0 | 0 |
| RSLMS                | 2 | 2 |
| SAS                  | 0 | 0 |
| TestComplete         | 0 | 0 |
| TODS                 | 0 | 0 |
| TrendReader          | 0 | 0 |
| WWLIMS               | 0 | 6 |

#### Traceability URS URS/FRS Abbott Transfusion Medicine ADD Shop Floor Paper (SFP) Report System AFMS Alinity S Non-LIMS spreadsheets Alinity Source Verifier MMAAP 24 CIP Apollo/PHM Assay File Database BioCommand Batch Control Plus ${\tt CMSnext}$ CMSNext ${\tt DARA}$ Filler DHM and RU DaVinci DFCS DPW **EDMS** ${\tt eNovator}$ EP Evaluator GDSN/GS1 Groninger **GS** Reports ideaPointIRIS

| Knowledge Management Metrics Library Navigator PCN/SCN PEAR Power BI Print on Demand Pulse |      |        | 0<br>0<br>0<br>0<br>0<br>0<br>0 | 0<br>0<br>0<br>0<br>0<br>0 | 0<br>0<br>0<br>0<br>0<br>0 |
|--|------|--------|---------------------------------|----------------------------|----------------------------|
| QIMS   |      |        | 0                               | 0                          | 0                          |
| Reliasoft Xfmea  |      |        | 0                               | 0                          | 0                          |
| RSLMS  |      |        | 2                               | 1                          | 0                          |
| SAS  |      |        | 0                               | 0                          | 0                          |
| TestComplete   |      |        | 0                               | 0                          | 0                          |
| TODS   |      |        | 0                               | 0                          | 0                          |
| TrendReader  |      |        | 1                               | 0                          | 0                          |
| WWLIMS   |      |        | 3                               | 0                          | 0                          |
|  | User | Accept | tanc                            | e Pr                       | otocol                     |
|  |      |        |                                 |                            | 0                          |
| Abbott Transfusion Medicine  |      |        |                                 |                            | 0                          |
| ADD Shop Floor Paper (SFP) Report System   | 1    |        |                                 |                            | 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<br>DFCS  |      |        |                                 |                            | 0<br>0                     |
| DPW  |      |        |                                 |                            | 0                          |
| EDMS   |      |        |                                 |                            | 0                          |
| eNovator   |      |        |                                 |                            | 0                          |
| EP Evaluator   |      |        |                                 |                            | 0                          |
| GDSN/GS1   |      |        |                                 |                            | 0                          |
| Groninger  |      |        |                                 |                            | 0                          |
| GS Reports   |      |        |                                 |                            | 0                          |
| ideaPoint  |      |        |                                 |                            | 0                          |
| IRIS   |      |        |                                 |                            | 0                          |
| Knowledge Management   |      |        |                                 |                            | 0                          |
| Metrics Library  |      |        |                                 |                            | 0                          |
| Navigator  |      |        |                                 |                            | 0                          |
| -  |      |        |                                 |                            |                            |

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### User Acceptance Protocol results

|  | 0 |
|--|---|
| 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 |
| ideaPoint                                | 0 |
| IRIS                                     | 0 |
| Knowledge Management                     | 0 |
| Metrics Library                          | 0 |
| Navigator                                | 0 |
| PCN/SCN                                  | 0 |
| PEAR                                     | 0 |
| Power BI                                 | 0 |

| Print on Demand | 0 |
|-----------------|---|
| Pulse           | 0 |
| QIMS            | 0 |
| Reliasoft Xfmea | 0 |
| RSLMS           | 0 |
| SAS             | 0 |
| TestComplete    | 0 |
| TODS            | 0 |
| TrendReader     | 0 |
| WWLIMS          | 1 |

#### Validation Plan 0 Abbott Transfusion Medicine 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 0 CMSnext CMSNext 0 DARA Filler DHM and RU 0 DaVinci 0 DFCS 0 DPW 0 **EDMS** 0 eNovator0 EP Evaluator 0 GDSN/GS1 0 ${\tt Groninger}$ 0 GS Reports 0 ideaPoint 0 IRIS 0 Knowledge Management 0 Metrics Library 0 0 Navigator 0 PCN/SCN PEAR 0 Power BI 0 Print on Demand 0 Pulse 0 QIMS 0

| Reliasoft Xfmea | 0 |
|-----------------|---|
| RSLMS           | 0 |
| SAS             | 0 |
| TestComplete    | 0 |
| TODS            | 0 |
| TrendReader     | 0 |
| WWLIMS          | 0 |

## 4.11 Table of Rejection Reasons

| Inaccurate information                 | Incorrect scope                        |
|--|--|
| 23                                     | 0                                      |
| Insufficient testing                   | Insufficient traceability              |
| 0                                      | 0                                      |
| N/A                                    | Not compliant with procedure           |
| 0                                      | 0                                      |
| Not following configuration management | Not following document version control |
| 0                                      | 0                                      |
| Not using template                     | Other                                  |
| 0                                      | 1                                      |
| Requirement deficiency                 |  |
| 0                                      |  |

Pulse RSLMS

| .12 Defec   | ts Verses A  | application  | ı                                     |                   |                |                            |
|---|--------------|--------------|---------------------------------------|-------------------|----------------|----------------------------|
|   | Inaccurate i | information  | Incorrec                              | t scope           | Insufficient   | testing                    |
| Apollo/PHM  |              | 8            |                                       | 0                 |                | 0                          |
| DFCS  |              | 3            |                                       | 0                 |                | 0                          |
| Pulse   |              | 3            |                                       | 0                 |                | 0                          |
| RSLMS   |              | 5            |                                       | 0                 |                | 0                          |
| TrendReader   |              | 0            |                                       | 0                 |                | 0                          |
| WWLIMS  |              | 4            |                                       | 0                 |                | 0                          |
| Apollo/PHM<br>DFCS<br>Pulse<br>RSLMS<br>TrendReader<br>WWLIMS | Insufficient | traceabili   | 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | ot comp           | liant with pro | 0<br>0<br>0<br>0<br>0<br>0 |
| Apollo/PHM  | Not followin | ng configura | ation mar                             | agement<br>0<br>0 |                |                            |

0

| TrendReader<br>WWLIMS |     |           |                  |         | 0       |     |       |          |       |
|-----------------------|-----|-----------|------------------|---------|---------|-----|-------|----------|-------|
|                       |     |           |                  |         |         |     |       |          |       |
|                       | Not | following | ${\tt document}$ | version | control | Not | using | template | Other |
| Apollo/PHM            |     |           |                  |         | 0       |     |       | 0        | 0     |
| DFCS                  |     |           |                  |         | 0       |     |       | 0        | 0     |
| Pulse                 |     |           |                  |         | 0       |     |       | 0        | 0     |
| RSLMS                 |     |           |                  |         | 0       |     |       | 0        | 0     |
| TrendReader           |     |           |                  |         | 0       |     |       | 0        | 1     |
| WWLIMS                |     |           |                  |         | 0       |     |       | 0        | 0     |

|             | Requirement | deficiency |
|-------------|-------------|------------|
| Apollo/PHM  |             | 0          |
| DFCS        |             | 0          |
| Pulse       |             | 0          |
| RSLMS       |             | 0          |
| TrendReader |             | 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 |
|--------------------------------|------------|-------------|-----------|-------|
| Design Verification            |            | 2           |           | 0     |
| FRS                            |            | 1           |           | 0     |
| IIVP results                   |            | 2           |           | 0     |
| Software Change Request        |            | 3           |           | 0     |
| Software Compliance Assessment |            | 1           |           | 0     |
| System Certification Summary   |            | 3           |           | 0     |
| Test Protocol Results          |            | 4           |           | 0     |
| Traceability                   |            | 4           |           | 0     |
| URS                            |            | 3           |           | 0     |

|                                | Insufficient | testing | Insufficient | traceability |
|--------------------------------|--------------|---------|--------------|--------------|
| Design Verification            |              | 0       |              | 0            |
| FRS                            |              | 0       |              | 0            |
| IIVP results                   |              | 0       |              | 0            |
| Software Change Request        |              | 0       |              | 0            |
| Software Compliance Assessment |              | 0       |              | 0            |
| System Certification Summary   |              | 0       |              | 0            |
| Test Protocol Results          |              | 0       |              | 0            |
| Traceability                   |              | 0       |              | 0            |
| URS                            |              | 0       |              | 0            |

| Design Verification FRS IIVP results Software Change Request Software Compliance Assessment System Certification Summary Test Protocol Results                  | N/A<br>0<br>0<br>0<br>0<br>0 | Not compliant with procedure  0 0 0 0 0 0 0 0 0 0                       |
|---|------------------------------|---|
| Traceability<br>URS   | 0                            | 0   |
| Olto  |                              | •   |
| Design Verification FRS IIVP results Software Change Request Software Compliance Assessment System Certification Summary Test Protocol Results Traceability URS | Not                          | following configuration management  0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0     |
| Design Verification FRS IIVP results Software Change Request Software Compliance Assessment System Certification Summary Test Protocol Results Traceability URS | Not                          | following document version control  0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 |
| Design Verification FRS IIVP results Software Change Request Software Compliance Assessment System Certification Summary Test Protocol Results Traceability     | Not                          | using template Other  0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 0 0 0               |
| URS   | Req                          | 0 0   |

Design Verification

| FRS                            | 0 |  |  |
|--------------------------------|---|--|--|
| IIVP results                   | 0 |  |  |
| Software Change Request        | 0 |  |  |
| Software Compliance Assessment | 0 |  |  |
| System Certification Summary   |   |  |  |
| Test Protocol Results          |   |  |  |
| Traceability                   |   |  |  |
| URS                            | 0 |  |  |

#### 4.14 Rejection Reason by Deliverable

| Design Verification            | FRS                          |
|--------------------------------|------------------------------|
| 2                              | 1                            |
| IIVP results                   | Software Change Request      |
| 2                              | 3                            |
| Software Compliance Assessment | System Certification Summary |
| 1                              | 4                            |
| Test Protocol Results          | Traceability                 |
| 4                              | 4                            |
| URS                            |                              |
| 3                              |                              |

#### 4.15 Number of Rejections by Project

| Apollo/PHM | DFCS | Pulse | RSLMS | ${\tt TrendReader}$ | WWLIMS |
|------------|------|-------|-------|---------------------|--------|
| 8          | 3    | 3     | 5     | 1                   | 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] 0.7818182

#### 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] 0.5454545