SQA Metric Items From FPA Spreadsheet - February 2019

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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 February 2019.

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| | 4.6 4.7 | Started | 3 4 4 | 5 | Rat 5.1 5.2 | e Metrics Document Approval Rate First Pass Acceptance . | 17 17 18 |

 $^{^{1}\}mathrm{Date}$ Ran: Friday 1^{st} March, 2019 at 09:31

1 Introduction

The data is processed using R^2 , version 3.5.2 named "Eggshell Igloo". 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 that are needed are are computed in R 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_{ε} a typeseting program to produce a PDF file. LATEX 2_{ε} in implented in MiTeX. LATEX 2_{ε} is utilizing the following packages to control style and formating:

- datetime and
- multitoc
- hyperref
- xcolor

This will only show a point in time summary and no long term trending.

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 Functions

Some calculations would be better implemented as functions The calculations need to be evulated and the functions developed where needed.

3.2 Trending

Eventually the "application" will be updated to select the data on a for a calander month. After processing the results will be stored in a seperate file. This will allow for longer term trending of this data.

 $^{^2}$ RStudio is utilized as an IDE

3.2.1 Graphs

When "trending" is implented graphs of the trends will also be added.

4 Quanity Metrics

4.1 Application supported

This is a list of all application support this period.

```
[1] "Acceptance Sampling Plan Generator (ASPG)"
[2] "AFMS"
[3] "Alinity Source Verifier"
[4] "BioCommand Batch Control Plus"
[5] "BioXpert"
[6] "CHaRM"
[7] "Clinical Chemistry Excel Spreadsheet for Digital Printing"
[8] "CMSNext"
[9] "DARA Filler DHM and RU"
[10] "DFCS"
[11] "Empower"
[12] "GDSN/GS1"
[13] "GS Reports"
[14] "IRIS"
[15] "Metrics Library"
[16] "Print on Demand"
[17] "Pulse"
[18] "QIMS"
[19] "RSLMS"
```

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] 55

[20] "TODS"

[21] "TrendReader"
[22] "WWLIMS"

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] 277

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] 210

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 or the Project Plan for GS Reports, Metrics Library or Power BI.

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

[1] 11

4.6 Projects Completed

The point at which a project is considered completed is when version 1 of the System Certification Summary or a Decommissioning Report is approved or the Project Plan for GS Reports, Metrics Library or Power BI.

[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 | CII |
|---------------------|----------------------|
| 2 | 12 |
| Data Migration Plan | Design Documentation |
| 1 | 2 |
| Design Verification | ERES |
| 3 | 1 |
| FRS | IDP |
| 7 | 3 |
| IIVP | IIVP results |
| 7 | 23 |
| IIVP Results | ISSD |
| 5 | 3 |
| Maintenance Plan | Move to Production |
| 1 | 4 |

| Project Plan | Software Change Request |
|----------------------------------|------------------------------|
| 5 | 14 |
| Software Compliance Assessment | System Certification Summary |
| 5 | 6 |
| Test protocol | Test Protocol |
| 2 | 36 |
| Test Protocol Results | Traceability |
| 35 | 16 |
| URS/FRS | User Acceptance Protocol |
| 5 | 2 |
| User Acceptance Protocol results | Validation Plan |
| 6 | Δ |

4.8 Number of Deliverable by Application

This is the number of unique deliverables that each application submitted. It only counts each document once, regardless of the status.

```
Acceptance Sampling Plan Generator (ASPG)
                                                         5
                                                      AFMS
                                                        13
                                   Alinity Source Verifier
                            BioCommand Batch Control Plus
                                                  BioXpert
                                                         1
                                                     CHaRM
                                                         2
Clinical Chemistry Excel Spreadsheet for Digital Printing
                                                   CMSNext
                                    DARA Filler DHM and RU
                                                        16
                                                      DFCS
                                                        32
                                                   Empower
                                                  GDSN/GS1
                                                        10
                                                GS Reports
                                                         9
                                                      IRIS
                                                          4
```

Metrics Library
9
Print on Demand
3
Pulse
30
QIMS
2
RSLMS
2
TODS
8
TrendReader
3
WWLIMS
42

4.9 Number of Approvals, Disapprovals, and First Pass Approvals

A A-FP D 58 146 73

4.10 Table of Deliverables by Application

| | Acceptance | Sampling | Plan | Generator | (ASPG) |
|--------------------------------|------------|----------|------|-----------|--------|
| Cancellation | - | | | | 0 |
| CII | | | | | 0 |
| Data Migration Plan | | | | | 0 |
| Design Documentation | | | | | 0 |
| Design Verification | | | | | 0 |
| ERES | | | | | 0 |
| FRS | | | | | 0 |
| IDP | | | | | 0 |
| IIVP | | | | | 0 |
| IIVP results | | | | | 2 |
| IIVP Results | | | | | 0 |
| ISSD | | | | | 1 |
| Maintenance Plan | | | | | 0 |
| Move to Production | | | | | 0 |
| Project Plan | | | | | 0 |
| Software Change Request | | | | | 0 |
| Software Compliance Assessment | | | | | 0 |
| System Certification Summary | | | | | 1 |
| Test protocol | | | | | 0 |
| Test Protocol | | | | | 0 |

| Test Protocol Results | | | | | | | | 1 |
|----------------------------------|-------|-------|--------|--------|------|------|----------|-------|
| Traceability | | | | | | | | 0 |
| URS/FRS | | | | | | | | 0 |
| User Acceptance Protocol | | | | | | | | 0 |
| User Acceptance Protocol results | | | | | | | | 0 |
| Validation Plan | | | | | | | | 0 |
| | | | | | | | | |
| | AFMS | Alini | ty Sou | ırce V | erif | ier | | |
| Cancellation | 0 | | | | | 0 | | |
| CII | 0 | | | | | 0 | | |
| Data Migration Plan | 0 | | | | | 0 | | |
| Design Documentation | 0 | | | | | 0 | | |
| Design Verification | 0 | | | | | 0 | | |
| ERES | 0 | | | | | 0 | | |
| FRS | 1 | | | | | 2 | | |
| IDP | 0 | | | | | 0 | | |
| IIVP | 1 | | | | | 0 | | |
| IIVP results | 0 | | | | | 0 | | |
| IIVP Results | 1 | | | | | 0 | | |
| ISSD | 0 | | | | | 0 | | |
| Maintenance Plan | 0 | | | | | 0 | | |
| Move to Production | 0 | | | | | 0 | | |
| Project Plan | 0 | | | | | 0 | | |
| Software Change Request | 1 | | | | | 2 | | |
| Software Compliance Assessment | 0 | | | | | 1 | | |
| System Certification Summary | 0 | | | | | 0 | | |
| Test protocol | 0 | | | | | 0 | | |
| Test Protocol | 8 | | | | | 0 | | |
| Test Protocol Results | 0 | | | | | 0 | | |
| Traceability | 0 | | | | | 1 | | |
| URS/FRS | 0 | | | | | 0 | | |
| User Acceptance Protocol | 0 | | | | | 0 | | |
| User Acceptance Protocol results | 0 | | | | | 0 | | |
| Validation Plan | 1 | | | | | 0 | | |
| | | | | | | | | |
| | BioCo | mmand | Batch | n Cont | rol | Plus | BioXpert | CHaRM |
| Cancellation | | | | | | 0 | 0 | 0 |
| CII | | | | | | 0 | 0 | 0 |
| Data Migration Plan | | | | | | 0 | 0 | 0 |
| Design Documentation | | | | | | 0 | 0 | 0 |
| Design Verification | | | | | | 0 | 0 | 0 |
| ERES | | | | | | 0 | 0 | 0 |
| FRS | | | | | | 0 | 0 | 1 |
| IDP | | | | | | 0 | 0 | 0 |
| IIVP | | | | | | 0 | 0 | 0 |
| IIVP results | | | | | | 1 | 0 | 0 |
| | | | | | | _ | Ŭ | • |

| IIVP Results | 0 | 0 | 0 |
|----------------------------------|---|---|---|
| ISSD | 0 | 0 | 0 |
| Maintenance Plan | 0 | 0 | 0 |
| Move to Production | 0 | 0 | 0 |
| Project Plan | 0 | 0 | 0 |
| Software Change Request | 0 | 1 | 0 |
| Software Compliance Assessment | 0 | 0 | 0 |
| System Certification Summary | 0 | 0 | 0 |
| Test protocol | 0 | 0 | 0 |
| Test Protocol | 0 | 0 | 0 |
| Test Protocol Results | 0 | 0 | 0 |
| Traceability | 0 | 0 | 0 |
| URS/FRS | 0 | 0 | 0 |
| User Acceptance Protocol | 0 | 0 | 0 |
| User Acceptance Protocol results | 0 | 0 | 0 |
| Validation Plan | 0 | 0 | 1 |

Clinical Chemistry Excel Spreadsheet for Digital Printing

| | OTTHIOUT | omin to or j | D1100 T | produbilee | T 0 T | 2-6-00 |
|----------------------------------|----------|--------------|----------------|------------|-------|--------|
| Cancellation | | | | | | |
| CII | | | | | | |
| Data Migration Plan | | | | | | |
| Design Documentation | | | | | | |
| Design Verification | | | | | | |
| ERES | | | | | | |
| FRS | | | | | | |
| IDP | | | | | | |
| IIVP | | | | | | |
| IIVP results | | | | | | |
| IIVP Results | | | | | | |
| ISSD | | | | | | |
| Maintenance Plan | | | | | | |
| Move to Production | | | | | | |
| Project Plan | | | | | | |
| Software Change Request | | | | | | |
| Software Compliance Assessment | | | | | | |
| System Certification Summary | | | | | | |
| Test protocol | | | | | | |
| Test Protocol | | | | | | |
| Test Protocol Results | | | | | | |
| Traceability | | | | | | |
| URS/FRS | | | | | | |
| User Acceptance Protocol | | | | | | |
| User Acceptance Protocol results | | | | | | |
| | | | | | | |

 ${\tt CMSNext}$ DARA Filler DHM and RU DFCS Empower

Validation Plan

| CII Data Migration Plan | 0 | | | | 1 0 | 2 0 | 1 |
|----------------------------------|----------|----|---------|------|---------|---------|---|
| Design Documentation | 0 | | | | 0 | 0 | 0 |
| Design Verification | 0 | | | | 0 | 2 | 0 |
| ERES | 0 | | | | 0 | 0 | 0 |
| FRS | 0 | | | | 0 | 0 | 0 |
| IDP | 0 | | | | 1 | 0 | 1 |
| IIVP | 0 | | | | 1 | 2 | 1 |
| IIVP results | 0 | | | | 5 | 2 | 0 |
| IIVP Results | 0 | | | | 0 | 0 | 0 |
| ISSD | 0 | | | | 1 | 0 | 0 |
| Maintenance Plan | 0 | | | | 0 | 0 | 0 |
| Move to Production | 0 | | | | 0 | 0 | 0 |
| Project Plan | 0 | | | | 0 | 1 | 0 |
| Software Change Request | 2 | | | | 1 | 1 | 1 |
| Software Compliance Assessment | 0 | | | | 1 | 0 | 0 |
| System Certification Summary | 0 | | | | 1 | 0 | 0 |
| Test protocol | 0 | | | | 0 | 0 | 0 |
| Test Protocol | 0 | | | | 1 | 3 | 1 |
| Test Protocol Results | 0 | | | | 1 | 17 | 0 |
| Traceability | 0 | | | | 2 | 0 | 1 |
| URS/FRS | 0 | | | | 0 | 0 | 1 |
| User Acceptance Protocol | 0 | | | | 0 | 2 | 0 |
| User Acceptance Protocol results | 0 | | | | 0 | 0 | 0 |
| Validation Plan | 0 | | | | 0 | 0 | 0 |
| | GDSN/GS1 | GS | Reports | IRIS | Metrics | Library | |
| Cancellation | 0 | | 0 | 0 | | 0 | |

Cancellation CII Data Migration Plan Design Documentation Design Verification **ERES** FRS IDP IIVP IIVP results IIVP Results ISSD Maintenance Plan Move to Production Project Plan Software Change Request Software Compliance Assessment System Certification Summary

| Test protocol | 1 | 0 | 0 | 0 |
|----------------------------------|---|---|---|---|
| Test Protocol | 3 | 0 | 0 | 4 |
| Test Protocol Results | 0 | 1 | 0 | 2 |
| Traceability | 0 | 0 | 0 | 0 |
| URS/FRS | 1 | 0 | 0 | 0 |
| User Acceptance Protocol | 0 | 0 | 0 | 0 |
| User Acceptance Protocol results | 0 | 0 | 0 | 0 |
| Validation Plan | 0 | 0 | 1 | 1 |

Print on Demand Pulse QIMS RSLMS TODS Cancellation CII Data Migration Plan Design Documentation Design Verification **ERES** FRS IDP IIVP IIVP results IIVP Results ISSD Maintenance Plan Move to Production Project Plan Software Change Request Software Compliance Assessment System Certification Summary Test protocol Test Protocol Test Protocol Results Traceability URS/FRS User Acceptance Protocol User Acceptance Protocol results Validation Plan

| | TrendReader | WWLIMS |
|----------------------|-------------|--------|
| Cancellation | 0 | 0 |
| CII | 0 | 4 |
| Data Migration Plan | 0 | 0 |
| Design Documentation | 0 | 0 |
| Design Verification | 0 | 0 |
| ERES | 0 | 1 |
| FRS | 0 | 2 |
| IDP | 0 | 1 |

| IIVP | 0 | 0 |
|----------------------------------|---|----|
| IIVP results | 0 | 9 |
| IIVP Results | 3 | 0 |
| ISSD | 0 | 0 |
| Maintenance Plan | 0 | 0 |
| Move to Production | 0 | 0 |
| Project Plan | 0 | 0 |
| Software Change Request | 0 | 0 |
| Software Compliance Assessment | 0 | 0 |
| System Certification Summary | 0 | 0 |
| Test protocol | 0 | 0 |
| Test Protocol | 0 | 1 |
| Test Protocol Results | 0 | 10 |
| Traceability | 0 | 8 |
| URS/FRS | 0 | 0 |
| User Acceptance Protocol | 0 | 0 |
| User Acceptance Protocol results | 0 | 6 |
| Validation Plan | 0 | 0 |
| | | |

4.11 Table of Rejection Reasons

| Inaccurate information | Incorrect Objective Evidence |
|--|--|
| 50 | 2 |
| Incorrect scope | Insufficient testing |
| 4 | 2 |
| Insufficient traceability | Multible Errors |
| 1 | 2 |
| Not following configuration management | Not following document version control |
| 1 | 1 |
| Other | |
| 8 | |

${\bf 4.12}\quad {\bf Defects\ Verses\ Application}$

| | | Inaccurate | information |
|------------------------------------|--------|------------|-------------|
| Acceptance Sampling Plan Generator | (ASPG) | | 3 |
| AFMS | | | 3 |
| BioXpert | | | 1 |
| CHaRM | | | 0 |
| CMSNext | | | 0 |
| DARA Filler DHM and RU | | | 7 |
| DFCS | | | 3 |
| Empower | | | 8 |
| GDSN/GS1 | | | 4 |
| Metrics Library | | | 0 |
| Print on Demand | | | 1 |

| Pulse QIMS WWLIMS | 11 4 4 |
|--|--|
| Acceptance Sampling Plan Generator (ASPG) AFMS BioXpert CHaRM CMSNext DARA Filler DHM and RU DFCS Empower GDSN/GS1 Metrics Library Print on Demand Pulse QIMS WWLIMS | Incorrect Objective Evidence |
| Acceptance Sampling Plan Generator (ASPG) AFMS BioXpert CHaRM CMSNext DARA Filler DHM and RU DFCS Empower GDSN/GS1 Metrics Library Print on Demand Pulse QIMS WWLIMS | Incorrect scope 0 0 0 1 0 0 0 0 0 0 0 0 0 0 1 1 2 0 0 0 0 |
| Acceptance Sampling Plan Generator (ASPG) AFMS BioXpert CHaRM CMSNext DARA Filler DHM and RU DFCS Empower GDSN/GS1 | Insufficient testing |

| Metrics Library Print on Demand Pulse QIMS WWLIMS | 0 0 0 0 |
|--|---|
| Acceptance Sampling Plan Generator (ASPG) AFMS BioXpert CHaRM CMSNext DARA Filler DHM and RU DFCS Empower GDSN/GS1 Metrics Library Print on Demand Pulse QIMS WWLIMS | Insufficient traceability |
| Acceptance Sampling Plan Generator (ASPG) AFMS BioXpert CHaRM CMSNext DARA Filler DHM and RU DFCS Empower GDSN/GS1 Metrics Library Print on Demand Pulse QIMS WWLIMS | Multible Errors 0 0 0 0 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 |
| Acceptance Sampling Plan Generator (ASPG) AFMS BioXpert CHaRM CMSNext DARA Filler DHM and RU DFCS | Not following configuration management 0 1 0 0 0 0 0 0 0 0 |

```
Empower
                                                                                   0
GDSN/GS1
                                                                                   0
Metrics Library
                                                                                   0
Print on Demand
                                                                                   0
Pulse
                                                                                   0
QIMS
                                                                                   0
WWLIMS
                                                                                    0
                                            Not following document version control
Acceptance Sampling Plan Generator (ASPG)
AFMS
                                                                                   1
                                                                                   0
BioXpert
CHaRM
                                                                                   0
CMSNext
                                                                                   0
DARA Filler DHM and RU
                                                                                   0
DFCS
                                                                                   0
                                                                                   0
Empower
GDSN/GS1
                                                                                   0
Metrics Library
                                                                                   0
Print on Demand
                                                                                   0
Pulse
                                                                                   0
QIMS
                                                                                   0
WWLIMS
                                                                                   0
                                            Other
Acceptance Sampling Plan Generator (ASPG)
AFMS
                                                1
BioXpert
                                                0
CHaRM
                                                1
CMSNext
                                                0
DARA Filler DHM and RU
                                                0
DFCS
                                                0
                                                0
Empower
GDSN/GS1
                                                5
Metrics Library
                                                1
Print on Demand
                                                0
Pulse
                                                0
QIMS
                                                0
WWLIMS
                                                0
```

4.13 Defects Verses Deliverable

Inaccurate information

| CII | 3 |
|------------------------------|----|
| FRS | 2 |
| IDP | 2 |
| IIVP | 2 |
| IIVP results | 1 |
| IIVP Results | 0 |
| ISSD | 2 |
| Software Change Request | 12 |
| System Certification Summary | 9 |
| Test Protocol | 5 |
| Test Protocol Results | 5 |
| Traceability | 2 |
| URS/FRS | 4 |
| Validation Plan | 0 |
| | |

Incorrect Objective Evidence Incorrect scope CII FRS IDP IIVP IIVP results IIVP Results ISSD Software Change Request System Certification Summary Test Protocol Test Protocol Results Traceability URS/FRS Validation Plan

| | Insufficient | testing | Insufficient | traceability |
|------------------------------|--------------|---------|--------------|--------------|
| CII | | 0 | | 0 |
| FRS | | 0 | | 0 |
| IDP | | 0 | | 0 |
| IIVP | | 0 | | 0 |
| IIVP results | | 0 | | 0 |
| IIVP Results | | 0 | | 0 |
| ISSD | | 0 | | 0 |
| Software Change Request | | 0 | | 0 |
| System Certification Summary | | 0 | | 0 |
| Test Protocol | | 2 | | 0 |
| Test Protocol Results | | 0 | | 0 |
| Traceability | | 0 | | 1 |
| URS/FRS | | 0 | | 0 |
| Validation Plan | | 0 | | 0 |

| | Muli | tible Erro | rs | | | |
|------------------------------|------|------------|-----------|---------|------------|---|
| CII | | | 0 | | | |
| FRS | | | 0 | | | |
| IDP | | | 0 | | | |
| IIVP | | | 0 | | | |
| | | | - | | | |
| IIVP results | | | 0 | | | |
| IIVP Results | | | 0 | | | |
| ISSD | | | 0 | | | |
| Software Change Request | | | 2 | | | |
| System Certification Summary | | | 0 | | | |
| Test Protocol | | | 0 | | | |
| Test Protocol Results | | | 0 | | | |
| Traceability | | | 0 | | | |
| URS/FRS | | | 0 | | | |
| Validation Plan | | | 0 | | | |
| | | | | | | |
| | Not | following | configura | ation r | management | |
| CII | | | | | 0 | |
| FRS | | | | | 1 | |
| IDP | | | | | 0 | |
| IIVP | | | | | 0 | |
| IIVP results | | | | | 0 | |
| IIVP Results | | | | | 0 | |
| ISSD | | | | | 0 | |
| Software Change Request | | | | | 0 | |
| System Certification Summary | | | | | 0 | |
| Test Protocol | | | | | 0 | |
| | | | | | | |
| Test Protocol Results | | | | | 0 | |
| Traceability | | | | | 0 | |
| URS/FRS | | | | | 0 | |
| Validation Plan | | | | | 0 | |
| | | | | | | |
| | Not | following | document | versi | on control | |
| CII | | | | | 0 | 0 |
| FRS | | | | | 0 | 0 |
| IDP | | | | | 0 | 0 |
| IIVP | | | | | 0 | 1 |
| IIVP results | | | | | 0 | 0 |
| IIVP Results | | | | | 0 | 5 |
| ISSD | | | | | 0 | 0 |
| Software Change Request | | | | | 0 | 0 |
| System Certification Summary | | | | | 0 | 0 |
| Test Protocol | | | | | 0 | 0 |
| Test Protocol Results | | | | | 0 | 1 |
| | | | | | - | _ |

Traceability

 URS/FRS
 0
 0

 Validation Plan
 1
 1

4.14 Rejection Reason by Deliverable

```
CII
                                                        FRS
                            3
                                                           3
                          IDP
                                                        IIVP
                            2
                                                           3
                IIVP results
                                               IIVP Results
                            2
                         ISSD
                                   Software Change Request
System Certification Summary
                                              Test Protocol
       Test Protocol Results
                                               Traceability
                                                           3
                      URS/FRS
                                            Validation Plan
                            4
```

4.15 Number of Rejections by Project

```
Acceptance Sampling Plan Generator (ASPG)
                                         3
                                      AFMS
                                  BioXpert
                                     CHaRM
                                   CMSNext
                   DARA Filler DHM and RU
                                        10
                                      DFCS
                                         6
                                   Empower
                                  GDSN/GS1
                          Metrics Library
                          Print on Demand
                                         2
                                     Pulse
                                        13
```

QIMS 4 WWLIMS 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] 0.7364621

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] 0.5270758