

SQA Metric Items From FPA Spreadsheet - October 2018

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Abstract

Evaluation of various potential metrics, performance indicators from the Excel workbook that Software Quality Assurance collected called First Pass Acceptance. This will only be run for the month of October 2018. ¹

Contents

1	Introduction	1		
2	Data and Calculations	1		
2.1	Data	1		
2.2	Calculations	2		
3	Work Yet to be Completed	2		
3.1	Formula	2		
3.2	Trending	2		
3.2.1	Graphs	2		
4	Quantity Metrics	2		
4.1	Application supported .	2		
4.2	Number of Projects . . .	3		
4.3	Number of Reviews . . .	3		
4.4	Number of Items Reviewed	3		
4.5	Number of Projects Started	3		
4.6	Projects Completed . . .	3		
4.7	Number Of Deliverables by Type	4		
4.8	Number of Deliverable by Application	4		
4.9	Number of Approvals, Disapprovals, and First Pass Approvals	7		
4.10	Table of Deliverables by Application	7		
4.11	Table of Rejection Reasons	38		
4.12	Defects Verses Application	38		
4.13	Defects Verses Deliverable	44		
4.14	Rejection Reason by Deliverable	48		
4.15	Number of Rejections by Project	49		
5	Rate Metrics	50		
5.1	Document Approval Rate	50		
5.2	First Pass Acceptance .	50		

¹Date Ran: Monday 4th February, 2019 at 09:48

1 Introduction

The data is processed using R², Version 3.5.1 named “Feather Spray”. The only extension (package or library) utilized is lubridate (version 1.7.4) to provide key functionality in the processing of dates.

The data is read into R from a comma seperated value (csv) file which is derived (saved) from the spreadsheet without modification. Additional values are computed as needed.

This report is prepared in the R enviroment using a collection of packages know as Sweave that included knitr which in turn feeds the package into L^AT_EX 2_ε a typesetting program to produce a PDF file. L^AT_EX 2_ε is implmented in MiT_EX. L^AT_EX 2_ε is utilizing the folowing packages to control style and formating:

- datetime and
- multitoc

This will only show a point in time summary and no trends.

2 Data and Calculations

2.1 Data

A seperate data dictionary will be prepared to for both the source data and computed values stored in R.

2.2 Calculations

All calculations presented here have not been implemented in R as formulas.

3 Work Yet to be Completed

3.1 Formula

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

3.2 Trending

Eventually the “System” will be updated to select the data on a for a calander month. After processing the resulots will be stored in a seperate file. This will allow for longer term trending of this data.

3.2.1 Graphs

When “trending” is implmented graphs of the trends will also be added.

²RStudio is utilized as an IDE

4 Quantity Metrics

4.1 Application supported

This is a list of all application support this period.

Note: Alphabetize the list

- [1] "AFMS"
- [2] "WWLIMS"
- [3] "QIMS"
- [4] "PEAR"
- [5] "Acceptance Sampling Plan Generator (ASPG)"
- [6] "DFCS"
- [7] "IRIS"
- [8] "Pulse"
- [9] "Groninger"
- [10] "Clinical Chemistry Excel Spreadsheet for Digital Printing"
- [11] "GDSN/GS1"
- [12] "TODS"
- [13] "CHaRM"
- [14] "TrendReader"
- [15] "Qualtrics"
- [16] "GS Reports"
- [17] "Metrics Library"
- [18] "Universal Protocol Emulator (UPE)"
- [19] "Power BI"
- [20] "DaVinci"

4.2 Number of Projects

The total number of projects worked on in this period. This may differ from the application list because some applications may have more than one project in the period.

- [1] 55

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] 374

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] 267

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] 12

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] 10

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.

Addendum	Cancellation
1	1
CII	Data Migration Plan
14	3
Data Privacy Plan	Decommissioning Report
0	0
Design Documentation	Design Verification
0	31
ERES	FRS
1	11
IDP	IIVP
5	12
IIVP results	IIVP Results
18	2
ISSD	Maintenance Plan
3	2
Move to Production	Other
3	2

Project Plan	Release Notes
11	3
Risk Assessment	Software Change Request
2	12
Software Compliance Assessment	System Certification Summary
5	8
Test protocol	Test Protocol
0	42
Test Protocol Results	Traceability
31	25
URS	URS/FRS
6	2
User Acceptance Protocol	User Acceptance Protocol results
0	4
Validation Plan	
7	

4.8 Number of Deliverable by Application

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

Abbott Transfusion Medicine
0
Acceptance Sampling Plan Generator (ASPG)
16
ADD Shop Floor Paper (SFP) Report System
0
AFMS
6
Alinity S Non-LIMS spreadsheets
0
Alinity Source Verifier
0
AMM
0
AP 24 CIP
0
Apollo/PHM
0
ASPG
0
Assay File Database
0
BioCommand Batch Control Plus
0

	BioXpert	0
	CHARM	4
Clinical Chemistry Excel Spreadsheet for Digital Printing		14
	CMSnext	0
	CMSNext	0
DARA Filler DHM and RU		0
	DaVinci	1
	DFCS	24
	DPW	0
	EDMS	0
	eNovator	0
EP Evaluator		0
	GDSN/GS1	18
	Groninger	12
GS Reports		9
	Helios	0
Helios Global Contact Center		0
IDA Reporting		0
	ideaPoint	0
	IRIS	6
Knowledge Management		0
Metrics Library		2
MQA Protocol		0

Navigator	0
PCN/SCN	0
PEAR	2
Power BI	2
Print on Demand	0
Pulse	39
QIMS	13
QPI	0
Qualtrics	1
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	17
TrendReader	2
Universal Protocol Emulator (UPE)	5
WWLIMS	74

4.9 Number of Approvals, Disapprovals, and First Pass Approvals

A	A-FP	D
106	151	117

4.10 Table of Deliverables by Application

	Addendum
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	1
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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

Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WWLIMS	0

	Cancellation	CII
Abbott Transfusion Medicine	0	0
Acceptance Sampling Plan Generator (ASPG)	0	2
ADD Shop Floor Paper (SFP) Report System	0	0
AFMS	0	1
Alinity S Non-LIMS spreadsheets	0	0
Alinity Source Verifier	0	0
AMM	0	0
AP 24 CIP	0	0
Apollo/PHM	0	0
ASPG	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
BioXpert	0	0
CHaRM	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	1
CMSnext	0	0
CMSNext	0	0
DARA Filler DHM and RU	0	0
DaVinci	1	0
DFCS	0	1
DPW	0	0
EDMS	0	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	1
Groninger	0	1
GS Reports	0	0
Helios	0	0
Helios Global Contact Center	0	0
IDA Reporting	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	1
QIMS	0	0
QPI	0	0
Qualtrics	0	0
R&D Data Management Dashboard	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	0	0
Universal Protocol Emulator (UPE)	0	0
WVLIMS	0	6

Data Migration Plan	
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	2
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	1
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0

Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WVLIMS	0

Data Privacy Plan

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0

CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WVLIMS	0
Decommissioning Report	
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0

AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WVLIMS	0

	Design Documentation
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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
Qualtrics	0

R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WVLIMS	0

	Design Verification
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	2
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	1
Groninger	1
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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	4
QIMS	0
QPI	0
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	17
TrendReader	0
Universal Protocol Emulator (UPE)	0
WWLIMS	6

	ERES	FRS	IDP	IIVP
Abbott Transfusion Medicine	0	0	0	0
Acceptance Sampling Plan Generator (ASPG)	0	1	1	1
ADD Shop Floor Paper (SFP) Report System	0	0	0	0
AFMS	0	2	0	1
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
ASPG	0	0	0	0
Assay File Database	0	0	0	0
BioCommand Batch Control Plus	0	0	0	0
BioXpert	0	0	0	0
CHaRM	0	0	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	0	2	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	0	0	1	1
DPW	0	0	0	0
EDMS	0	0	0	0
eNovator	0	0	0	0
EP Evaluator	0	0	0	0
GDSN/GS1	0	1	0	1
Groninger	0	0	1	1

GS Reports	0	0	0	0
Helios	0	0	0	0
Helios Global Contact Center	0	0	0	0
IDA Reporting	0	0	0	0
ideaPoint	0	0	0	0
IRIS	0	0	0	0
Knowledge Management	0	0	0	0
Metrics Library	0	0	0	0
MQA Protocol	0	0	0	0
Navigator	0	0	0	0
PCN/SCN	0	0	0	0
PEAR	0	0	0	0
Power BI	0	0	0	0
Print on Demand	0	0	0	0
Pulse	0	3	0	1
QIMS	0	0	0	0
QPI	0	0	0	0
Qualtrics	0	0	0	0
R&D Data Management Dashboard	0	0	0	0
Reliasoft Xfmea	0	0	0	0
RSLMS	0	0	0	0
SAS	0	0	0	0
TestComplete	0	0	0	0
TODS	0	0	0	0
TrendReader	0	0	0	0
Universal Protocol Emulator (UPE)	1	0	0	0
WVLIMS	0	4	0	6

IIVP results

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0

DARA Filler DHM and RU	0
DaVinci	0
DFCS	1
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	2
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	2
QIMS	0
QPI	0
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WVLIMS	13

	IIVP Results	ISSD
Abbott Transfusion Medicine	0	0
Acceptance Sampling Plan Generator (ASPG)	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
ASPG	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
BioXpert	0	0
CHaRM	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	0
CMSnext	0	0
CMSNext	0	0
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	0	0
DPW	0	0
EDMS	0	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	1
Groninger	0	1
GS Reports	0	0
Helios	0	0
Helios Global Contact Center	0	0
IDA Reporting	0	0
ideaPoint	0	0
IRIS	0	1
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
Qualtrics	0	0
R&D Data Management Dashboard	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	2	0
Universal Protocol Emulator (UPE)	0	0
WVLIMS	0	0

	Maintenance Plan
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	1
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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
Qualtrics	0
R&D Data Management Dashboard	0

Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WVLIMS	0

	Move to Production	
Abbott Transfusion Medicine		0
Acceptance Sampling Plan Generator (ASPG)		0
ADD Shop Floor Paper (SFP) Report System		0
AFMS		0
Alinity S Non-LIMS spreadsheets		0
Alinity Source Verifier		0
AMM		0
AP 24 CIP		0
Apollo/PHM		0
ASPG		0
Assay File Database		0
BioCommand Batch Control Plus		0
BioXpert		0
CHaRM		0
Clinical Chemistry Excel Spreadsheet for Digital Printing		0
CMSnext		0
CMSNext		0
DARA Filler DHM and RU		0
DaVinci		0
DFCS		0
DPW		0
EDMS		0
eNovator		0
EP Evaluator		0
GDSN/GS1		0
Groninger		0
GS Reports		3
Helios		0
Helios Global Contact Center		0
IDA Reporting		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
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WWLIMS	0

	Other Project Plan	
Abbott Transfusion Medicine	0	0
Acceptance Sampling Plan Generator (ASPG)	0	2
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
ASPG	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
BioXpert	0	0
CHaRM	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	0
CMSnext	0	0
CMSNext	0	0
DARA Filler DHM and RU	0	0
DaVinci	0	0
DFCS	0	1
DPW	0	0
EDMS	0	0
eNovator	0	0
EP Evaluator	0	0
GDSN/GS1	0	1
Groninger	0	0
GS Reports	0	5

Helios	0	0
Helios Global Contact Center	0	0
IDA Reporting	0	0
ideaPoint	0	0
IRIS	0	0
Knowledge Management	0	0
Metrics Library	0	1
MQA Protocol	0	0
Navigator	0	0
PCN/SCN	0	0
PEAR	0	0
Power BI	0	1
Print on Demand	0	0
Pulse	2	0
QIMS	0	0
QPI	0	0
Qualtrics	0	0
R&D Data Management Dashboard	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	0	0
Universal Protocol Emulator (UPE)	0	0
WVLIMS	0	0

	Release Notes
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0

DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	1
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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	2
QPI	0
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WWLIMS	0

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

ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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	1
QIMS	0
QPI	0
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WVLIMS	0

Software Change Request

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
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	1
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	0
ideaPoint	0
IRIS	3
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	3
QIMS	0
QPI	0
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0

RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	1
WVLIMS	3

Software Compliance Assessment

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	0
ideaPoint	0
IRIS	2
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
Qualtrics	1
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	1
WVLIMS	1

System Certification Summary

Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	2
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	1
Groninger	1
GS Reports	0
Helios	0

Helios Global Contact Center	0
IDA Reporting	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	1
Power BI	0
Print on Demand	0
Pulse	2
QIMS	1
QPI	0
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WVLIMS	0

	Test protocol
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0

DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WWLIMS	0

	Test Protocol
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	2
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0

Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	1
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	14
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	1
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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	8
QIMS	0
QPI	0
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	1
WVLIMS	15

Test Protocol Results

Abbott Transfusion Medicine

0

Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	2
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	2
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	1
Groninger	1
GS Reports	1
Helios	0
Helios Global Contact Center	0
IDA Reporting	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	0
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	1
Power BI	1
Print on Demand	0
Pulse	6
QIMS	0
QPI	0
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0

SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WVLIMS	16

	Traceability	URS
Abbott Transfusion Medicine	0	0
Acceptance Sampling Plan Generator (ASPG)	3	1
ADD Shop Floor Paper (SFP) Report System	0	0
AFMS	0	1
Alinity S Non-LIMS spreadsheets	0	0
Alinity Source Verifier	0	0
AMM	0	0
AP 24 CIP	0	0
Apollo/PHM	0	0
ASPG	0	0
Assay File Database	0	0
BioCommand Batch Control Plus	0	0
BioXpert	0	0
CHaRM	0	1
Clinical Chemistry Excel Spreadsheet for Digital Printing	2	1
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	2	0
Groninger	1	0
GS Reports	0	0
Helios	0	0
Helios Global Contact Center	0	0
IDA Reporting	0	0
ideaPoint	0	0
IRIS	0	0
Knowledge Management	0	0
Metrics Library	0	0
MQA Protocol	0	0
Navigator	0	0
PCN/SCN	0	0
PEAR	0	0

Power BI	0	0
Print on Demand	0	0
Pulse	6	0
QIMS	10	0
QPI	0	0
Qualtrics	0	0
R&D Data Management Dashboard	0	0
Reliasoft Xfmea	0	0
RSLMS	0	0
SAS	0	0
TestComplete	0	0
TODS	0	0
TrendReader	0	0
Universal Protocol Emulator (UPE)	0	0
WVLIMS	1	2

	URS/FRS
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	1
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0

IDA Reporting	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
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	1
WWLIMS	0

User Acceptance Protocol	
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	0
ADD Shop Floor Paper (SFP) Report System	0
AFMS	0
Alinity S Non-LIMS spreadsheets	0
Alinity Source Verifier	0
AMM	0
AP 24 CIP	0
Apollo/PHM	0
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	0

DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	0
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	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
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0
TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WWLIMS	0

User Acceptance Protocol results

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

BioCommand Batch Control Plus
 BioXpert
 CHaRM
 Clinical Chemistry Excel Spreadsheet for Digital Printing
 CMSnext
 CMSNext
 DARA Filler DHM and RU
 DaVinci
 DFCS
 DPW
 EDMS
 eNovator
 EP Evaluator
 GDSN/GS1
 Groninger
 GS Reports
 Helios
 Helios Global Contact Center
 IDA Reporting
 ideaPoint
 IRIS
 Knowledge Management
 Metrics Library
 MQA Protocol
 Navigator
 PCN/SCN
 PEAR
 Power BI
 Print on Demand
 Pulse
 QIMS
 QPI
 Qualtrics
 R&D Data Management Dashboard
 Reliasoft Xfmea
 RSLMS
 SAS
 TestComplete
 TODS
 TrendReader
 Universal Protocol Emulator (UPE)
 WVLIMS

	Validation Plan
Abbott Transfusion Medicine	0
Acceptance Sampling Plan Generator (ASPG)	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
ASPG	0
Assay File Database	0
BioCommand Batch Control Plus	0
BioXpert	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
CMSnext	0
CMSNext	0
DARA Filler DHM and RU	0
DaVinci	0
DFCS	2
DPW	0
EDMS	0
eNovator	0
EP Evaluator	0
GDSN/GS1	2
Groninger	0
GS Reports	0
Helios	0
Helios Global Contact Center	0
IDA Reporting	0
ideaPoint	0
IRIS	0
Knowledge Management	0
Metrics Library	1
MQA Protocol	0
Navigator	0
PCN/SCN	0
PEAR	0
Power BI	0
Print on Demand	0
Pulse	0
QIMS	0
QPI	0
Qualtrics	0
R&D Data Management Dashboard	0
Reliasoft Xfmea	0
RSLMS	0
SAS	0

TestComplete	0
TODS	0
TrendReader	0
Universal Protocol Emulator (UPE)	0
WVLIMS	1

4.11 Table of Rejection Reasons

Inaccurate information	Incorrect Approvers
56	13
Incorrect Objective Evidence	Incorrect scope
8	4
Insufficient testing	Insufficient traceability
1	3
N/A	Not compliant with procedure
0	10
Not following configuration management	Not following document version control
0	0
Not using template	other
3	0
Other	Requirement deficiency
14	1

4.12 Defects Verses Application

	Inaccurate information
Acceptance Sampling Plan Generator (ASPG)	13
AFMS	2
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	5
DFCS	2
GDSN/GS1	5
Groninger	8
GS Reports	0
IRIS	1
PEAR	1
Pulse	10
QIMS	1
Qualtrics	0
TODS	0
Universal Protocol Emulator (UPE)	0
WVLIMS	8
	Incorrect Approvers
Acceptance Sampling Plan Generator (ASPG)	2
AFMS	1

CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	1
GDSN/GS1	0
Groninger	0
GS Reports	0
IRIS	2
PEAR	0
Pulse	1
QIMS	3
Qualtrics	0
TODS	0
Universal Protocol Emulator (UPE)	0
WVLIMS	3

	Incorrect Objective Evidence	
Acceptance Sampling Plan Generator (ASPG)		0
AFMS		0
CHaRM		0
Clinical Chemistry Excel Spreadsheet for Digital Printing		0
DFCS		1
GDSN/GS1		0
Groninger		0
GS Reports		0
IRIS		0
PEAR		1
Pulse		1
QIMS		0
Qualtrics		0
TODS		0
Universal Protocol Emulator (UPE)		0
WVLIMS		5

	Incorrect scope	
Acceptance Sampling Plan Generator (ASPG)		0
AFMS		0
CHaRM		0
Clinical Chemistry Excel Spreadsheet for Digital Printing		1
DFCS		0
GDSN/GS1		1
Groninger		1
GS Reports		0
IRIS		0
PEAR		0
Pulse		1
QIMS		0

Qualtrics	0
TODS	0
Universal Protocol Emulator (UPE)	0
WVLIMS	0
	Insufficient testing
Acceptance Sampling Plan Generator (ASPG)	0
AFMS	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
GDSN/GS1	0
Groninger	0
GS Reports	0
IRIS	0
PEAR	0
Pulse	1
QIMS	0
Qualtrics	0
TODS	0
Universal Protocol Emulator (UPE)	0
WVLIMS	0
	Insufficient traceability
Acceptance Sampling Plan Generator (ASPG)	1
AFMS	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
GDSN/GS1	0
Groninger	0
GS Reports	0
IRIS	0
PEAR	0
Pulse	2
QIMS	0
Qualtrics	0
TODS	0
Universal Protocol Emulator (UPE)	0
WVLIMS	0
	N/A
Acceptance Sampling Plan Generator (ASPG)	0
AFMS	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0

DFCS	0
GDSN/GS1	0
Groninger	0
GS Reports	0
IRIS	0
PEAR	0
Pulse	0
QIMS	0
Qualtrics	0
TODS	0
Universal Protocol Emulator (UPE)	0
WWLIMS	0

Not compliant with procedure

Acceptance Sampling Plan Generator (ASPG)	1
AFMS	1
CHaRM	3
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	1
GDSN/GS1	0
Groninger	0
GS Reports	1
IRIS	1
PEAR	0
Pulse	0
QIMS	0
Qualtrics	0
TODS	0
Universal Protocol Emulator (UPE)	1
WWLIMS	1

Not following configuration mana

Acceptance Sampling Plan Generator (ASPG)
AFMS
CHaRM
Clinical Chemistry Excel Spreadsheet for Digital Printing
DFCS
GDSN/GS1
Groninger
GS Reports
IRIS
PEAR
Pulse
QIMS
Qualtrics
TODS

Universal Protocol Emulator (UPE)
WVLIMS

Not following document version c

Acceptance Sampling Plan Generator (ASPG)
AFMS
CHaRM
Clinical Chemistry Excel Spreadsheet for Digital Printing
DFCS
GDSN/GS1
Groninger
GS Reports
IRIS
PEAR
Pulse
QIMS
Qualtrics
TODS
Universal Protocol Emulator (UPE)
WVLIMS

Not using template

Acceptance Sampling Plan Generator (ASPG)	1
AFMS	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
GDSN/GS1	0
Groninger	0
GS Reports	0
IRIS	0
PEAR	0
Pulse	0
QIMS	0
Qualtrics	0
TODS	0
Universal Protocol Emulator (UPE)	2
WVLIMS	0

other Other

Acceptance Sampling Plan Generator (ASPG)	0	0
AFMS	0	0
CHaRM	0	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0	0
DFCS	0	0
GDSN/GS1	0	2

Groninger	0	0
GS Reports	0	0
IRIS	0	0
PEAR	0	0
Pulse	0	0
QIMS	0	0
Qualtrics	0	1
TODS	0	9
Universal Protocol Emulator (UPE)	0	2
WWLIMS	0	0

	Requirement deficiency
Acceptance Sampling Plan Generator (ASPG)	1
AFMS	0
CHaRM	0
Clinical Chemistry Excel Spreadsheet for Digital Printing	0
DFCS	0
GDSN/GS1	0
Groninger	0
GS Reports	0
IRIS	0
PEAR	0
Pulse	0
QIMS	0
Qualtrics	0
TODS	0
Universal Protocol Emulator (UPE)	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 Approvers
CII	1	1
Data Migration Plan	0	0
Design Verification	0	0
ERES	0	0
FRS	5	0
IDP	1	1
IIVP	3	0
IIVP results	5	0
ISSD	1	0
Move to Production	0	0
Project Plan	3	1

Release Notes	1	3
Software Change Request	4	1
Software Compliance Assessment	0	1
System Certification Summary	5	0
Test Protocol	9	1
Test Protocol Results	4	3
Traceability	11	0
URS	0	1
URS/FRS	0	0
User Acceptance Protocol results	0	0
Validation Plan	3	0

	Incorrect Objective Evidence	Incorrect scope
CII	0	0
Data Migration Plan	0	0
Design Verification	0	0
ERES	0	0
FRS	0	0
IDP	0	0
IIVP	0	0
IIVP results	3	0
ISSD	0	0
Move to Production	0	0
Project Plan	0	0
Release Notes	0	0
Software Change Request	0	1
Software Compliance Assessment	0	0
System Certification Summary	0	0
Test Protocol	0	2
Test Protocol Results	5	0
Traceability	0	0
URS	0	0
URS/FRS	0	0
User Acceptance Protocol results	0	0
Validation Plan	0	1

	Insufficient testing
CII	0
Data Migration Plan	0
Design Verification	0
ERES	0
FRS	0
IDP	0
IIVP	0
IIVP results	0
ISSD	0

Move to Production	0	
Project Plan	0	
Release Notes	0	
Software Change Request	0	
Software Compliance Assessment	0	
System Certification Summary	0	
Test Protocol	1	
Test Protocol Results	0	
Traceability	0	
URS	0	
URS/FRS	0	
User Acceptance Protocol results	0	
Validation Plan	0	
Insufficient traceability N/A		
CII	0	0
Data Migration Plan	0	0
Design Verification	0	0
ERES	0	0
FRS	1	0
IDP	0	0
IIVP	0	0
IIVP results	0	0
ISSD	0	0
Move to Production	0	0
Project Plan	0	0
Release Notes	0	0
Software Change Request	0	0
Software Compliance Assessment	0	0
System Certification Summary	0	0
Test Protocol	0	0
Test Protocol Results	0	0
Traceability	2	0
URS	0	0
URS/FRS	0	0
User Acceptance Protocol results	0	0
Validation Plan	0	0
Not compliant with procedure		
CII	1	
Data Migration Plan	2	
Design Verification	1	
ERES	0	
FRS	0	
IDP	0	
IIVP	1	

IIVP results	0
ISSD	0
Move to Production	1
Project Plan	0
Release Notes	0
Software Change Request	3
Software Compliance Assessment	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0
URS/FRS	1
User Acceptance Protocol results	0
Validation Plan	0

Not following configuration management

CII	0
Data Migration Plan	0
Design Verification	0
ERES	0
FRS	0
IDP	0
IIVP	0
IIVP results	0
ISSD	0
Move to Production	0
Project Plan	0
Release Notes	0
Software Change Request	0
Software Compliance Assessment	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0
URS/FRS	0
User Acceptance Protocol results	0
Validation Plan	0

Not following document version control

CII	0
Data Migration Plan	0
Design Verification	0
ERES	0
FRS	0

IDP	0
IIVP	0
IIVP results	0
ISSD	0
Move to Production	0
Project Plan	0
Release Notes	0
Software Change Request	0
Software Compliance Assessment	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0
URS/FRS	0
User Acceptance Protocol results	0
Validation Plan	0

	Not using template	other	Other
CII	0	0	0
Data Migration Plan	0	0	0
Design Verification	1	0	9
ERES	0	0	1
FRS	0	0	0
IDP	0	0	0
IIVP	0	0	1
IIVP results	0	0	0
ISSD	0	0	0
Move to Production	0	0	0
Project Plan	0	0	0
Release Notes	0	0	0
Software Change Request	0	0	0
Software Compliance Assessment	0	0	2
System Certification Summary	0	0	0
Test Protocol	1	0	0
Test Protocol Results	0	0	0
Traceability	0	0	0
URS	0	0	0
URS/FRS	1	0	0
User Acceptance Protocol results	0	0	1
Validation Plan	0	0	0

	Requirement deficiency
CII	0
Data Migration Plan	0
Design Verification	0

ERES	0
FRS	1
IDP	0
IIVP	0
IIVP results	0
ISSD	0
Move to Production	0
Project Plan	0
Release Notes	0
Software Change Request	0
Software Compliance Assessment	0
System Certification Summary	0
Test Protocol	0
Test Protocol Results	0
Traceability	0
URS	0
URS/FRS	0
User Acceptance Protocol results	0
Validation Plan	0

4.14 Rejection Reason by Deliverable

CII	Data Migration Plan
3	2
Design Verification	ERES
13	1
FRS	IDP
7	2
IIVP	IIVP results
5	8
ISSD	Move to Production
1	1
Project Plan	Release Notes
4	4
Software Change Request	Software Compliance Assessment
9	3
System Certification Summary	Test Protocol
6	14
Test Protocol Results	Traceability
12	13
URS	URS/FRS
1	2
User Acceptance Protocol results	Validation Plan
2	4

4.15 Number of Rejections by Project

Acceptance Sampling Plan Generator (ASPG)	19
AFMS	4
CHaRM	3
Clinical Chemistry Excel Spreadsheet for Digital Printing	6
DFCS	5
GDSN/GS1	9
Groninger	11
GS Reports	1
IRIS	4
PEAR	2
Pulse	16
QIMS	4
Qualtrics	1
TODS	10
Universal Protocol Emulator (UPE)	5
WWLIMS	17

5 Rate Metrics

5.1 Document Approval Rate

This is portion of documents that are approved upon review.

It is computed by counting the number of approvals divided that by the total number of reviews.

[1] 0.6871658

5.2 First Pass Acceptance

this is the portion of documents that are approved on the first review conducted by SQA.

It is computed by counting the number of first pass approvals divided by the number of reviews.

[1] 0.4037433