



Reconstructing "Performance Monitoring" within CSA

NOV 2024

BRIDGING THE GAP BETWEEN IT & QA

Technologists

LANGUAGES

COBOL
EASYTRIEVE
ASSEMBLER
REXX
JCL

C / C++
JAVA
TCL
PERL

ANT
MAKE

SECURITY

PEN-TEST
VULNERABILITY
DESIGN
GOVERNANCE

DATABASES

PL/SQL
ORACLE
MYSQL
POSTGRES
DB2
ISAM
MS SQL SERVER

INTERFACE PROTOCOLS

CORBA
SS7
OIP
TCP / IP
RESTful

OPERATING SYSTEMS

MAINFRAME
MVS
SOLARIS
FEDORA
CENTOS
WINDOWS

HARDWARE

SUN T2000
V480
D2 DISK ARRAYS

STANDARDS

ISO
CMMi
NIST
IEEE

OPERATIONS

END 2 END SLC

METHODOLOGY

'AGILE'
UML
OOAD
RAD
DSDM
W-MODEL

QUALITY MANAGEMENT

MEASUREMENT
OPTIMISATION
AUDIT
SOP AUTHORIZING

REGULATORY INDUSRTY

GMP / GCP / PV /
21 CFR PT 11

GDPR

EMPOWERMENT QUALITY ENGINEERING

CSV PROJECTS

ADVICE & RESEARCH

SOP AUTHORIZING

AUDIT TRAINING

VENDOR SLC
IMPROVEMENT

AUDIT:
COMPLIANCE &
VENDOR

250+AUDITS

Technical

Complex Systems

IT ADMINISTRATION: NETWORKS, FAULT
TOLERANCE, REDUNDANT ARRAYS, CHANGE
MANAGEMENT....

IT & QA & COMPLIANCE: IS A
LAYERED APPROACH

AGENDA



Applying 'Assurance' to support RBA

- Context
- Reconstructing the QMS
- CSA
 - Assurance
 - Monitoring – QMS remit
 - Software production line monitoring
- Examples
- Summary



Reconstruct the QMS



QMS

Defined set of processes.. that make your business run how it is supposed to.

- Policies, processes & procedures to elevate customer **satisfaction**.
- Benefits:
 - Elevated **consistency** & standardization of processes & (software product) outputs.
 - Reduced **errors** & increased operational **efficiency**.
 - Improved customer satisfaction via **quality** product & services.
 - **Continuous** evaluation & improvement of organisation operations.

Reconstruct QMS



→ QMS

The QMS manages the Software Lifecycle - SLC

The SLC is the Software Production Line - SPL

The SPL defines the level of Software Product Quality - SPQ

Reconstruct: Types

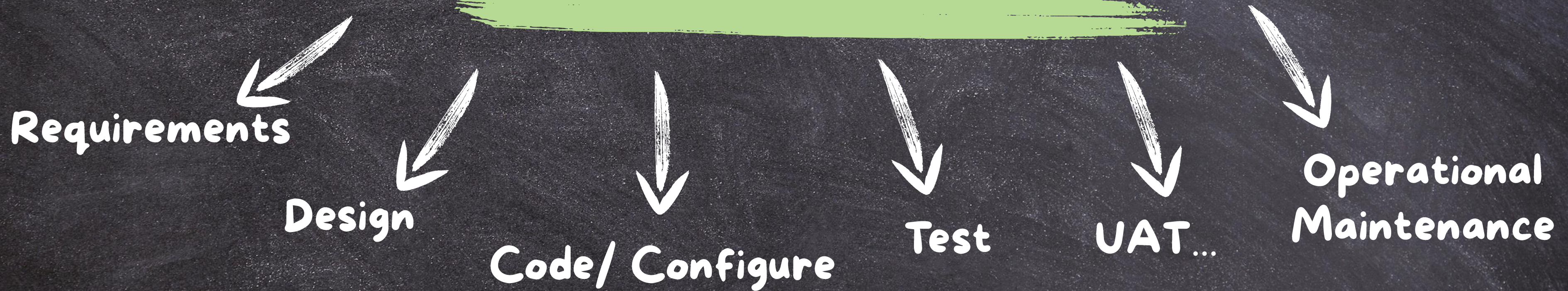


QMS Types

Standardised systems

- ISO 90003 – 9001 tailored for software production & maintenance
- CMMi
- **Total Quality Management**: focus on customer satisfaction by every employee.
- **Lean**: reduce waste from inefficiencies. Focus on process optimisation.
- **6 Sigma**: Use data driven techniques in pursuit of near perfect products & services

Software Production Line



QMS: a lifecycle process.
This product is software.

The lifecycle processes is a software production line
The better the production line the better the software product quality

Findings: 2023/24 Vendors

1

QMS focus on WHAT
and not HOW?

ICH E6 R2 – uniformity...

2

Internal audit

Focus on test documentation

Doesn't cover SPL process..
Software production line
quality not independently
'managed'



3

QMS Measurement
CAPA management.

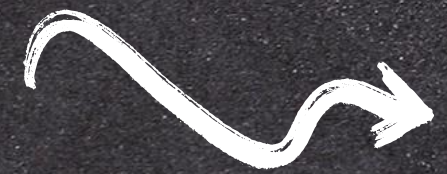
But not software
production line.

4

Reliance on vendor testing

Often too focused on UAT
compliance...

RBA: CSA



Section A: identify the intended use

- Guidance on **system categorization** based on individual features.

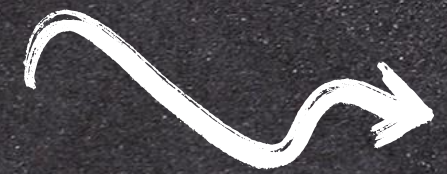
RBA: CSA



Section B: Determine the RBA

- Identify foreseeable software **failures**, associated risk, select & perform **assurance activities**.
- Consider factors to prevent the system functioning as intended (**failures**):
 - Incorrect configuration.
 - Security.
 - Data transfer and storage.
 - Operator error.
- **Differentiate activities between risk severity.**

RBA: CSA



Section C: Consider appropriate assurance activities

- Test case documentation granularity: (un)scripted testing.

RBA: CSA



Section D: Establish the appropriate record

- Sufficient objective evidence to demonstrate software functions as intended.
- Describes the structure of objective evidence record, with associated outputs.
- Followed by (un)scripted examples.

Validation Benefit



→ FDA's CSA in use.

- Large pharma pilot 23/24
- 30% schedule reduction
- Unknown if product quality improved?
- Getting to the same destination
 - But more economically.

Validation issue



Software Product Quality?

- It would be great if we could get a sense of software product quality....

CSA is here to help



Section C: Consider appropriate assurance activities

- Other ways to indicate how Quality System decrease of risk of failure....
 - Production activities, personnel & process to ensure integrity.
 - Leverage vendor SLC & elicit what scope of work to do.
 - Process monitoring to detect issues: critical parameter monitoring, process output test.
 - Data collected by software functions (e.g. logs).
 - Bug tracker tool use / automation test for assurance.
 - Iterative & continuous test throughout SLC.
- Process/Train
- Supplier evidence
- Monitoring
- Monitoring
- Monitoring

Monitoring SPL is not new



ISO

- ISO 9001 '94: appropriate sources of information... to ... analyse & eliminate.. non conformities (failure).
- ISO 9001-3 4.14.3: analysis of root cause of non conformities...(as) input to PA.... reverse unfavorable trends in metric levels may be considered as PA.
- ISO 9001 2015 9.1.3 Analysis & Evaluation:
 - Conformity of (software) product.
 - Measure the performance & effectiveness of the QMS (Software production line).

RQA 2024

CMMi

- Apply management via quantitative analysis
- 5 levels of maturity:
 - 1 – Initial: None
 - 2 – Managed: measurement & analysis.
 - 3 – Defined: process instruction.
 - 4 – Quantitatively managed: process performance.
 - 5 – Optimising: causal analysis & resolution.

Suppliers: 'General' Aspects



↪ 2023/24 - Audit Findings

- QMS:
 - (Some) ISO accredited / more 'adhered' to ISO
 - **Scope:** largely focused on documentation from formal test phase.
 - **Monitoring:** Mostly on CAPA management.
 - **Internal Audit:** Did not include QPL processes.
 - (Some) SPL **instruction:** "off-QMS" in web pages – Parallel Management System
- **Documentation:** 'Abstract' and localised to a test activity.
- **Validation report:** Documentation approved by QA.
 - **Test report:** '50' tests: Defects will be fixed. QA approved.

Does it answer the question of reducing the risk of failure?

Metrics - shared during audit. – levels of quality..

Software Product Quality



Defect Metrics are most likely to be available

- Defect category (data, usability, error handling)
- Root cause distribution chart (across the SPL processes)
- Defect distribution(features)
- Defect Detection Point (where a defect is found)
- Defect severity
- Number of defects
- Time (remediation)
- Time (schedule)
- Scope of change
- Satisfaction metrics
- SLA metrics
-

Supplier 1: Improving quality



CTMS Automation Tool

- Overall Defect Trend

Defects Per Year		
2022	2023	2024 6mths
162	110	43

- Decreasing defect count, indicates:
 - Improving software production line effectiveness.
 - Improving software product quality.

Supplier I: Feature quality



CTMS Automation Tool

- Defect Trend Per Key Feature

			Defects Per Year		
Feature	Total	Percent	2022	2023	2024
A	136	43%	70	39	27
B	13	4%	4	8	1
C	15	4%	9	5	1
D	11	4%	7	3	1
E	20	6	10	10	0
F	59	19	36	18	5

- Defect trend decreasing, except:
- Feature B: 100% increased 2023.
- Feature E: no improvement 2023.

Good: Outliers for changes/patches: RBA

Supplier I: RCA: SPL - Change



CTMS Automation Tool

RCA	Bug	Percent	2022	2023	2024	
External System Behaviour not Understood	29	9%	9	17	3	Increase in customer automation scope of the system under test – more complex scenarios are challenging the tool.
Inadequate Test	89	28%	38	40	11	Review the current testing strategy – how to shift left, trend tests that were missing (that customers found) and deploy
Scenario not considered	105	33%	43	40	22	Shift Left: Introduce formal system testing phase to SLC – include scenario flow testing based on common defect process flow.
Other RCA	-	-	-	-	-	Remaining metrics not displayed for expediency

RCA is a positive indicator measurement focus.

Outcome: Aggregation of information



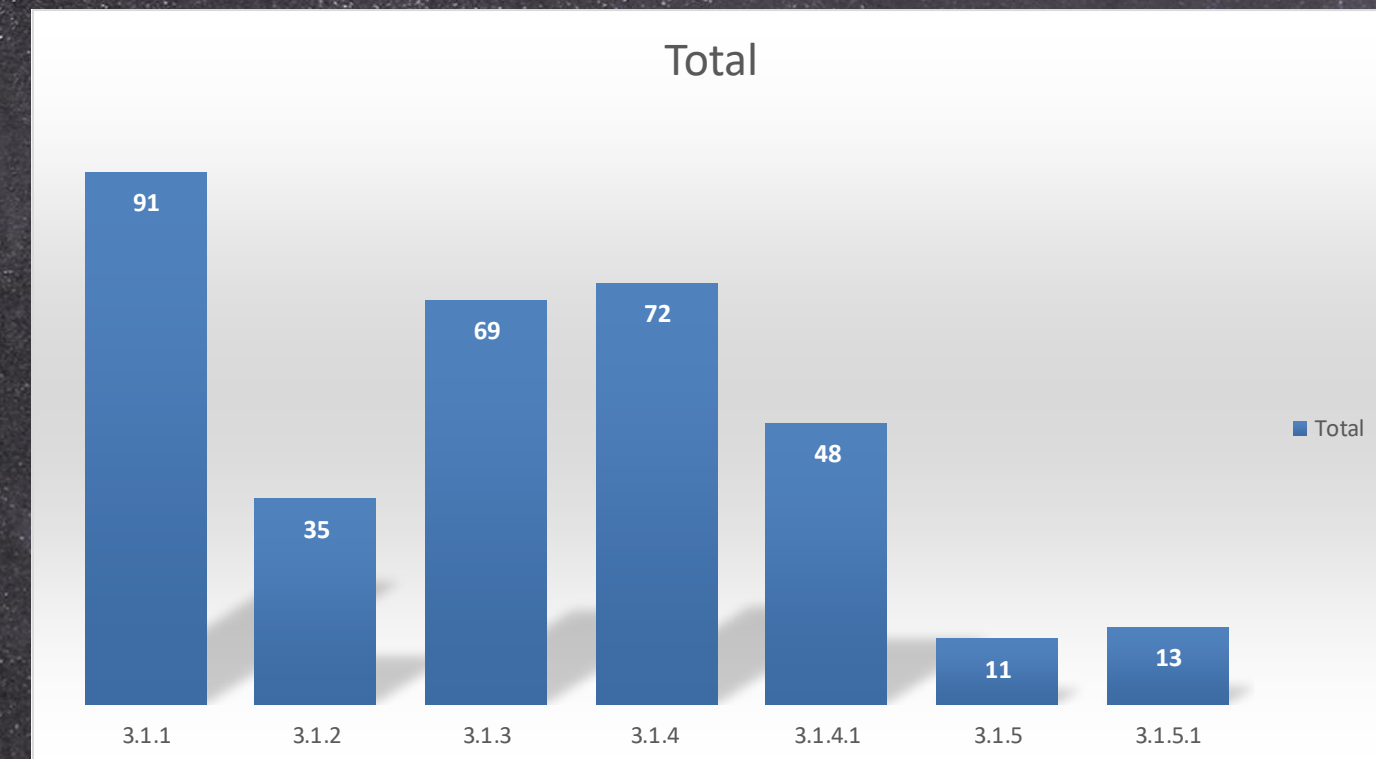
- Analysis reinforced SPL Gaps
 - Feature B has a greater risk of failure
 - Feature E has risk of failure.
 - Complex process flow use increases the risk of failure.
 - More focus in these areas / scenarios during change controls and tool use.
 - Increased supplier collaboration for more complex scenarios.
- 'Simple' use of system is low risk.
 - Reduced effort in change controls: apply regression cycle.

Supplier 2: Defect trend / release



PV System: customers raised defects

Release	Customer Defects	Performance
3.1.1	91	27%
3.1.2	35	10%
3.1.3	69	20%
3.1.4	72	21%
3.1..4.1	48	14%
3.1.5	11	3%
3.1.5.1	13	4%
	339	



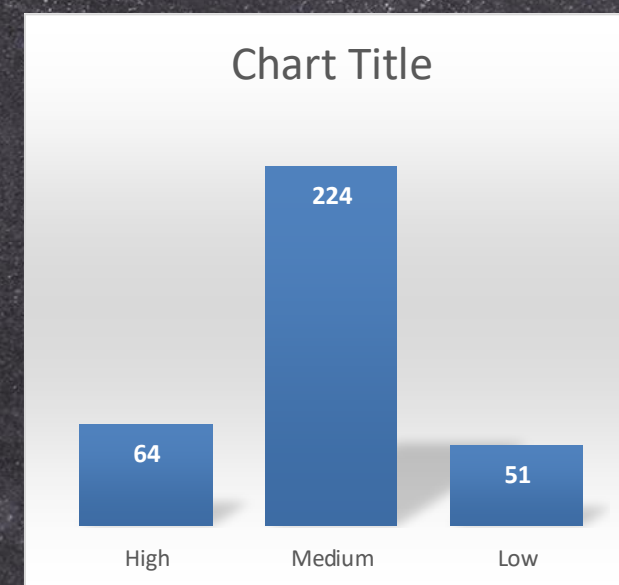
- Overall **downward trend** of defects getting into customer's domain

Supplier 2: Defect Severity Trend



PV System

Defect severity total	High	Medium	Low
	64	224	51
	19%	66%	15%



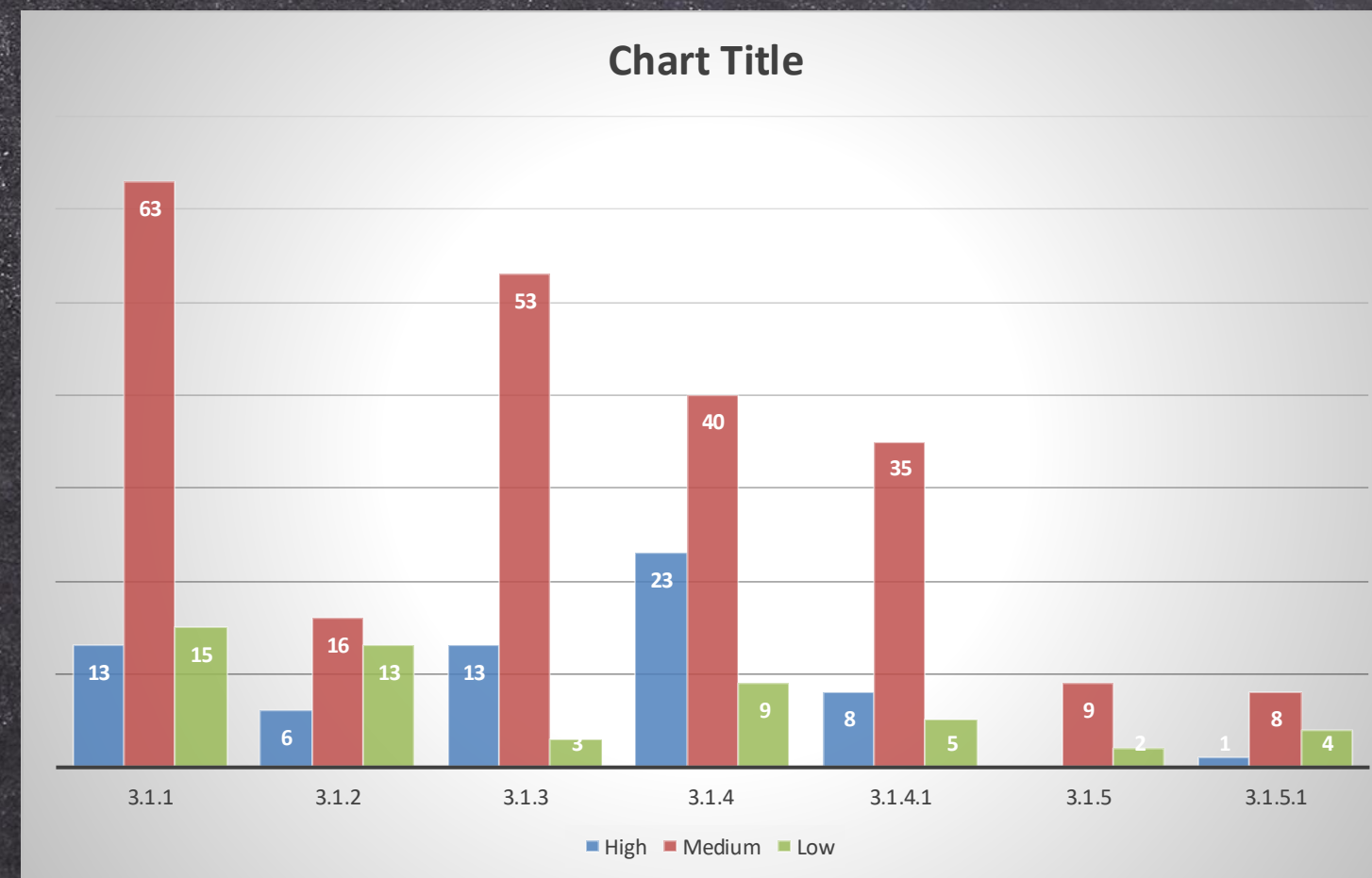
- **Objective evidence** collaborated discussion of RBA – targeting of High severity failures.

Supplier 2: Defect Severity



PV System

Release	High	Medium	Low	Grand Total
3.1.1	13	63	15	91
3.1.2	6	16	13	35
3.1.3	13	53	3	69
3.1.4	23	40	9	72
3.1.4.1	8	35	5	48
3.1.5		9	2	11
3.1.5.1	1	8	4	13



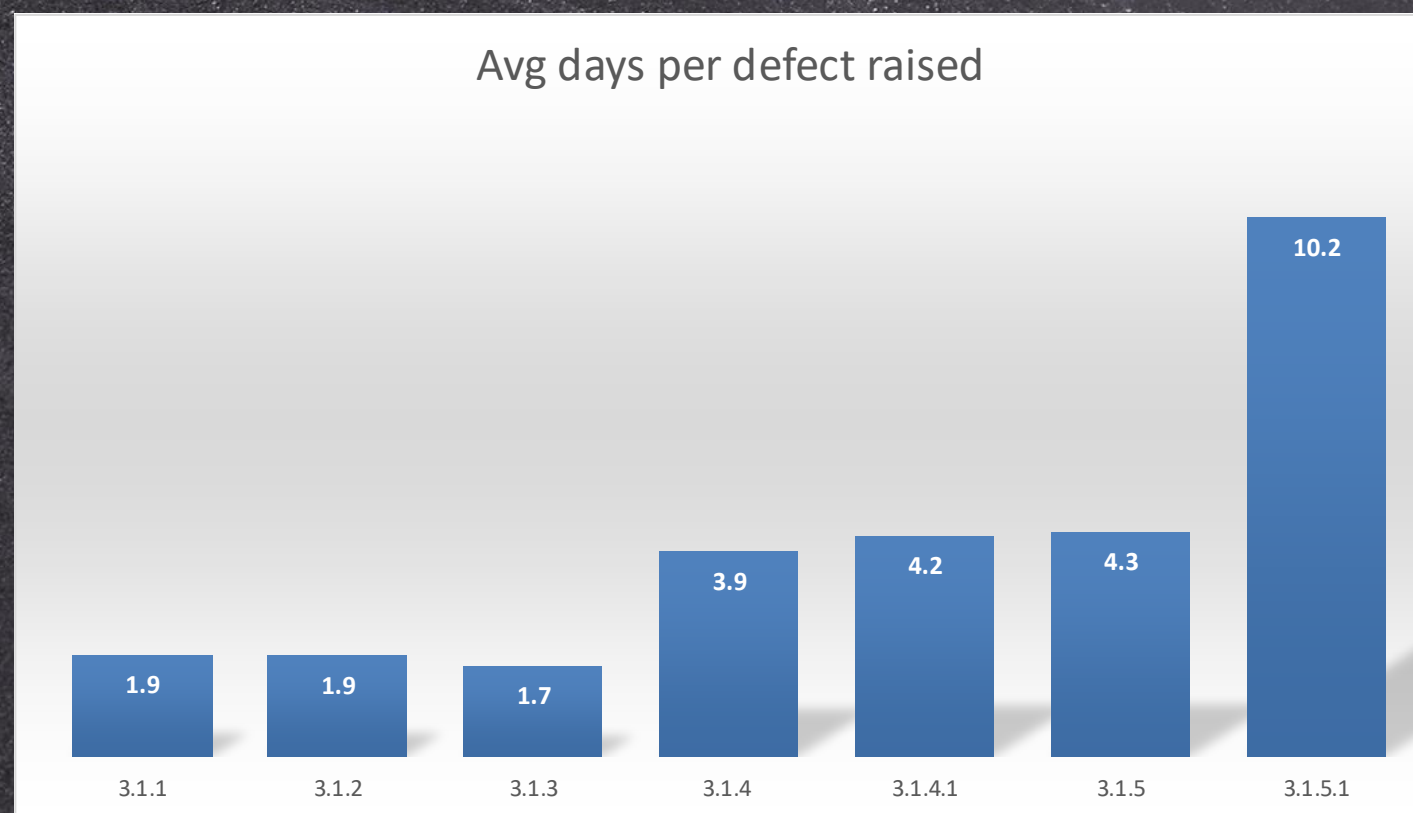
- Objective evidence collaborated discussion of RBA – targeting of High severity failures.

Supplier 2: Days / Defect find



PV System: more customers = more system use

Release	Avg days per defect raised
3.1.1	1.9
3.1.2	1.9
3.1.3	1.7
3.1.4	3.9
3.1.4.1	4.2
3.1.5	4.3
3.1.5.1	10.2



- Increased quality trend across releases.

Outcome: Aggregation of information



PV System: 'Difficult' features

Key customer features	ETL Feature	Performance	Alerts
Total defects (339)	10	28	25
	3%	8%	7%
			18%

- 18% product defects across 3 feature areas
- 8% related to performance.
- Code review for release of database connections.
- DB design review / restructure?
- PL/SQL tuning rules
- Performance testing at every SLC phase.
- Supplier has introduced a target as a CAPA.
- Cust: The features will result in more rigor.

Supplier 3: Economics – Improve Quality



Internal ERP Project:

Release	Effort %	Total Cost	Count	Average Defect Cost
R1.9	22	\$204,663.00	218	\$938.82
R1.10	18	\$203,271.00	188	\$1,081.23
R1.11	12	\$132,984.00	124	\$1,072.45
Total		\$540,918.00	530	\$1,020.60

- Per release:
 - **Effort**: percentage of total time spent on defects.
 - **Total (Defect) Cost**: Apply effort to total cost of release.
 - **Count**: Number of defects found during SPL (pre operations).
 - **Average defect cost**: calculated by dividing total cost by count.
- Defect trend is going down.
- Further analysis.
- Average remediation costs increased.
- Outlier:
 - Further investigation...
 - Defects being detected, late....
 - Code released late into testing...
 - Developer estimation not tracked
 - Poor design approach..
 - No integration test phase..

Defect Detection Point



Percentage of defects found during the entire lifecycle (IBM 1973)

Supplier	UAT	Operations
Identifies 90 defects	Identifies 7 defects	Identifies 3 defects

DDP: 90%
efficient

DDP: 97%
efficient

Remaining defects
3%

The less defects found in operations, the more effective Supplier & UAT are.

The less defects found in UAT & operations, the more effective the SPL is.

- 99% Excellent - quality in all SPL
- ~ 95% Good - 1 or 2 quality gap in SPL
- <90% Poor - many gaps (delays/patches...)

* Capers Jones.

** EmpowermentQE.

Supplier 4: DDP

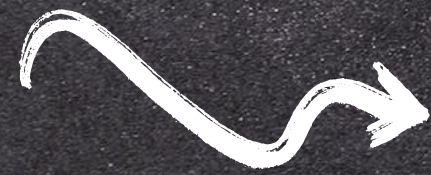


Measure the SPQ across releases

Version	Release Date	SLC Defects	Operation Defect	Total	DDP
System 4.0	Dec-21	186	11	197	94%
System 4.1	Nov-22	133	10	143	93%
System 4.2	Mar-23	177	27	204	87%
System 5.0	Dec-23	271	61	332	82%

- Quality **regressed** since 2022
 - Increased customers.
 - No process instruction.
 - Missing system test function.
 - Project configuration weak.

Supplier 5: 2005 – not solely testing

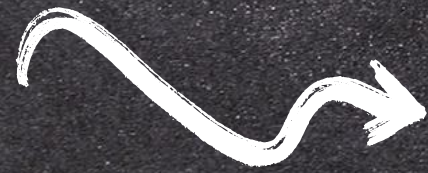


Measure SPL effectiveness

Item	Ma	Mi	Q	I	Comment
URS	-	-	-	-	Not reviewed by SQA function for this project. Already signed off.
FRS	4	6	4	9	Transferred Review information to correct template.
SAO	?	?	?	?	Incorrect Review Template.
HLD	5	3	16	16	
Delivery Doc (HO3)	1	1	-	2	Missing Review Action List and Information Form.
SDP	1	6	10	7	Missing Review Action List and Information Form Also, version signed is 0.4 and not 1.0
STP	-	1	-	-	To be signed off by Dev Mgr.
TSP	0	9	1	14	Needs another review.
Code Review	-	-	-	-	Performed and appear to be detailed. Not following SQMS review template. Needs to be enforced in projects.

- Not just reliant on testing
- **Static analysis/inspection process**
 - Defect measures
 - Preventative focus
 - Comments:
 - Process issues for improvement.
- Objective evidence: SPL quality story

Supplier 6: DDP – 2005 Report



Test measurements

	_1.3.0 HO 1	_1.3.0 HO 2	_1.3.0 HO 3	_1.3.0 HO 4	_1.3.0 HO 5	_1.3.0 HO 6	Total
Totals	62	15	1	2	3	3	86
DDP %	80.5	98.72	97.5	96.39	96.51	-	

- High risk features delivered in HO1
- Regressed across 2 to 6
- 86 defects = 96.51 % of total DDP
 - Corresponds with issues/gaps from static analysis.
- Prediction:
 - 3 defects remain latent in the release.
- Actual:
 - Operations (3 months use) 4
 - Annual management review topic.

Curse the darkness or light a candle — its your choice (Boris Beizer)

- QMS compliance may not equate to SPL oversight.
- Supplier information may be inadequate.
- Need information to gauge the level of SPL effectiveness / SPQ
- Defect Metrics Analysis:
 - Provides additional layer(s) of information in support for RBA.
 - Provides insight into QMS effectiveness.
 - More attention amongst suppliers.
 - Economic theme is less subjective than 'quality' theme.
- Defect tool label application can be erratic.
- Some suppliers may be wary to share.
- Start with your own measures.

Curse the darkness or light a candle – its your choice (Boris Beizer)

- **Approach:**
 - **Start** with validation/operation measures.
 - **Start small** – select a small number of measurements & trend these.
 - **Rationale** – ‘explainability’ of motivation of measurement & why it will be useful.
 - **Analyse the trends** - over time & seek to interpret trends, especially outliers.

Thank you