



**Dr. Reddy's Laboratories Ltd.**

## **Internal Quality Audits Summary – 2018**

Good  
Health  
Can't  
Wait.

**GLOBAL QUALITY MANAGEMENT**

# Audit Plan Vs. Completed - 2018

Jan – Mar		Apr – Jun		Jul – Sep			Oct – Dec				
GQM : Regulatory Compliance	✓	CTO-1	✓	FTO-6	✓	GDC-Ghaziabad	✓	Cambridge	✓	CTO-3	✓
Biologics	✓	CTO-2	✓	CTO-5	✓	CFA (01)	€	Mirfield	✓	FTO SEZ PU –I	✓
GDC-HYD	✓	CTO-3	✓	FTO-3	✓	Vendor Quality	✓	Beverly	✓	CTO-1	€
CFA (06)	✓	CTO-6	✓	CTO-SEZ	✓	IPDO-Hyderabad	✓	FTO SEZ PU –II	€	FTO-7 & 9	€
CWH	✓	FTO-2	✓	Shreveport	✓	IPDO-Bangalore	✓	CTO-6	✓	FTO-2	✓
CTO-4	✓	FTO-SEZ PU-I	✓	Middleburg	✓ *	CTO-4	✓	FTO 8	✓		
FTO-1	✓	CFA (3)	✓	Bristol	€	GQM : Harmonization & Compliance	✓	CTO-5	✓		
FTO-3	✓	FTO-7 & 9	✓	Mexico	✓	Biologics	✓	Brazil	✓		
South Africa	✓	FTO SEZ-PU-II	✓	CPS	✓	CTO-2	✓				
CFA (01)	Ⓟ	Basel	✓	Octoplus	✓						
		CFA (1)	Ⓟ	CFA (02)	✓						
IPDO	✓ ϕ	Betapharm	✓								
Internal Audits (Total – 65)											
Year 2018	Planned	65	Completed (✓)	59	Withdrawn (✗)	6	*Middleburg audit was performed in January 2019.				

ϕ Unscheduled audit performed for GMP labs in IPDO.

## High and Moderate Risk Audit observations : 2017 Vs 2018 – FTO Units and Development Labs

Unit	2017	2018 (Cumulative)	2018 (cycle wise)				Unit	2017		2018			
			Cycle-1		Cycle-2			2017		2018			
			High	Moderate	High	Moderate		High	Moderate	High	Moderate		
FTO-01	0	4	0	6	0	6	NA	NA	Betapharm	0	1	0	0
FTO-02	4	6	1	11	1	7	0	4	Basel	--	--	0	1
FTO-03	0	6	5	10	3	6	2	4	Beverley	0	4	0	3
FTO-06	0	5	0	5	0	5	NA	NA	Shreveport	0	2	0	11
FTO-07	0	5	0	5	0	5	ND	ND	South Africa	--	--	0	1
FTO-08	0	4	0	5	0	5	NA	NA	Brazil	--	--	0	3
FTO-09	1	7	0	4	0	4	ND	ND	IPDO	1	5	0	4
FTO SEZ-PU-1	0	8	1	9	1	5	0	4	IPDO-Bangalore	0	5	0	3
FTO SEZ-PU-2	0	5	0	6	0	6	NA	NA	Octoplus Cambridge	--	--	0	2

NA: Not Applicable (Planned one audit), ND: Not Done (Performed one audit, planned was twice)

### Summary: There is increase in the number of High Risk observations in *FTO-3 and FTO SEZ-PU-1*.

There is increase in the number of Moderate Risk observations in *FTO-1, FTO-2, FTO SEZ-PU-2 and Shreveport*.

## High and Moderate Risk Audit observations : 2017 Vs 2018 - CTOs and Biologics Units

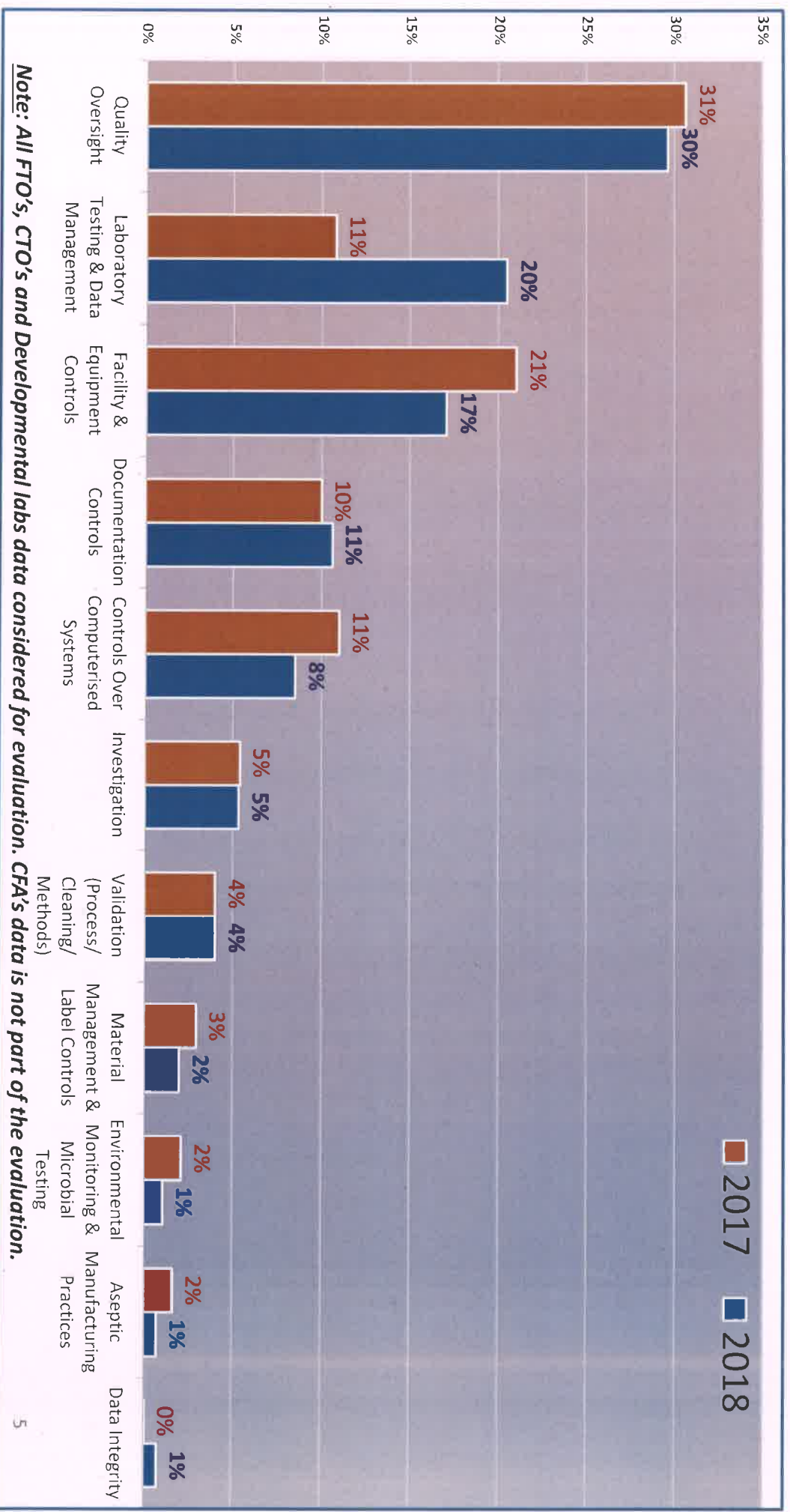
Year	2017		2018 cumulative		2018 Cycle wise			
Unit	High	Moderate	High	Moderate	Cycle-1		Cycle-2	
					High	Moderate	High	Moderate
CTO-01	1	9	0	4	0	4	ND	ND
CTO-02	3	15	0	10	0	5	0	5
CTO-03	1	3	0	8	0	5	0	3
CTO-04	2	4	1	6	1	4	0	2
CTO-05	0	8	0	9	0	4	0	5
CTO-06	0	8	0	8	0	5	0	3
Biologics	3	11	5	12	4	6	1	6
CTO-SEZ	0	4	0	2	0	2	ND	ND
Mirfield	1	5	0	2	NA			
CPS	0	3	0	6				
Mexico	0	0	0	2				

NA: Not Applicable (Planned one audit), ND: Not Done (Performed one audit, planned was twice)

### Summary: There is Increase in the number of High risk observations in **Biologics**

There is Increase in the number of Moderate risk observations in **CTO-3, CPS and Mexico**

# Categorization of Internal Audit Observations : 2017 Vs 2018



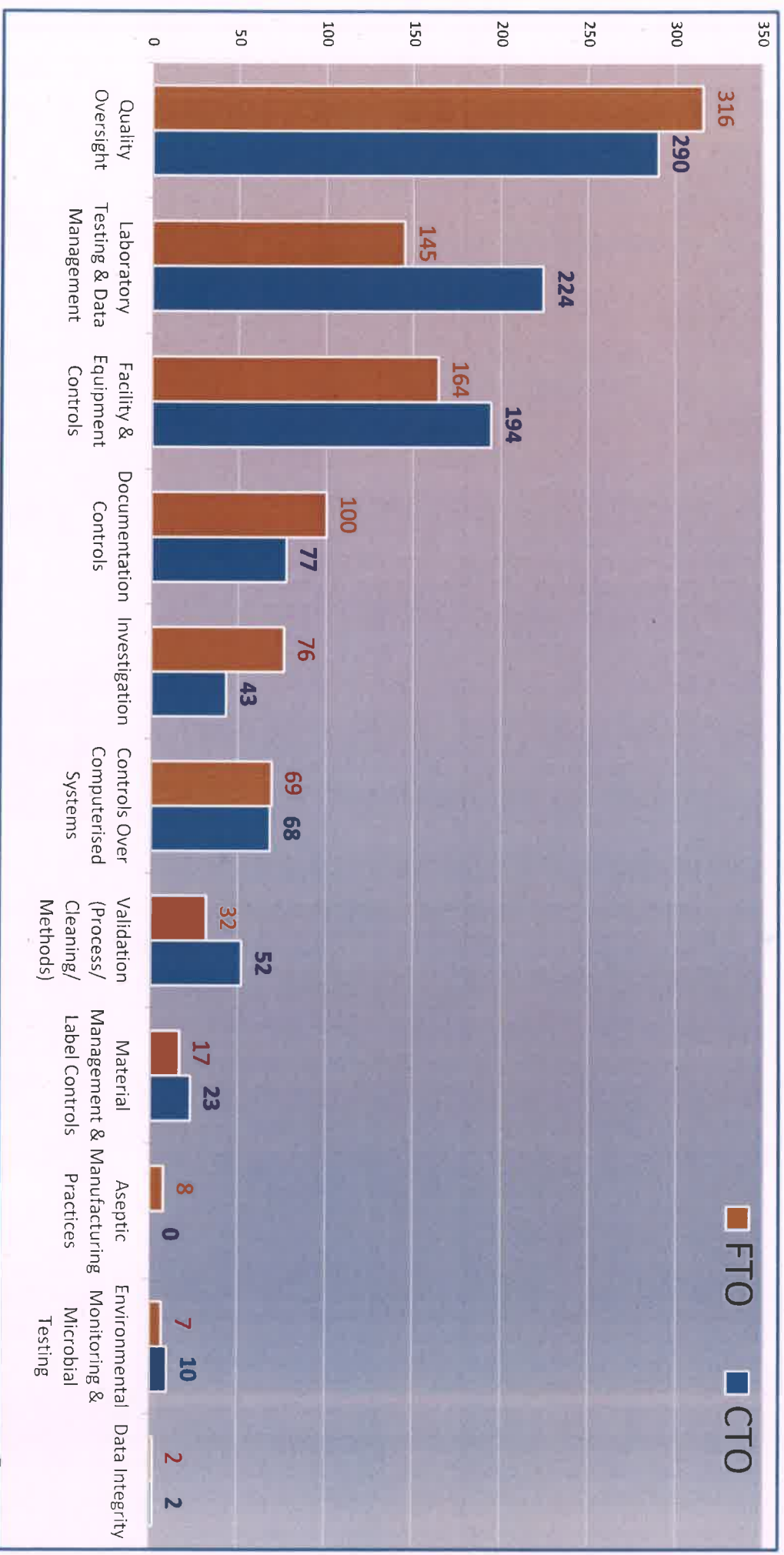
# Categorization of Internal Audit Observations : 2017 Vs 2018

Inference: Upon application of the Pereto, 86% of the observations i.e. 2012 observations out of 2318 observations were from 5 categories and considered as fragile system. These systems are

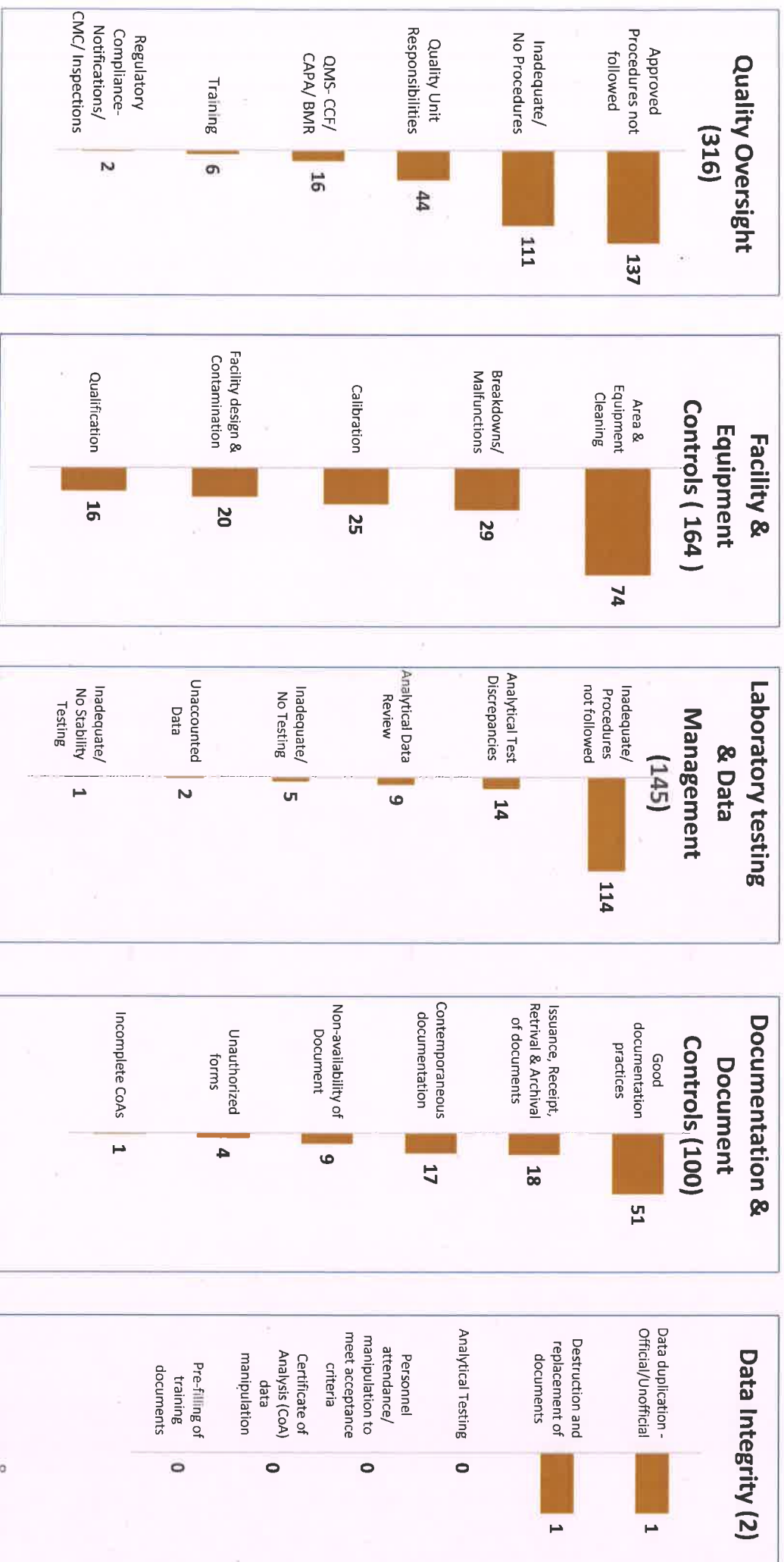
1. Quality Oversight
  2. Laboratory testing and Data Management
  3. Facility & Equipment Controls
  4. Documentation & Document Controls
  5. Control over Computerized systems
- Data Integrity: Owing to the criticality of the observations falling under Data Integrity category, it is considered a fragile system irrespective of the number of observations identified.
  - Observations related to laboratory testing and data management and documentation and documentation controls increased in 2018 when compared to 2017.
  - Observations related to Quality Oversight, Facility and equipment controls, Control over Computerized systems and Material management/ label controls decreased in 2018 when compared to 2017.



# Categorization of Internal Audit Observations : FTOs Vs CTOs

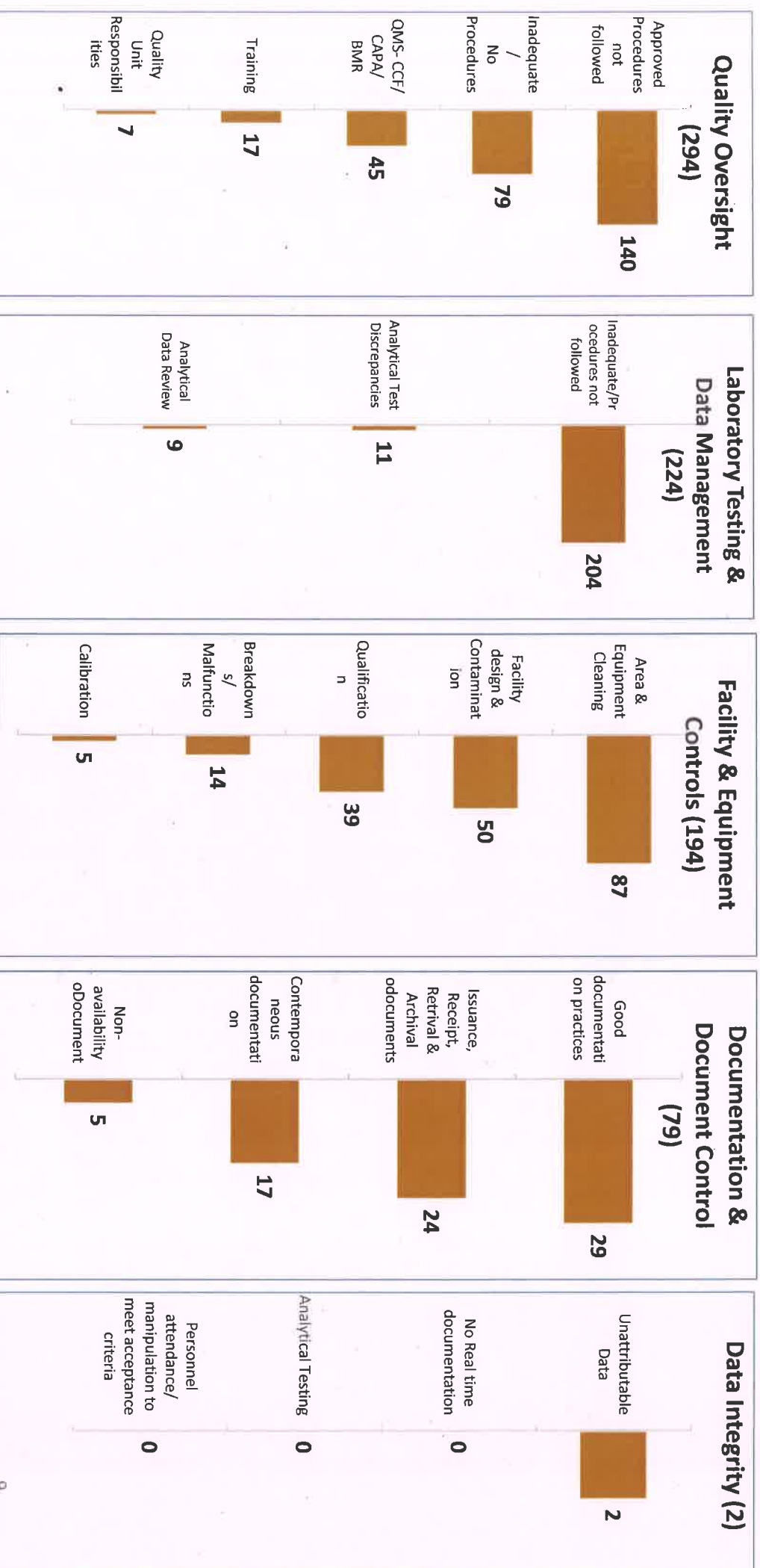


# Top Five Category of audit observation : FTO Units -2018

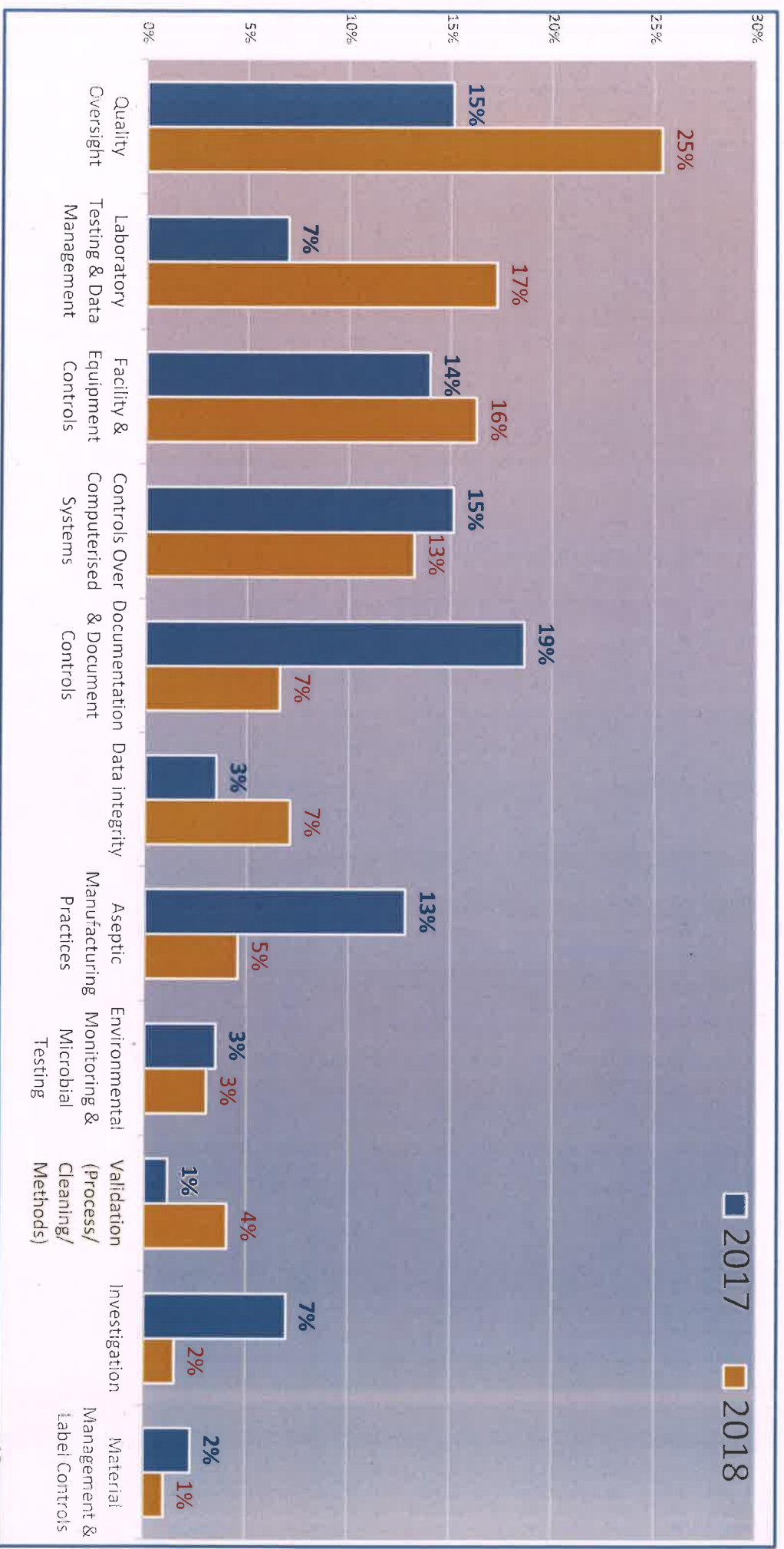




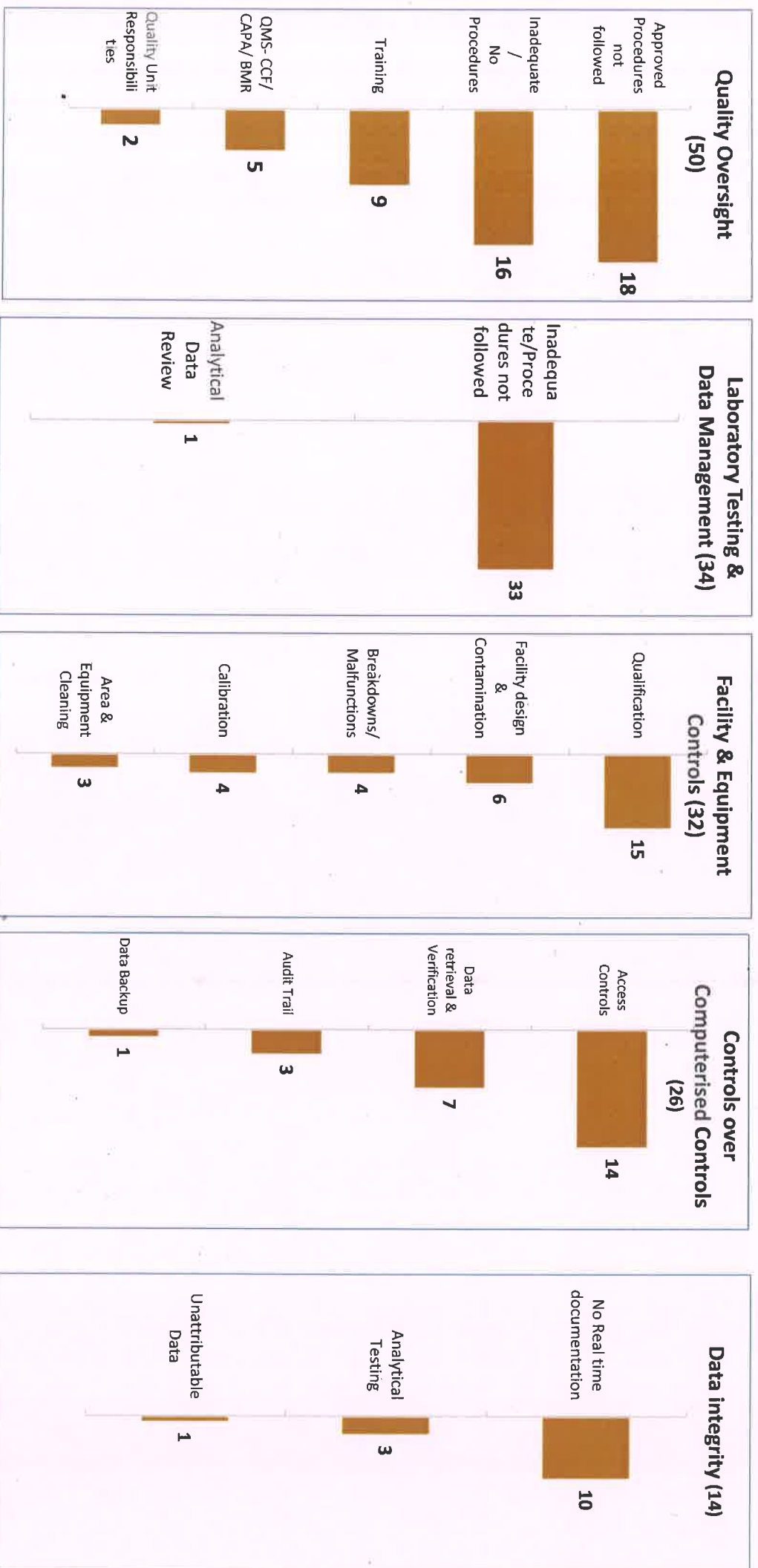
# Top Five Category of audit observation : CTO Units -2018



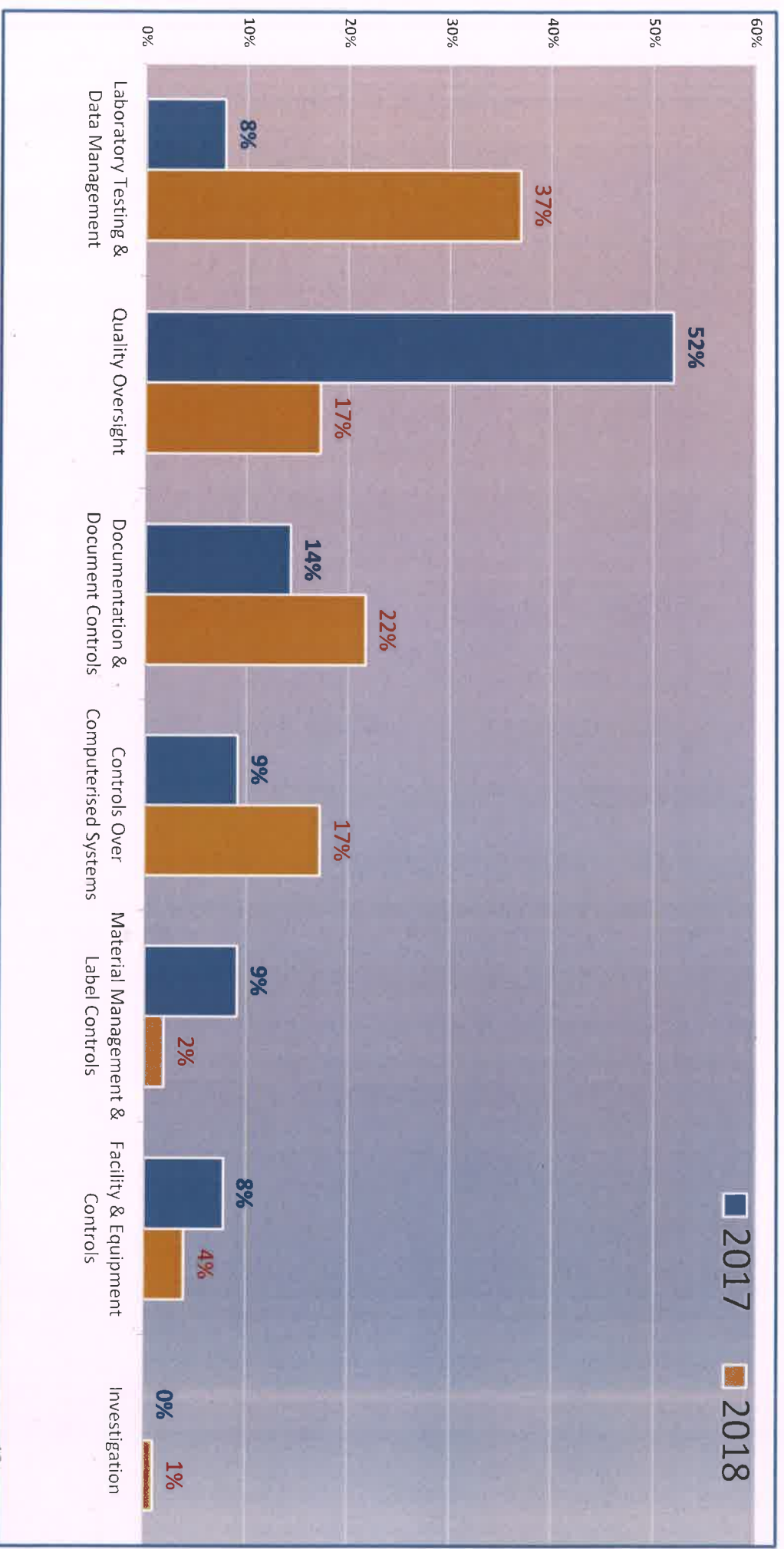
## Categorization of Internal Audit Observations : 2017 Vs 2018- Biologics



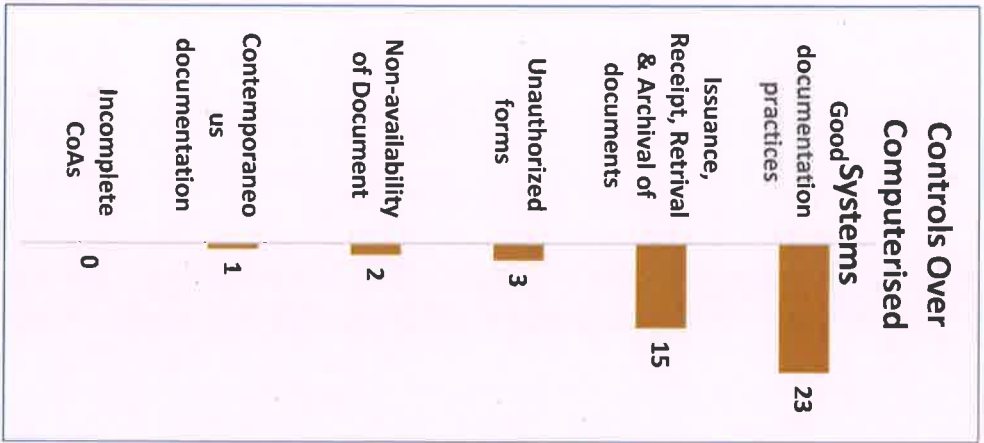
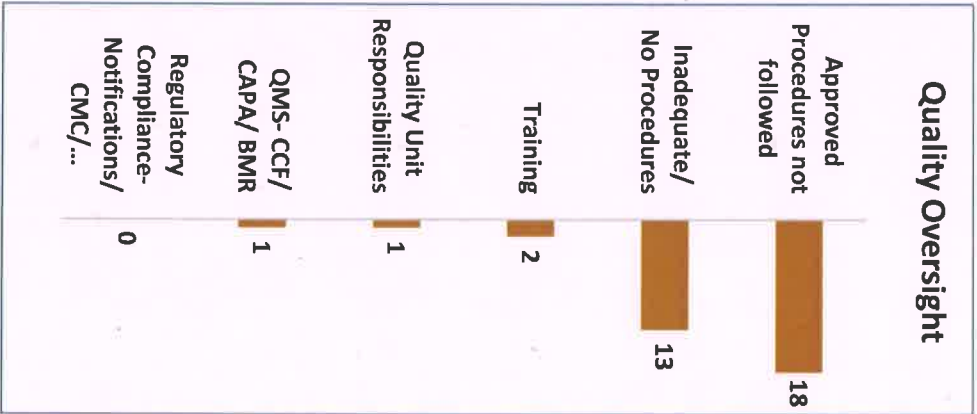
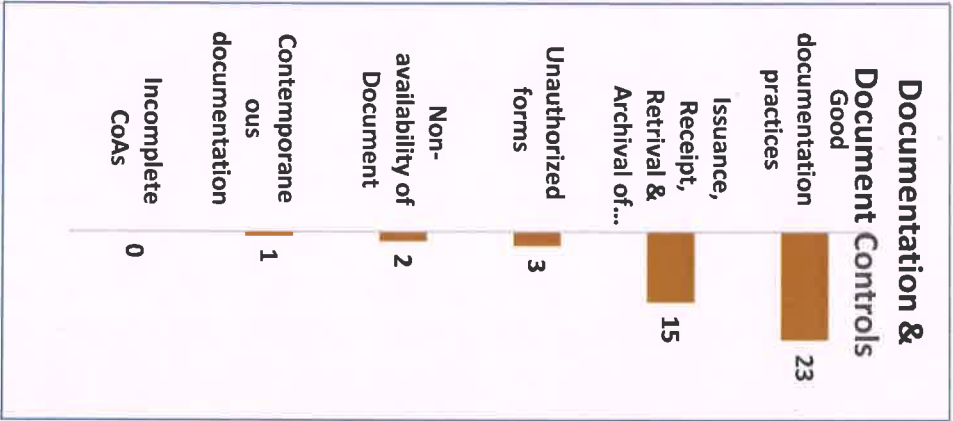
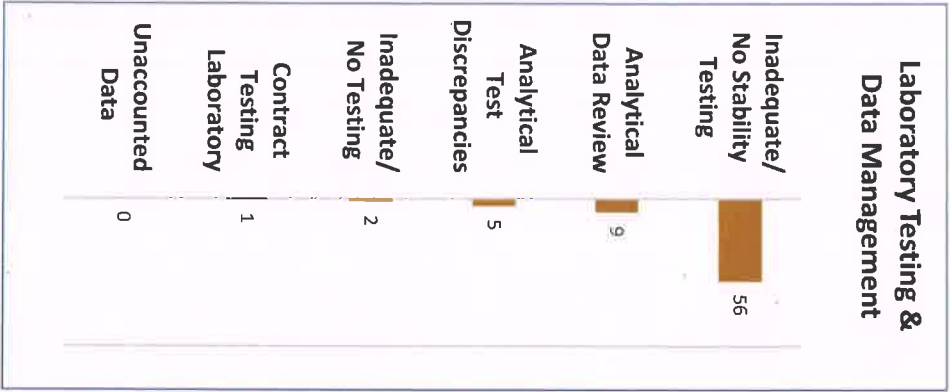
# Top Five Category of audit observation : 2018, Biologics



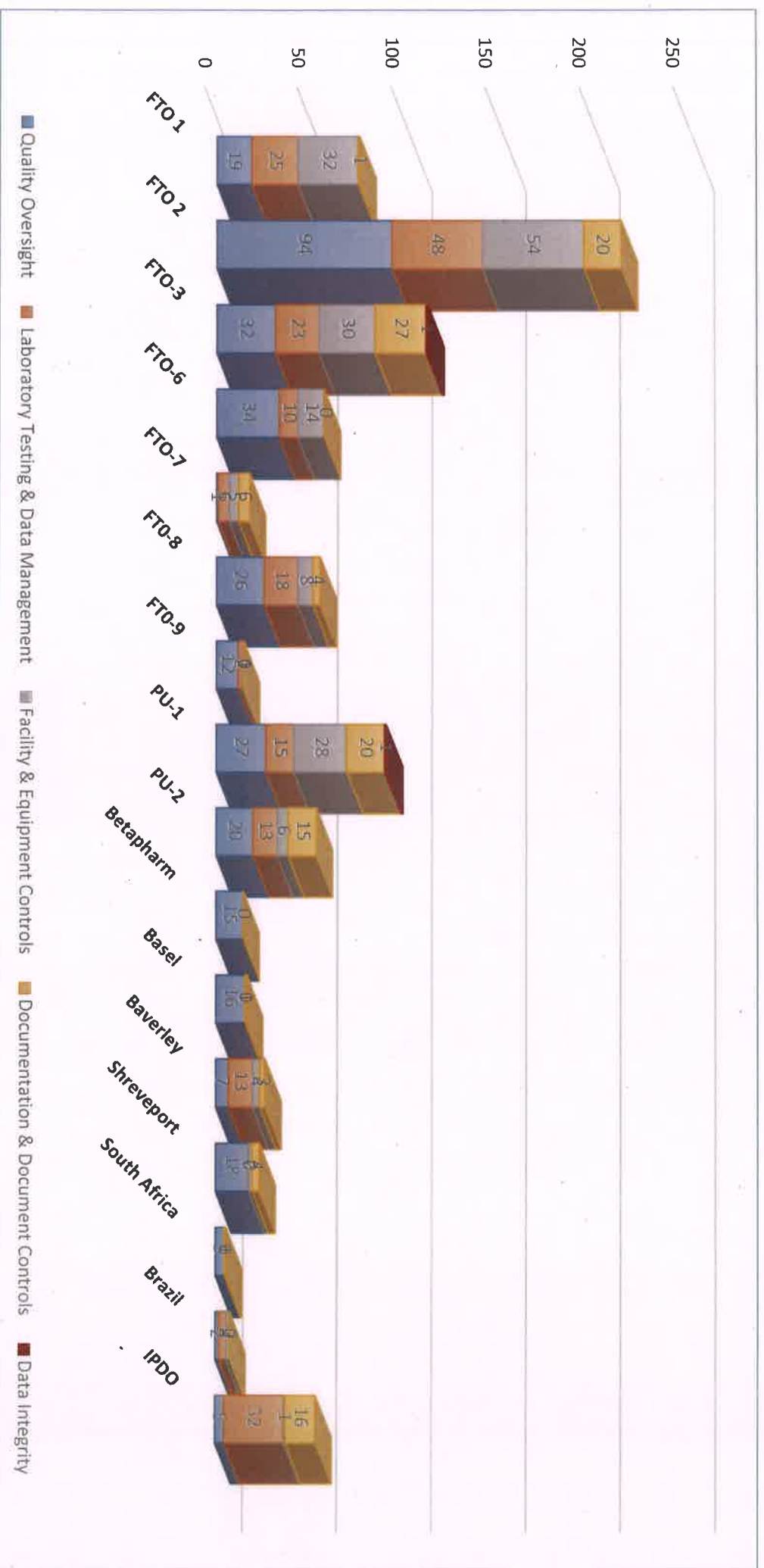
# Categorization of Internal Audit Observations : 2017 Vs 2018- IPDO



# Top Four category of audit observation : IPDO

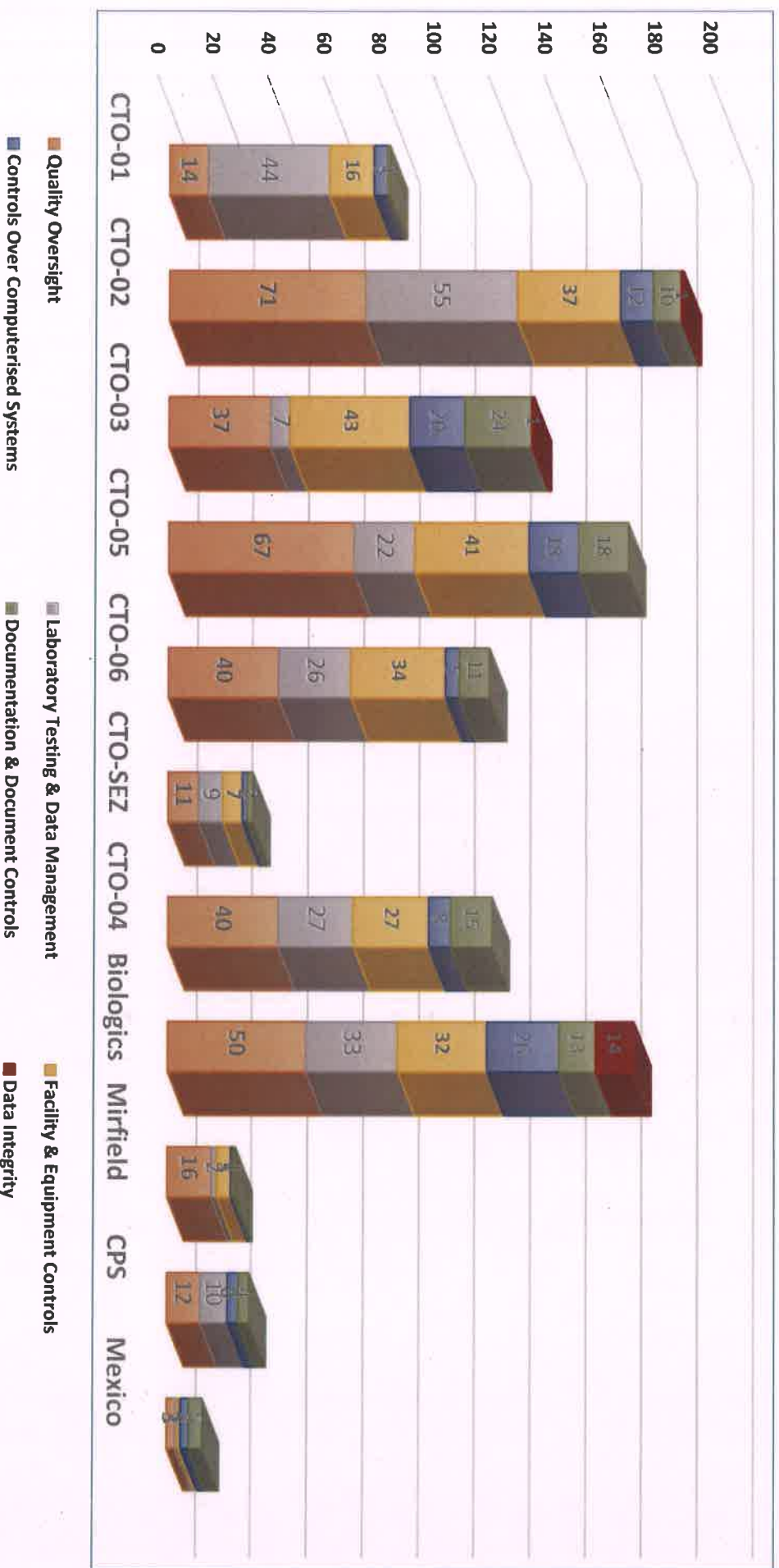


# Site wise Fragile systems overview – FTO Units -2018

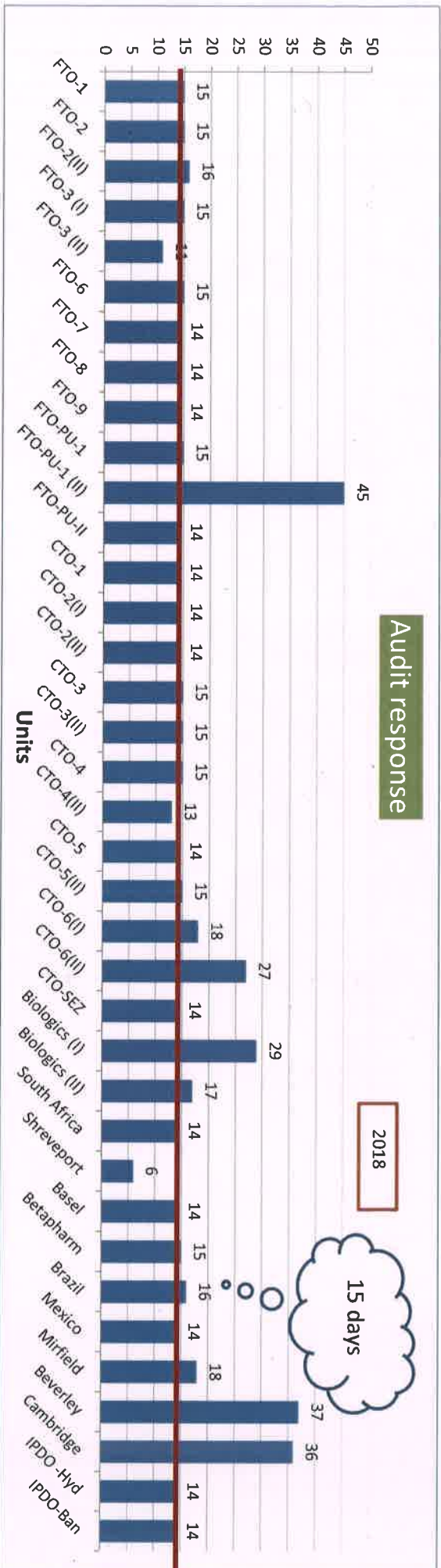
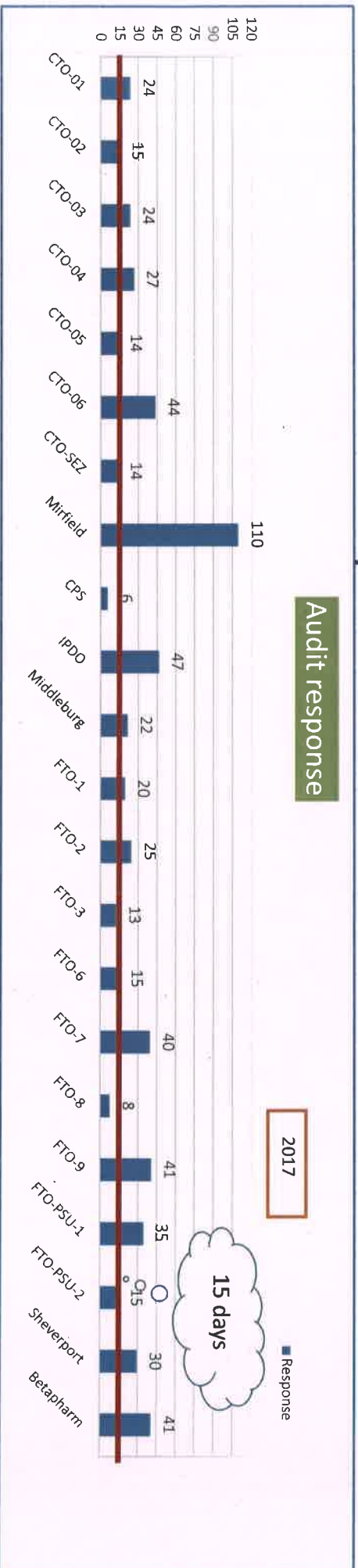




# Site wise Fragile systems overview –CTOs & Biologics-2018,



# Feedback on Audit response – 2017 vs 2018



**Summary: 73% of the sites had responded to the internal audit findings within 15 days in 2018 vs 36% in the year 2017**


# Improvement Opportunities - Way forward


## Improvement opportunities

- Building Internal Audit team capability by
  - IA team training on investigations and Data Integrity with FDA trained personnel-Target Q1 FY20
  - Participating in the Mock audits conducted by professional agencies/consultancies.
  - Providing Training on LIMS and MES to understand the design of electronic worksheets/batch records and controls to the IA team-Target Q2 FY20
- Strengthening the Audit response by
  - Emphasizing root cause for the failure/ deficiency and
  - Horizontal implementation of the CAPA at the site.
- Monthly External audits observations trending and sharing to the sites.
- Performing In-depth investigation in case of any potential DI observation.

Done By:


Sign / Date :

  
08-03-2019  
(D. Kalyan Kumar)

  
08-03-2019  
(K. Ravi Shankar)

Reviewed By :

Sign/Date:

  
08-03-2019  
(M. S. Sareen)

THANK  
you