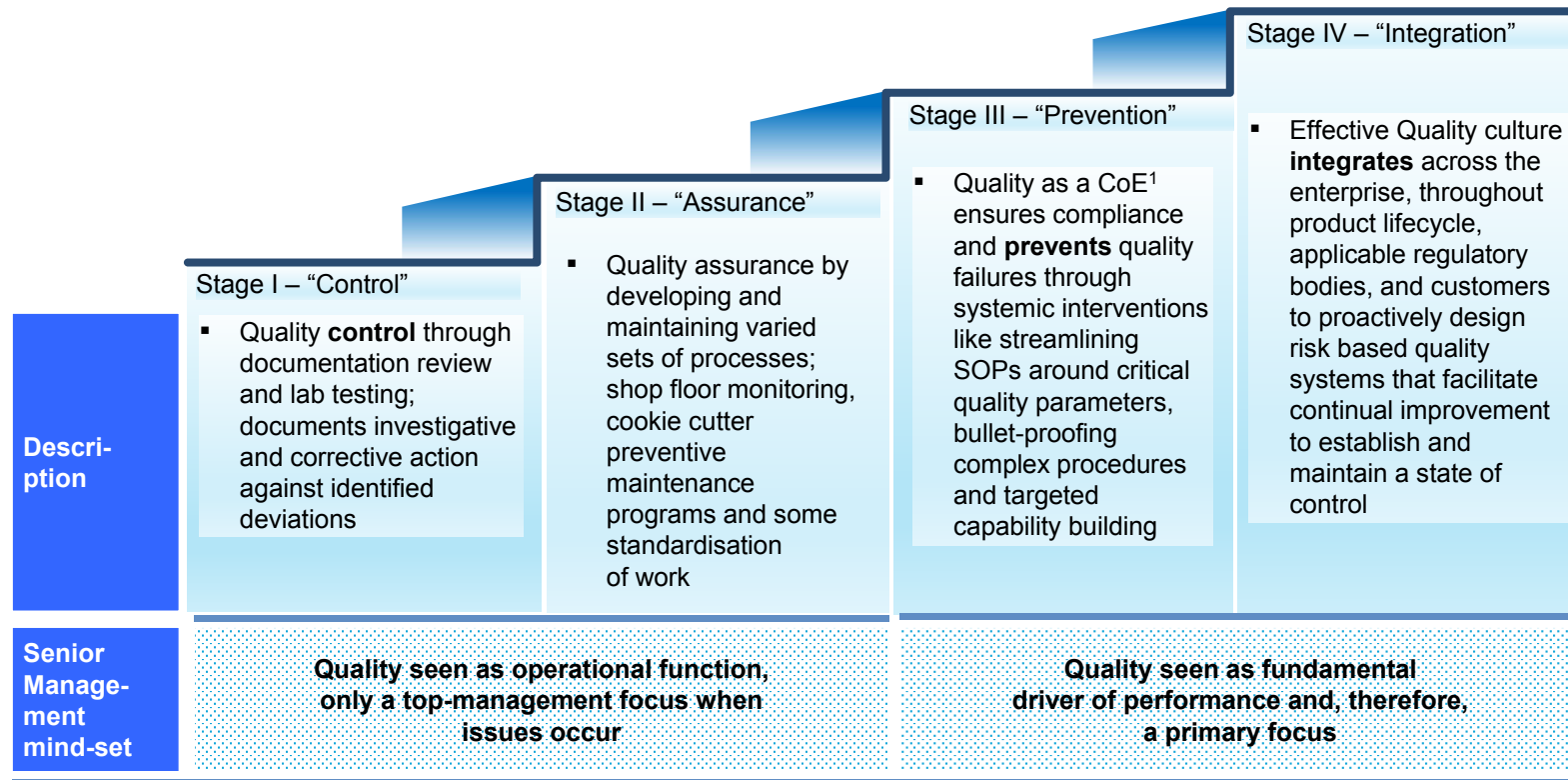




**QUALITY METRICS  
NOVEMBER 2018**



# Traditionally, organizations strengthen their quality functions over a 4 step journey



<sup>1</sup> Center of excellence

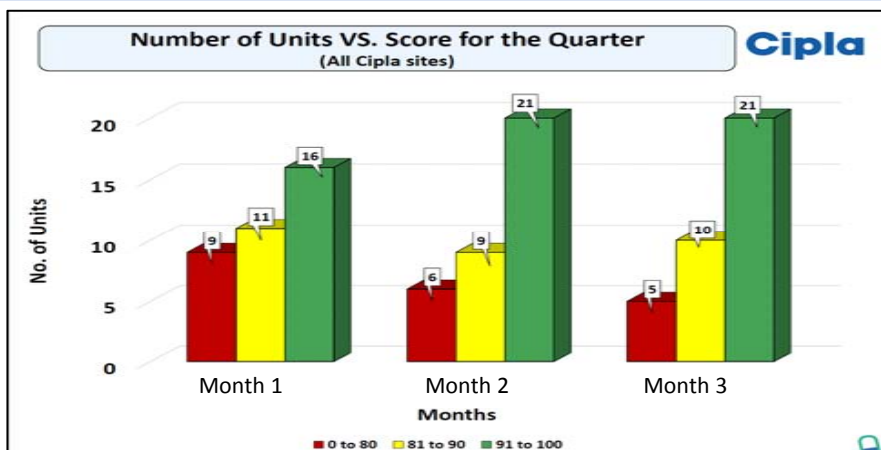
# Cipla followed a weighted average quality score approach to quality

## Quality metrics monitored earlier

KPI's Monitored	Weightage
Regulatory Audit	15
Corporate/ Customer Audit	5
Recall/ Return	7
Market Complaint	7
RFT/ Batch Failure	5
Stability	5
Deviation (Overdue and Repetitive)	10
CAPA (Overdue and Repetitive)	10
OOS (Invalid)	8
Change Request (Change Request > 60 days are monitored but not scored)	5
Laboratory Non Conformance	5
SLA	6
Investigation Closure (OOS, Complaints, Batch Failure)	12

- 13 metrics used to measure quality
- Each metric assigned a weight based on relative importance
- Quality score (out of 100) calculated for each site in the network based on the actual value of each metric at the site and the relative weightage
- Sites marked as Red, Green, Yellow based on weighted average score
  - 91 – 100 – Green
  - 81 – 90 – Yellow
  - 0 – 80 – Red

# Visual dashboards used to review overall site performance (1/2)



- Overall dashboard used to display number of sites performing well in the network and therefore the overall quality performance of the company

**DASHBOARD OF UNIT SCORES ( 1/3)**

Units	February 2018	March 2018	April 2018
Site 1	100	100	92
Site 2	87	67	91
Site 3	97	93	92
Site 4	96	95	100
Site 5	76	68	79
Site 6	100	100	94
Site 7	100	100	100
Site 8	100	93	88
Site 9	88	100	100
Site 10	97	98	91
Site 11	100	100	91

- Deep dive for each site across months to determine
  - Performance trend for each site; and
  - Sites for improvement focus

# However, there were some opportunities for improvement observed in this approach

1

**Opportunity to reduce number of metrics reviewed** – 13 metrics evaluated which restricted ability to focus improvement efforts across the network

2

**Opportunity for review of specific metrics** - Reduced focus on performance across specific metrics / indicators, as weighted average sum of performance reviewed across sites

3

**Opportunity to ease decision making** – difficult to identify specific actions and next steps for each site given scores reviewed are a combination of performance across 13 metrics

# Shift made towards a Balanced Scorecard approach to quality

## 5 broad objective metrics criteria

<b>Data Integrity (DI)</b>	
No DI Incident Logged	Green
DI Incident Logged	Red
<b>QMS (Quality Management System) Investigation Closure</b>	
QMS Investigation closed within 45/ 75 days	Green
QMS Investigation closed after 45/ 75 days	Red
<b>Quality of QMS (Quality Management System) Investigation</b>	
Root Cause Identified	Green
Probable Root Cause Identified	Yellow
No Root Cause Identified	Red
<b>RFT (Right First Time) Documentation</b>	
> 85%	Green
< 85%	Red
<b>SLA (Service Level Agreement)</b>	
>85%	Green
<85%	Red

QMS investigations for Deviations, OOS, OOT, OOAC, OOAL, *Complaints*

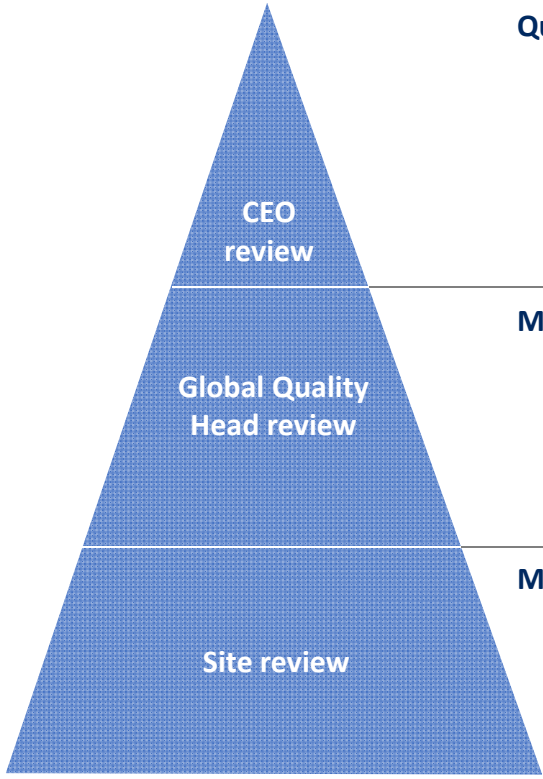
- 5 broad areas identified for focus
  - Data integrity
  - Investigation Closure
  - Quality of investigation
  - RFT documentation
  - Service level agreement adherence
- Criteria for performance measurement / evaluation (i.e. Red, Green, Yellow) identified for each metric
- Monthly review across sites of each focus area using the defined evaluation criteria

# Sample outcomes - Dashboards

Unit	Month 1														RFT Docs	SLA
	Data Integrity	QMS Closure						Quality of Investigation								
		Dev	OOS	OOT	OOAC	OOAL	Comp	Dev	OOS	OOT	OOAC	OOAL	Comp			
		Logged	>45 days	>45 days	>45 days	>45 days	>75 days	Root cause Identified/ Probable Cause Identified/ No Root cause Identified						>85%		
Site 1	0	0	1	1	0	0	3	0	2	0	0	0	0	55	74	
Site 2	0	1	6	0	0	0	40	0	0	0	0	0	0	66	83	
Site 3	0	0	7	2	0	0	3	0	1	1	0	0	0	62	92	
Site 4	0	4	1	1	0	0	2	0	0	3	0	0	0	67	90	
Site 5	0	3	0	0	74	4	2	0	0	0	0	0	0	40	100	
Site 6	1	0	0	0	32	8	0	0	0	0	0	0	0	56	51	
Site 7	0	0	0	0	0	0	0	0	0	0	0	0	0	55	76	
Site 8	0	3	3	1	26	2	0	0	0	2	0	0	0	24	68	
Site 9	0	2	3	0	109	39	0	0	0	0	0	0	0	25	45	
Site 10	0	0	1	9	5	2	0	0	1	0	0	0	0	53	90	
Site 11	0	0	0	0	0	0	0	3	0	0	0	0	0	81	89	
Site 12	0	0	0	0	1	0	0	0	0	0	0	0	0	86	96	
Site 13	0	8	2	0	0	0	5	0	0	1	0	0	0	64	82	
Site 14	0	0	10	4	94	25	1	0	0	2	0	1	0	16	90	
Site 15	1	0	1	0	12	1	2	0	2	1	0	0	0	85	80	
Site 16	0	1	2	1	17	4	0	0	3	1	0	0	0	67	63	
Site 17	1	4	12	7	10	5	5	0	0	7	0	1	0	82	86	
Site 18	0	19	0	0	0	0	1	0	0	0	0	0	5	44	99	
Site 19	0	0	0	0	0	0	1	0	1	0	0	0	0	20	100	
Site 20	0	6	0	0	2	1	1	0	2	1	0	0	0	65	88	

- Visual dashboard created for the company, displaying performance across the 5 metrics for each site in the network
- Ease in identifying key area of concern vis-à-vis the focus area for the company
  - Visual comparison across sites to identify areas of concern
- Inter-site comparison to identify strengths and potential opportunity for learning for other sites

# Governance and review structure

	<u>Frequency</u>	<u>Agenda</u>	<u>Chaired By</u>	<u>Participants</u>
 <p>CEO review</p>	<b>Quarterly</b>	<ul style="list-style-type: none"> <li>• Review of scorecard across sites</li> <li>• Market Complaints</li> <li>• Recalls</li> <li>• FAR</li> <li>• Batch Rejections</li> <li>• Any other Agenda Items</li> </ul>	CEO	<ul style="list-style-type: none"> <li>• Global Head Quality</li> <li>• Global Manufacturing head</li> <li>• Global IPD Head</li> <li>• Other function heads</li> <li>• Site heads</li> </ul>
<p>Global Quality Head review</p>	<b>Monthly</b>	<ul style="list-style-type: none"> <li>• Review of scorecard across sites</li> <li>• Market Complaints</li> <li>• Recalls</li> <li>• FAR</li> <li>• Batch Rejections</li> <li>• Any other Agenda Items</li> </ul>	Global Quality Head	<ul style="list-style-type: none"> <li>• Global Manufacturing head</li> <li>• Global IPD Head</li> <li>• Other function heads</li> <li>• Site heads</li> </ul>
<p>Site review</p>	<b>Monthly</b>	<ul style="list-style-type: none"> <li>• Review of scorecard for the site</li> <li>• APQR result</li> <li>• Change controls</li> <li>• Outstanding actions from last review</li> <li>• New product challenges, etc.</li> </ul>	Site Quality Head	<ul style="list-style-type: none"> <li>• Site Manufacturing Head</li> <li>• Cross-Functional Team</li> </ul>