

Background/Case Studies:

Heavily regulated organizations require visibility to metrics to determine the overall health of the Quality System. This helps management make risk-based decisions based on the information provided. However, as organizations implement digital or automated solutions including electronic Quality Management Systems (eQMS), it can be difficult to analyze all the data necessary to drive change and improve compliance. The creation of a quadrant-based scorecard was implemented at our organization to provide more transparency and help drive improved compliance from all employees.



Heavily regulated organizations like BioBridge Global must have easy access to metrics to monitor the overall health of the Quality System.

Study Design/Methods:

A quadrant-based scorecard was designed to differentiate the source of data. The X-axis was “People vs Process” while the Y-axis was “Internal vs External” allowing for the organization of data in an easily identifiable format. Metrics monitored included training, SOP periodic reviews, quality event closure time, audit response time, and complaint resolution. The bottom right quadrant was reserved for subsidiary-specific metrics that measured desired output such as testing turnaround time, blood on hand, and first-time right metrics. Each quadrant had a possible score of 25 points for a total possible score of 100 points. This scorecard was then distributed monthly to operational leadership and placed on the company intranet for visibility by all staff. July 2022 was the first month of scorecard use. The scorecard prioritized information that needed to be addressed by management and staff. Actions were created and followed up to improve the quality metrics.

	People / Leaders					Customers/External				
	Goal	Actual	Trend (+/-)	Points	Goal	Actual	Trend (+/-)	Points		
People	MC Training (% of People out of compliance)	<=10% = 12.5 pts <=25% people = 6 pts	8%	-5%	12.5	Complaints	<=30 days Close = 12.5 pts <=35 days Close = 6 pts	23	+1	12.5
	Total Training courses past due		100	-143		Number of Complaints Issued	<5/month = Good <3/month = Great	2	+1	Great
	Periodic Reviews (Avg Days past due)	<15 Overdue = 12.5 pts <30 Overdue = 6 pts	0	-21	12.5	Cust. Satisfaction Survey	>90% = 12.5 pts >80% = 6 pts >70% = 3 pts	92%	NC	12.5
	Count of SOP's past due		0	-2		SCAR's	<45 days Close = Great <60 days Close = Good	40	-5	Great
Process	Inventory Dollars									
	Internal	Goal	Actual	Trend (+/-)	Points	External	Goal	Actual	Trend (+/-)	Points
	Deviation	<30 days Close = 9 pts <40 days Close = 4.5pts	14	1	9	IRL-STAT Crossmatch Avg. TAT	Avg. TAT <= 1.5 hrs = 5 pts Avg. TAT <= 1.75 hrs = 2.5	1.5	+35	5
	CAPA	<120 days Close = 8 pts <150 days Close = 4 pts	136	-22	4	Donation Times -WB (Reg thru needle)	<35 min avg = 5 pts <40 min avg = 2.5 pts	29	-1	5
	Number of Deviations Issued	Total Number of Deviations	43	17		%Charts cleared of Goal	>80% = 5 pts >70% = 2.5pts	127%	+23%	5
	Internal Audits	<60 days Close = 8 pts <75 days Close = 4 pts	51	-8	8	All O Collections (monthly)	>= Goal 5 pts >= 94% Goal 2.5 pts	6029	NA	2.5
						Regulatory Audits	No Major, Critical or 483 Issued = 5 pts	0	NC	5

The scorecard prioritized information that needed to be addressed by management and staff.

Results/Findings:

Table 1: QA Scorecard Quality Metrics comparing first to most recent month of use. Over the first nine months of scorecard use, we saw improvement in all metrics, highlighted in Table 1. The audit response rate for blood operations showed an improvement of 51%. Periodic review improved by 88% for blood operations and decreased to 0 days in the processing lab. Overdue training decreased by 66% and 50% in biomanufacturing and blood operations, respectively. Deviation closure rates decreased by 40% in the Processing laboratory and 33% in blood operations.

Quality Metrics	July 2022	March 2023
Average Internal Audit Response Time – Blood Operations (days)	112	55
Average Days overdue: Periodic Review of SOPs – Blood Operations (days)	118	14
Average Days overdue: Periodic Review of SOPs – Processing Laboratory (days)	170	0
% Staff Overdue on Training – Blood Operations	20	10
% Staff Overdue on Training - Biomanufacturing	24	8
Average Deviation Closure – Processing Laboratory (days)	25	15
Average Deviation Closure – Blood Operations (days)	18	12

Conclusion:

The implementation of the Quality scorecard led to deviations closing faster (40% and 33%), decreasing of training non-compliance (66% and 50%), and timelier review of SOPs (88% and 100%) allowing for updates to occur more readily. This increase in awareness and visibility has helped improve the established culture of quality.