9.1. Monitoring, Measurement, Analysis and Evaluation

9.1.1. General

BAI has determined which aspects of its quality management system must be monitored and measured, as well as the methods to utilize and records to maintain, within this QM 9.1 Performance Evaluation and subordinate documentation.

Monitoring and measurement of the processes, as defined in QM 4.4 QMS and Its Processes, ensures that the QMR evaluates the performance and effectiveness of the quality management system itself.

BAI determines:

a. what needs to be monitored and measured

b. the methods for monitoring, measurement and analysis and evaluation needed to ensure valid results

c. when the monitoring and measuring shall be performed

d. when the results from the monitoring and measurement shall be analyzed and evaluated.

The DQMR of concerned division has overall responsibility for planning and implementing inspection and test activities needed to verify product requirements are met at appropriate stages of the product realization process in accordance with the applicable control plan. When selecting product parameters to monitor compliance to internal and external requirements, product characteristics are determined leading to the types of measurement, suitable measurement means, and the required capability and inspection/test skills needed.

The scope of our product monitoring and measurement system includes receiving inspection, in-process quality control, and final test.

Receiving Inspection. Incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements in accordance with documented procedures. Methods used to verify incoming product may include: receipt and evaluation of valid product certificates, formal receiving, inspection (GP BAI-16 Receiving, Inspection and Storage of Raw Materials) and/or test (GP BAI-15 Evaluation of Suppliers), and/or source inspections.

In-process Quality Control. Formal in-process quality control are performed by Specialist/Analyst in accordance with processes identified for monitoring as indicated in the technical procedures and testing methods used.

Final Inspection and Test. In-house quality testing of products is conducted on every batch of veterinary biologics and drugs produced. Selection criteria for apparently healthy unvaccinated laboratory animals are strictly employed for every delivery.

Reference standards are checked periodically to monitor quality. For doubtful or failed results, re-tests are automatically done to validate such findings.

Release. Products are not released for delivery until the products have passed the quality control tests done by the Veterinary Biologics Assay Section. For *certificates, permits, licenses*, test reports, results are checked twice before reports are released.

Evidence of Conformity. Test and inspection records are maintained for a minimum of three years (PL BAI-16 Master List of Records). These records include test results from the final inspection authority that identify and confirm that all critical parameters are in accordance with established requirements and specifications.

Product Release and Delivery. Product is not normally released or delivered until all tests have been completed, and records have been maintained providing evidence of conformity with acceptance criteria and identifying the person(s) authorizing release. In rare cases (due to customer demands and/or disease outbreak emergencies) unverified product may be released or delivered under controlled conditions and concessions and authorized by the Division Chief and, where applicable, approved by the customer. Nonconforming product is identified and controlled by red tagging to prevent its inadvertent use.

BAI retains appropriate documented information as evidence of the results.

9.1.2. Customer Satisfaction

BAI monitors customers' perceptions of the degree to which their needs and expectation have been fulfilled. BAI determines the methods for obtaining, monitoring and reviewing this information.

The methods for obtaining and using this information include:

- recording customer complaints
- product rejections or returns
- repeat orders for product
- changing volume of orders for product
- trends in on-time delivery
- obtain customer scorecards from certain customers
- submittal of customer satisfaction surveys

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

Customers are the reason we exist and drive our quality policy "to meet or exceed customer requirements." The DQMR has overall responsibility for identifying and reviewing customer requirements and for monitoring and measuring customer satisfaction according to GP BAI-17 Measuring Customer Satisfaction summarized as follows:

Data collected by customer contact personnel during routine communications provide our primary basis for assessing customer satisfaction. Each division utilizes a very simple customer satisfaction survey form to ascertain the customer's overall perception of how well we are meeting their requirements and to document any recommendations for improvement.

Customer complaints (whether received in writing, verbally, phone call or electronically) are immediately forwarded to concerned Section Head (SH)/supervisor for action. Customer complaints are documented and monitored through resolution according to GP BAI-10 Handling Customer Complaint.

Customer survey data along with other customer feedback (including written or verbal complaints and information collected during customer's visit) is reviewed daily by Section Heads concerned to initiate any improvement or corrective/preventive actions needed.

The QMR periodically reviews customer satisfaction survey data and other customer feedback (including complaints), as well as progress towards achievement of corporate level customer satisfaction improvement objectives and provides related recommendations for review by Top Management.

9.1.3. Analysis and Evaluation

BAI analyzes and evaluates the data and information arising from monitoring and measurement in order to evaluate:

a. conformity of Products or Services;
b. the degree of customer satisfaction;
c. the performance and effectiveness of the quality management system;
d. if planning has been implemented effectively;
e. the effectiveness of actions taken to address risks and opportunities;
f. the performance of external providers;
g. the need for improvements to the quality management system.

Statistical techniques used may be defined in appropriate documented procedures; in all cases, the methods are based on established standards or are otherwise determined to be statistically valid.

Top Management, DQMRs, Analysts, Specialists and Administrative Officers and Project Managers collect and analyze data using appropriate statistical techniques to determine the suitability and effectiveness of key QMS processes applicable to their area(s) of responsibility and to identify opportunities for improvement. At a minimum, data is analyzed to assess achievement of the laboratory level quality objectives. A monthly report about the achievement of quality objectives is prepared using GF BAI-57 Monthly Accomplishment Report Form. *And on a semi-annual basis, the officers and all employees are rated based on their OPCR, DPCR and IPCR respectively.*

A process is effective if desired results are achieved. Effectiveness can be measured in terms of product quality, process accuracy, schedule performance, budget performance, employee/function performance against established objectives, and/or customer satisfaction.

A process is efficient when resource utilization is optimal. Efficiency can be measured in terms of total resource utilization, productivity indicators, and or the cost of poor quality (such as waste/rework costs or hours).

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