Analytical Hub
Technical Bulletin

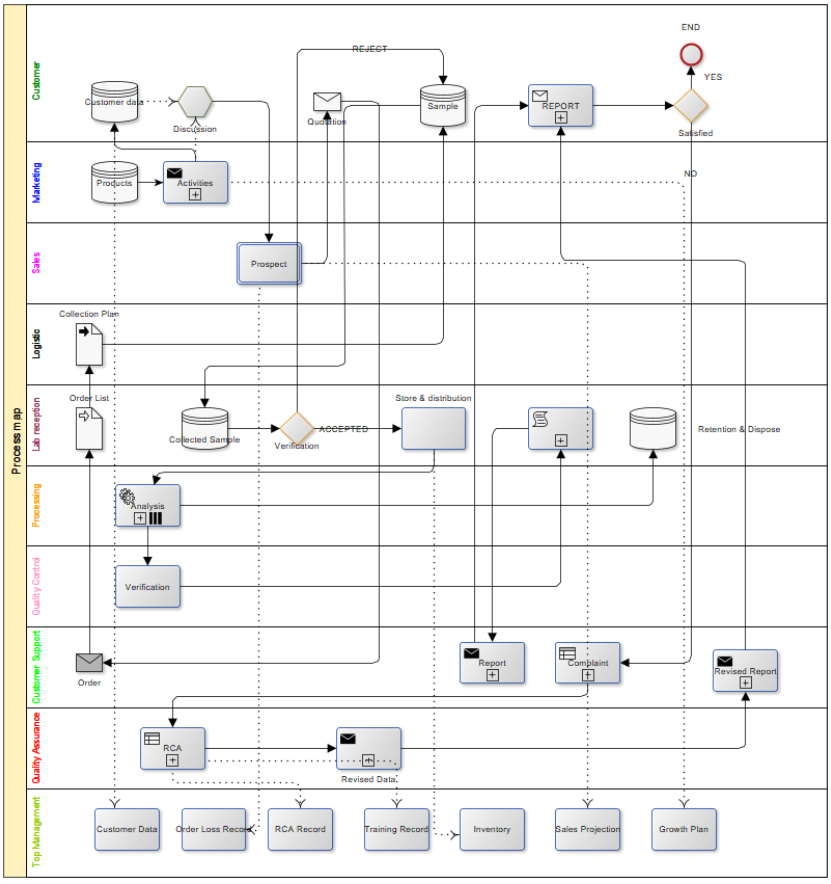
SQC
Risk Analysis

Risk management is one of the most important activities nowadays to maintain and improve quality of work, reduce the down time and expenses rise due to corrective actions.

To perform the risk management, following details needs to addressed and to be performed to practice Risk Management:

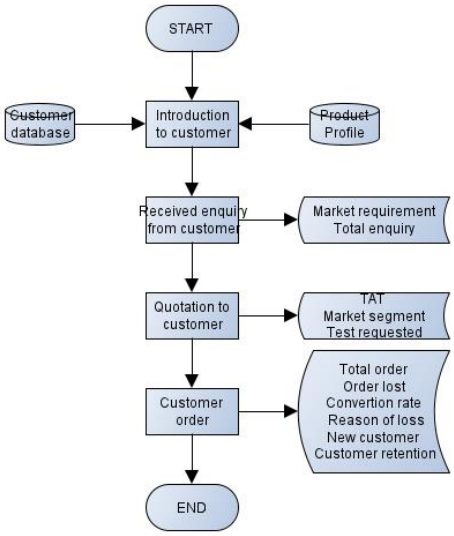
1. Organization process flow chart
2. Related work flow chart
3. Fish-bone
4. Identify the CTQ
5. SIPOC (Supplier, Input, Process, Output, Customer)
6. FMEA (Failure mode Effect Analysis)
7. Quantitative data of failure of each CTQ

Organization Flow Chart



Analytical Hub
Technical Bulletin

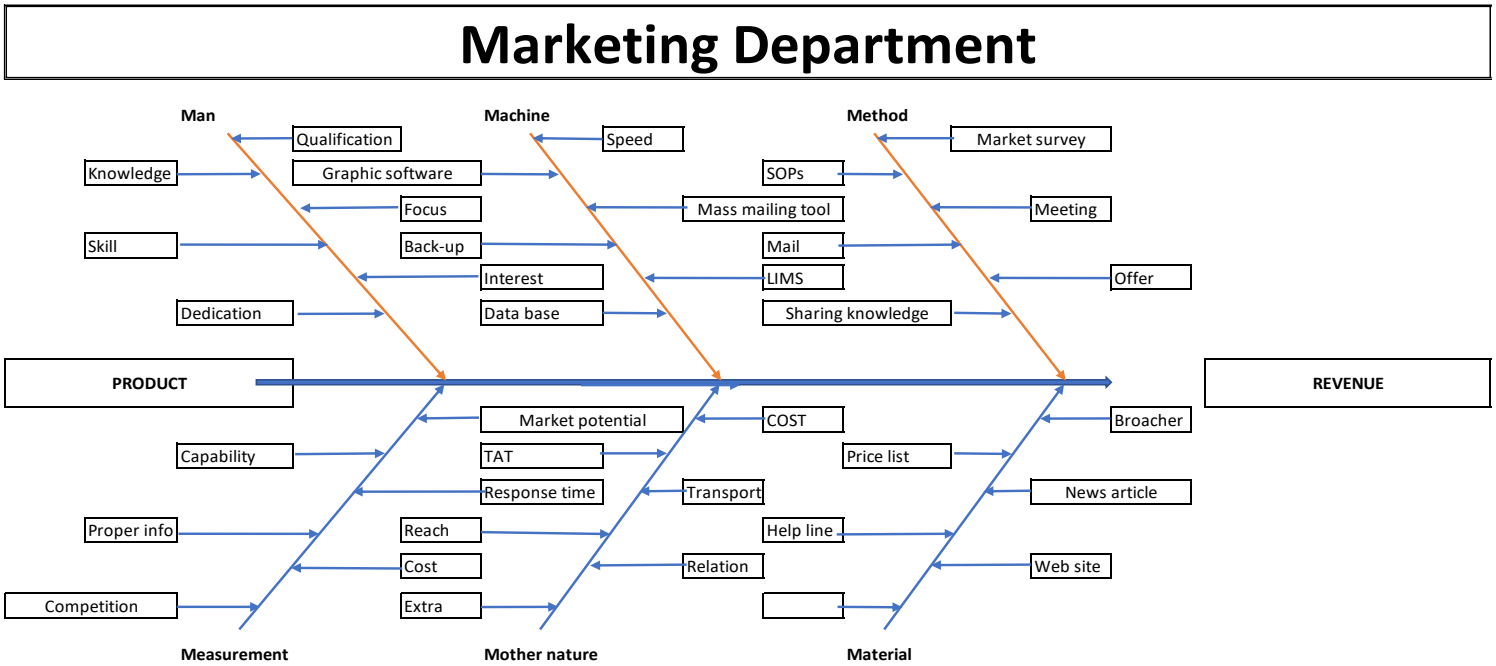
Marketing and Sales:



CTP	CTQ	Monitor
Customer database Product profile Test in scope	TAT Cost	Time to respond on enquiry Customer sector wise enquiry Wrong information provided to customer Identified wrong customer Order lost and reason Conversion rate – enquiry vs order New customer addition Customer retention (customer lost) Repeat business

Analytical Hub
Technical Bulletin

Fish-bone (Ishikawa diagram)



Factors extracted from Fish-bone:

Factors	CTP	Notes
Man	Qualification	Need to know about basic of marketing
	Knowledge	Should know and understand the market and customer requirement, needs of the test
	Focus	
	Skill	
	Interest	If not interested to make carrier in marketing then there will be no or very little output
	Dedication	Marketing is 24 hrs job. Need to spend time to analysis the market potentiality, our present position and plan to achieve the target/goal
Machine	Speed	The system using for data analysis should have enough speed to work fast
	Graphic software	Need to create effective and informative promotional materials
	Mass mailing tool	Sending promotional material to multiple customer, "single click" software will save time
	Back-up	Old data helps to analyze the market trend and consumer behaviour
	LIMS	LIMS manage plan, action, inputs and outputs
	Database	Need for business growth analysis
Method	Market survey	It is always important to move with market requirement
	SOPs	All actions to be written to check if any needs in planning and processes
	Meeting	Direct interaction creates relation and easily can understand the exact requirement
	Mail	Communication needs to be documented for future business analysis
	Offer	Periodical offer creates excitement to customer

	Knowledge sharing	Customer needs solution
Measurement	Market potential	Identify the test to be added or removed, load
	Capacity	How much we can complete against the market load
	Response time	How first we can respond with offer, solutions and reports
	Proper information	At first response to customer, proper information should go
	Cost	Should be competitive
	Competition	How others behaving
Mother nature	Cost	Market cost sensitive
	TAT	Everyone expects quick result. Automation can reduce TAT
	Transport	Sample transportation across India needs good logistic network
	Reach	How customer can reach to us
	Relation	Create good relation and maintain
	Extra	What extra we can give to customer for which customer is ready to pay
Material	Broacher	Sector wise broacher. Customer will not go through the details if it is not of their interest
	Pricelist	Profile includes selective test
	News article	Informative, helpful about regulations, guidelines, health related issues
	Help line	Always reachable and responded quickly
	Website	Fast, informative, should have booking and payment option, customer log-in option to down load reports, complaints

Analytical Hub
Technical Bulletin

CTQ (Critical to Quality)

Sr. No.	CTQ
1	Qualification of marketing personnel
2	Knowledge of marketing personnel
3	Focus of Marketing personnel
4	Skill of Marketing personnel to identify the market
5	Interest to the job of marketing personnel
6	Dedication to work and company of marketing personnel
7	Turnaround time to customer queries (Target 5 min)
8	Promotional material
9	Promotional informative mail to customer
10	Received enquiry
11	Customer feedback utilization
12	Database expansion
13	Customer complaint resolving rate
14	Cost of test
15	Meeting with customer
16	Handle customer call and queries
17	Adding new customer
18	Availability of test required by market
19	Market potential for the test offering

Analytical Hub
Technical Bulletin

SIPOC (Supplier, Input, Process, Output, Customer)

Supplier	Input	Process Requirement	Process	Output	Customer Requirement	Customer
Marketing Head	Sector details, profile and test details. (Measure the requirement received earlier and if it is a new test introducing in the market, then what is the return projected)	1. Sector details 2. Sector wise profile 3. Information to be printed in catalogue 4. If any pre-selected lay out by customer	1. Take required information 2. Select suitable pictures 3. Design and print 4. Send to customer for approval	Sector wise catalogue	1. Sector wise catalogue 2. Required information 1) Profile and test 2) Why to do test 3) Govt. regulation 4) Why from us 3. Pictures 4. Price	Marketing team
Marketing Team	Customer data base (Measure weekly addition of new customer in data base and customer feedback received)	1. Customer list 2. Soft ware to send promotional mails 3. Client meeting plan and reporting format 4. Facility visit plan for customer	1. Update customer data base 2. Link the document for each sector 3. Send mails 4. Contact customer and fix appointment 5. Visit customer	1. Increase customer data base 2. Customer requirement understood and shared with management 3. Competitor's activities	1. Business prospect	Sales Team

Issue No.: 25-26-01; Abhijit.bhar@outlook.com; Mobile/whatsap: +91 9867423453

			6. Understand their requirement 7. Prepare visit report			
Sales Team	Business prospect from marketing team (Monitor total enquiry, enquiry sector wise, lost cases with reasons)	1. Test profile and cost 2. Prospects 3. Our advantage details	1. Send quotation against mail received form customer 2. Visit customer to close the deal 3. Special price approval from management 4. Customer visit plan to laboratory if needed 5. Send order to logistic team	1. Order received 2. List of orders 3. List of new customer addition 4. Order lost details with reasons 5. New test request from customer to management 6. Competitor's activities	Clean order (Proper test profile, clear payment terms, if discounted then copy of management approval, agreed TAT)	Logistic team

Analytical Hub
Technical Bulletin

FMEA (Failure Mode and Effect Analysis)

FMEA #:	2020-11	**Process Responsibility:**	Dr. Karunakara	**Core Team:**	Abhijit Bhar
Process Name:	Marketing and Sales	**Prepared by:**			Karunakara
Affected Products:	Test Report				Thomas
FMEA Key Date:	2.6.2020	**FMEA Origin date:**	4.4.2020		
		FMEA Rev date:			

Sr. No.	*Process Function*	*Potential Failure Mode*	*Potential Failure Effects (KPOVs)*	*SEV*	*CLASS*	*Potential Causes of Failure (KPIVs)*	*OCC*	*Current Process Controls*	*DET*	*RPN*	*Recommended Actions*	*Responsible Person & Target date*	*Taken Actions*	*SEV*	*OCC*	*DET*	*RPN*
1	Market promotion	No enquiry generated	Loss of money and time	8		Wrong market sector focused	10	No control	10	**800**	Create marketing team. Abhijit need to complete before July2020	Abhijit, before July'20	Due to Lock-down no action taken	8	10	10	**800**
2		Proper information not provided	Customer stopped communication	8		Marketing material not availble	10	No control	10	**800**	Create promotional material. Abhijit to ensure before June2020	Abhijit, before June 2020	One test profile created	8	6	6	**288**
3	Handle customer enquiry	Delay in communication	Lost order	8		Manual entry of enquiry	8	Manual entry in enquiry form	1	**64**	Use LIMS to enter enquiry. Abhijit before Oct.2020			8	8	1	**64**
4		Quotation not considered	Lost order	8		Price at higher side	10	Price refered old quotation	10	**800**	Set test profile and cost. Abhijit before June2020	Abhijit, before June 2020	New price list prepared	8	1	1	**8**
5			Lost order	8		Test methodology not accepted by customer	1	Before quoting, method discussed with client	1	**8**							**0**
6			Lost order	8		Customer wants local laboratory	6	No control	10	**480**	Tie-up with other laboratory at regions. Abhijit before Oct.2020	Abhijit, before Oct'20	Due to Lock-down no action taken	8	6	10	**480**
7			Lost order	8		Requested sample volume cannot provide by customer	8	No control	10	**640**	Adopt new technology which consume less sample. Abhijit before Oct.2020	Abhijit, before Oct'20	Anion analysis method using IC verified. Need to participate in PT	8	8	6	**384**

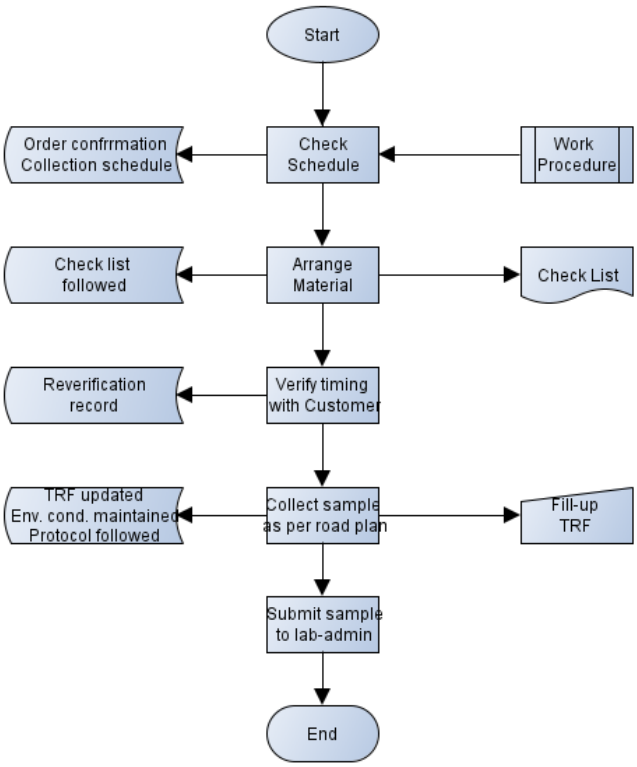
Analytical Hub
Technical Bulletin

Quantitative data of each CTQ:

Sr. No.	CTQ	Discrete data	Continuous data
1	Qualification of marketing personnel is up to the mark (Y/N)		
2	Knowledge of marketing personnel is up to the mark (Y/N)		
3	Marketing personnel have focus (Y/N)		
4	Marketing personnel have skill to identify the market (Y/N)		
5	Marketing personnel have interest to the job (Y/N)		
6	Marketing personnel have dedication to work and company (Y/N)		
7	How many reply to customer taken more than 5 minutes		
8	How many promotional material created in the month		
9	How many mails sent to customer in the month		
10	How many enquiry received in the month		
11	How many customer feedback received in the month		
12	How many data generated in the month		
13	How many complaint received in the month		
14	How many complaint are unresolved in the month		

Analytical Hub
Technical Bulletin

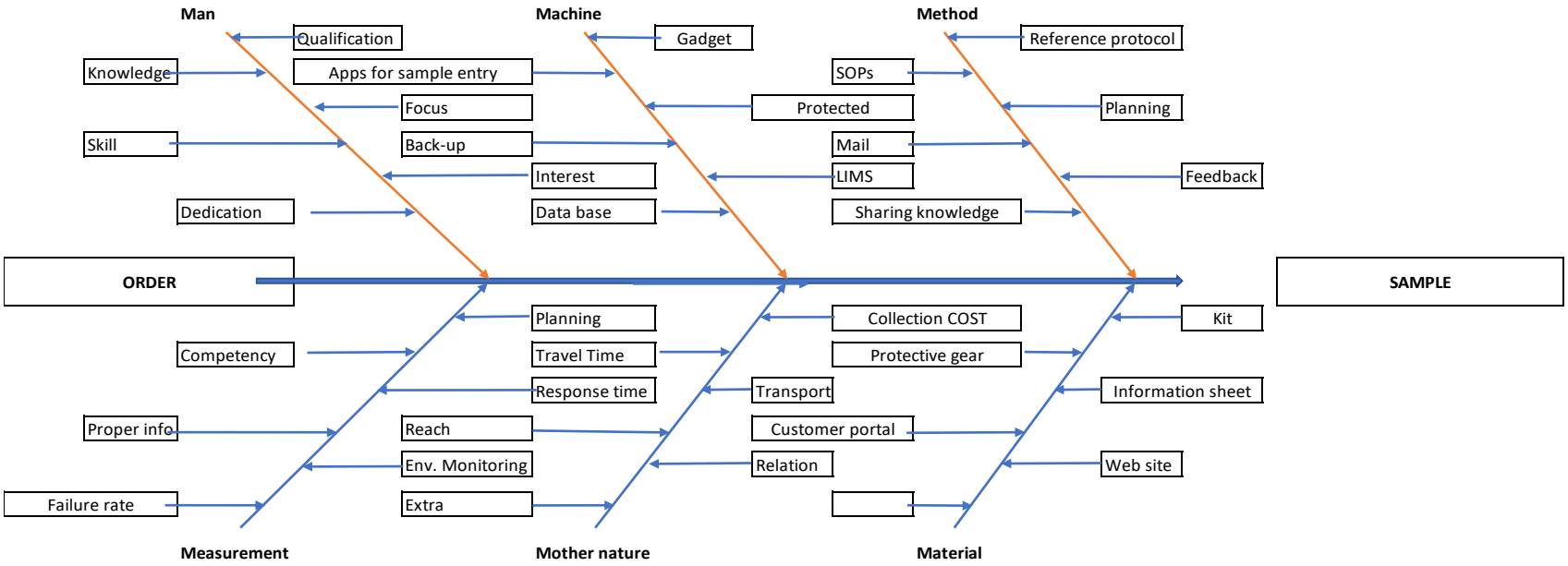
Sample Collection



CTP	CTQ	Monitor
Order confirmation Collection schedule	Collection checklist TAT Hygiene maintain	TAT for order confirmation TAT for sample receive Collection failure rate Rate of reschedule for collection Failure rate of hygiene Failure rate to maintain env. Cond.

Fish-bone (Ishikawa diagram)

Lab Admin - sample collection



Factors extracted from Fish-bone:

Factors	CTP	Notes
Man	Qualification	Need to know about basic of collection procedure
	Knowledge	Should know and understand about the cross contamination
	Focus	During sample collection / pick-up need to check all important areas has been addressed
	Skill	
	Interest	If not interested to travel then cannot utilise the working hour efficiently
	Dedication	Sample pick-up is 24 hrs job. Need to reach at customer place as per their convenient time
Machine	Gadget	Mobile or tab will help to do sample entry at real time
	Apps for sample entry	Apps will help to reduce sample entry and registration time, will reduce the error of sample information and test request
	Protected	The apps are protected with user ID and password, linked with main server
	Back-up	Old data helps to analyze the market trend, our performance and change of customer behaviour
	LIMS	LIMS manage plan, action, inputs and outputs
	Database	Need for business growth and change analysis
Method	Reference protocol	Important to maintain sample integrity and authenticity of procedures
	SOPs	All actions to be written to check if any needs in planning and processes
	Planning	Sample pick-up plan will reduce delay and cost
	Mail	Once sample collected and registered in laboratory, auto mail will inform customer that sample has taken into process
	Feedback	Feedback will help to improve our services

	Knowledge sharing	Customer needs solution
Measurement	Planning	Sample pick-up plan and failure rate to improve
	Competency	Periodical evaluation of person collecting sample
	Response time	How fast we are responding to customer
	Proper information	Incomplete information delay the process
	Env. Monitoring	Important to maintain sample integrity
	Failure rate	For the measurement of improvement
Mother nature	Collection Cost	Needs to reduce or nil
	Travelling time	Individual sample pick-up against bulk pick-up
	Transport	Sample transportation across India needs good logistic network
	Reach	How customer can get report instantly
	Relation	Create good relation and maintain
	Extra	What extra we can give to customer for which customer is ready to pay
Material	Kit	Uniform sample collection kit, so if needed customer can use it to send sample, avoid cross contamination and maintain sample integrity
	Protective gear	Maintain hygiene during sample collection
	Information sheet	All required information filled at first time to reduce delay in sample registration and cross check with data entered in portal
	Website	Customer can book test and pay on line, will help to spread business
	Customer portal	Customer can register themselves in website to get access in customer portal, where they can track their sample, can down load report and refer important information

Analytical Hub
Technical Bulletin

CTQ (Critical to Quality)

Sr. No.	CTQ
1	Qualification of sample collector
2	Knowledge of sample collector
3	Pick-up time and travelling time spent
4	Sample test request form
5	Env. Record
6	Check list
7	Sample in sterile container
8	Competency record
9	Checking sample integrity during transportation

Analytical Hub
Technical Bulletin

SIPOC (Supplier, Input, Process, Output, Customer)

Supplier	Input	Process Requirement	Process	Output	Customer Requirement	Customer
Logistic team	Client order from logistic team	1. Collection agent network along with contact details 2. Sample collection kit 3. Transportation net work	1. Client order 2. Identify the nearest and readily available collection agent 3. Talk to client and fix collection date and time 4. Pass on the information to collection agent 5. Ensure collection agent have collection kit 6. Co-ordinate with client and collection agent till sample received in lab	1. Sample collection instruction 2. Sample collection plan	1. Customer address 2. Sample collection instruction 3. Sample collection kit 4. Sample drop location	Sample collection agent
Sample collection agent	Sample with test request	1. Sample 2. Test Request 3. Codification system 4. LIMS	1. Do the entry in inward register 2. Do entry in Sample entry register	Sample list for the day	1. Clear information of test to be conducted	Lab Admin

			3. Assign lab code 4. Erase other Ref. No. 5. Check test request form 6. Do physical verification 7. Create job sheet 8. Send sample and job sheet to process		2. Clearly mention the sample matrix 3. Clearly mention the last date for report submission 4. Clearly mention the customer address 5. Details information of reference of quotation	

Analytical Hub
Technical Bulletin

FMEA (Failure Mode and Effect Analysis)

FMEA #:	01/02/2020	**Process Responsibility:**	Shruti	**Core Team:**	Abhijit Bhar
Process Name:	Lab Admin	**Prepared by:**			Karunakara
Affected Products:	Test Report				Thomas
FMEA Key Date:	4.4.2020	**FMEA Origin date:**	4.4.2020		Shruti
		FMEA Rev date:			

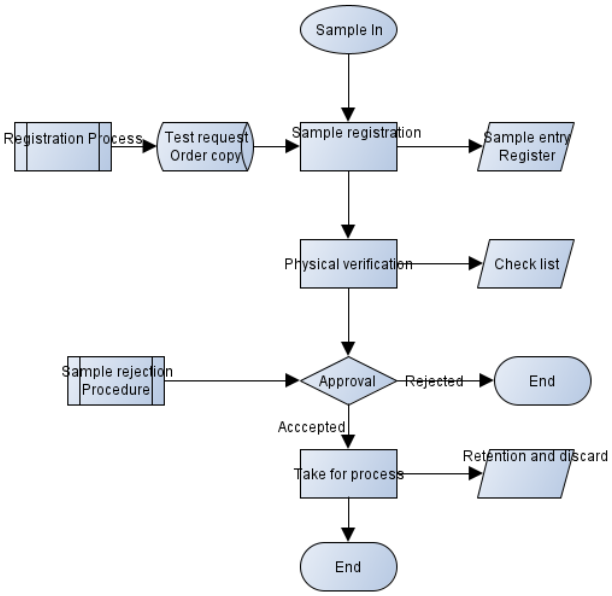
Sr. No.	*Process Function*	*Potential Failure Mode*	*Potential Failure Effects (KPOVs)*	*SEV*	*CLASS*	*Potential Causes of Failure (KPIVs)*	*OCC*	*Current Process Controls*	*DET*	*RPN*	*Recommended Actions*	*Responsible Person & Target date*	*Taken Actions*	*SEV*	*OCC*	*DET*	*RPN*
1	Order booking	Delay in order booking	Customer annoyed			No work plan				0							0
2	Sample pick-up	Delay in sample pick-up	Delay in process			Customer was not available				0							0
3						Collection plan was not proper				0							0
4						Collection kit was not ready				0							0
5	Sample information	Incomplete information	Sample rejistration delay			Manual entry, handwriting not clear				0							0
6	Customer information	Incomplete information	Sample rejistration delay			Manual entry, handwriting not clear				0							0
7	Sample transportation	Sample got contamianted	Sample rejection			Sample collected by non-trained person				0							0
						Not follwed the SOP				0							0
						Taken longer time to reach to laboratory				0							0
						env. Condition not verified				0							0

Analytical Hub
Technical Bulletin

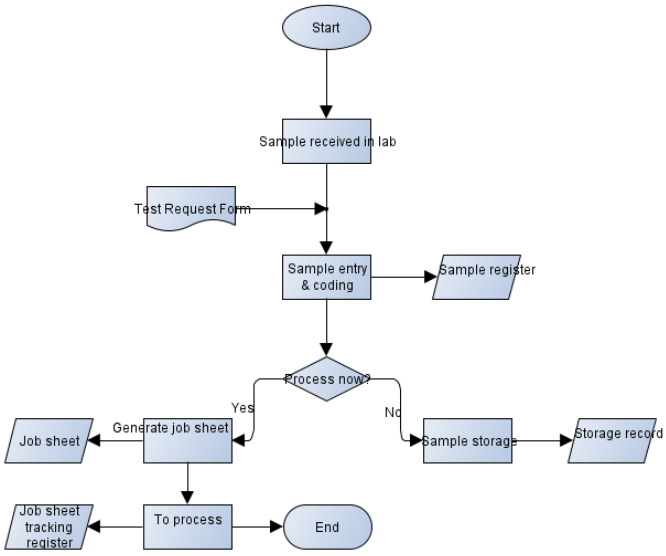
Quantitative data of each CTQ:

Sr. No.	CTQ	Discrete data	Continuous data
1	Qualification of sample collector is up to the mark (Y/N)		
2	Knowledge of sample collector is up to the mark (Y/N)		
3	Number of Evaluation of sample collector done per month		
4	Number of controlled sample checked during transportation per month		
5	Number of incomplete TRF for sample details per month		
6	Number of incomplete TRF for customer details per month		
7	How many times single customer attended per trip per month		
8	How many days per month was idle		
9	How many times sample reached laboratory after 4pm		
10	How many samples rejected per month due to loss of sample integrity during transportation		

Sample Registration (Lab-Admin Section)



Sample Distribution (Lab Admin Section)



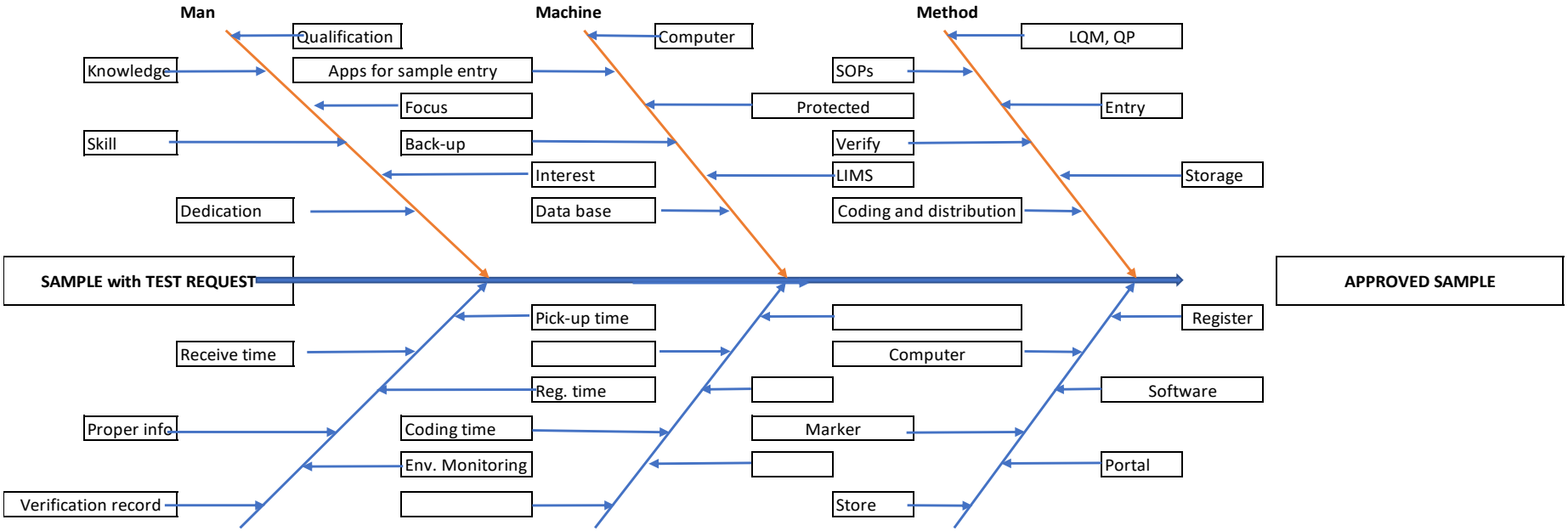
Analytical Hub
Technical Bulletin

CTP:	CTQ:	Monitor:
Sample registration	Verification check list	TAT for sample entry
Sample verification	Retention record	TAT for sample distribution
Sample retention – pre analysis	Discard record	Verification failure rate
Sample retention – post analysis	Jobsheet	Env. Cond. Record failure rate
		Wrong record of discard
		Inappropriate discard process

Issue No.: 25-26-01; Abhijit.bhar@outlook.com; Mobile/whatsap: +91 9867423453

Fish-bone (Ishikawa diagram)

Lab Admin - sample registration



Analytical Hub
Technical Bulletin

Factors extracted from Fish-bone:

Factors	CTP	Notes
Man	Qualification	Need to know computer, food test
	Knowledge	Computer, excel, bar code scanning
	Focus	During sample registration need to check sample container, env. Record (if applicable), proper coding, masking
	Skill	Typing speed
	Interest	If not interested on desktop work then cannot utilise the working hour efficiently
	Dedication	Lot of small critical parameters need to check. Should have a check list and need to follow
Machine	Gadget	Computer, barcode scanner
	Software for sample entry	Common software with restricted access at different parameters to avoid multiple entry of same data
	Protected	The computer should be password protected, software should have unique user ID and password with different user level
	Back-up	Old data helps to analyze the potential error happened in past to improve
	LIMS	LIMS manage plan, action, inputs and outputs
	Database	Need for business growth and change analysis
Method	LQM, QP	All should read the laboratory Quality manual and quality procedure which has documented that how all the activities of laboratory will perform
	SOPs	For each activity, SOPs are there, means each activity has been validated to ensure that the process is correct
	Entry	Sample entry in inward register ensures that laboratory has received the sample
	Verification	Physical verification ensures that the sample is fit for analysis

	Codification	Codification ensures that the source of samples is not accessible to chemist to maintain the confidentiality
	Storage	If the sample cannot send to process for the day, it stores under lab-admin in a proper environmental condition
Measurement	Pick-up time	This is the first step of sample analysis, so it is important to record the sample pick-up time
	Receive time	When laboratory received the sample after it picked-up
	Registration time	After received the sample, how much time the sample was under lab-admin custody
	Proper information	All required information to process the sample to be documented
	Environmental conditions	In which condition sample was transported
	Verification record	Once sample received, it should be evaluated if it is fit for analysis
Mother nature		
Material	Register	To do the entry of sample handling record
	Computer	To maintain the information about sample and analysis record. It should be fast to avoid any delay
	Software	Software will do the "Push" system of the documents though out the process cycle, avoid delay due to physical movement of record
	Marker	Proper marker (can be replaced with barcode) for sample code to ensure that during handling the sample code does not got erased. Sample code is the only traceable identification

	Portal	The required information at each step will be pooled to customer portal from where customer can always monitor their sample status (limited information only available)
	Store	If samples needs to be on hold at pre-analytical steps, it should be stored in proper environment and should be easily tracable

CTQ (Critical to Quality)

Sr. No.	CTQ
1	Sample holding time at each step
2	Environmental conditions of sample storage at each step
3	Fitness of sample to process
4	Entry of customer and sample information
5	Sample codification
6	Time taken to send sample to process
7	Sample movement and handling record
8	Job sheet (test request) of each sample

Analytical Hub
Technical Bulletin

SIPOC

Supplier	Input	Process Requirement	Process	Output	Customer Requirement	Customer
Lab Admin	Sample list for the day Test request form	1. Bar code scanning 2. LIMS software	1. Create job sheet as per details in sample register 2. Use Labcode to trace the sample, henceforth 3. Give the sample and job sheet to processing team 4. Retain the sample if cannot give to process today, maintain the document.	Job sheet	1. Sample matrix 2. Test to be performed 3. Due date for report submission	Processing team

Analytical Hub
Technical Bulletin

FMEA

FMEA #:	01/02/2020	**Process Responsibility:**	Shruti	**Core Team:**	Abhijit Bhar
Process Name:	Lab Admin	**Prepared by:**			Karunakara
Affected Products:	Test Report				Thomas
FMEA Key Date:	4.4.2020	**FMEA Origin date:**	4.4.2020		Shruti
		FMEA Rev date:			

Sr. No.	*Process Function*	*Potential Failure Mode*	*Potential Failure Effects (KPOVs)*	*SEV*	*CLASS*	*Potential Causes of Failure (KPIVs)*	*OCC*	*Current Process Controls*	*DET*	*RPN*	*Recommended Actions*	*Responsible Person & Target date*	*Taken Actions*	*SEV*	*OCC*	*DET*	*RPN*
1	Order booking	Delay in order booking	Customer annoyed			No work plan				0							0
2	Sample pick-up	Delay in sample pick-up	Delay in process			Customer was not available				0							0
3						Collection plan was not proper				0							0
4						Collection kit was not ready				0							0
5	Sample information	Incomplete information	Sample rejistration delay			Manual entry, handwriting not clear				0							0
6	Customer information	Incomplete information	Sample rejistration delay			Manual entry, handwriting not clear				0							0
7	Sample transportation	Sample got contamianted	Sample rejection			Sample collected by non-trained person				0							0
						Not follwed the SOP				0							0
						Taken longer time to reach to laboratory				0							0
						env. Condition not verified				0							0

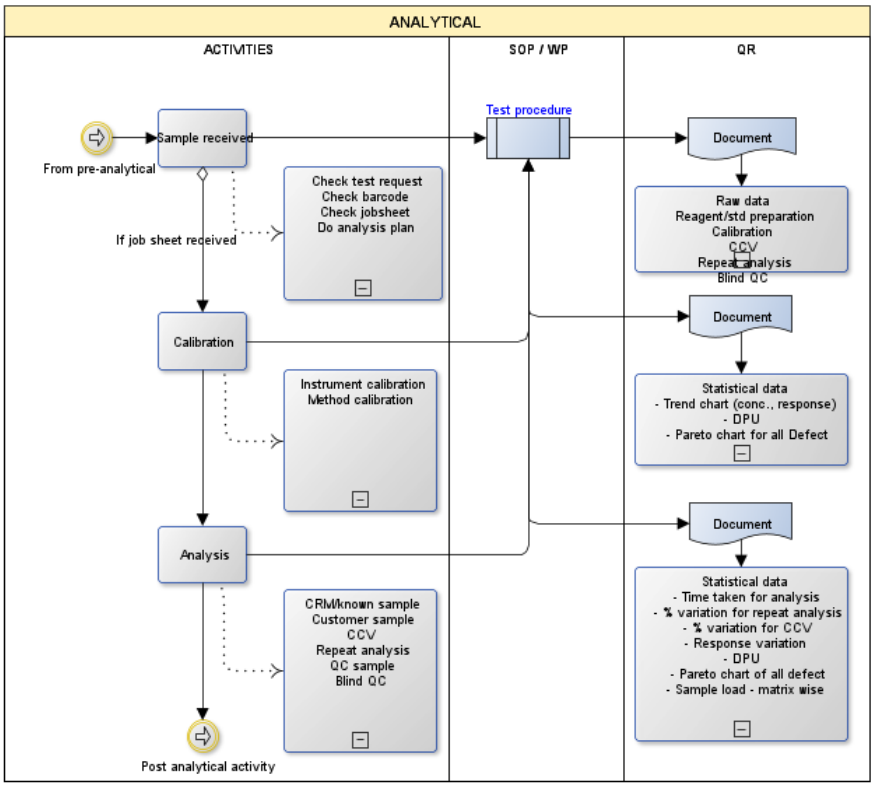
Analytical Hub
Technical Bulletin

Quantitative data of each CTQ:

Sr. No.	CTQ	Discrete data	Continuous data
1	How many incomplete TRF		
2	How many delayed in collection		
3	How many times sample integrity fails during transportation		
4	How many samples failed in physical verification		
5	How many entry has errors in data entry		
6	How many sample registration took times more than 5 minutes		
7	How many samples forwarded to process after 15 minutes from sample receive time		
8	How many samples entry is without date and time		
9	How many incomplete jobsheet issued		
10	How many samples retained but no record available		

Analytical Hub
Technical Bulletin

Flow chart for Processing (Chemistry and Microbiology section)



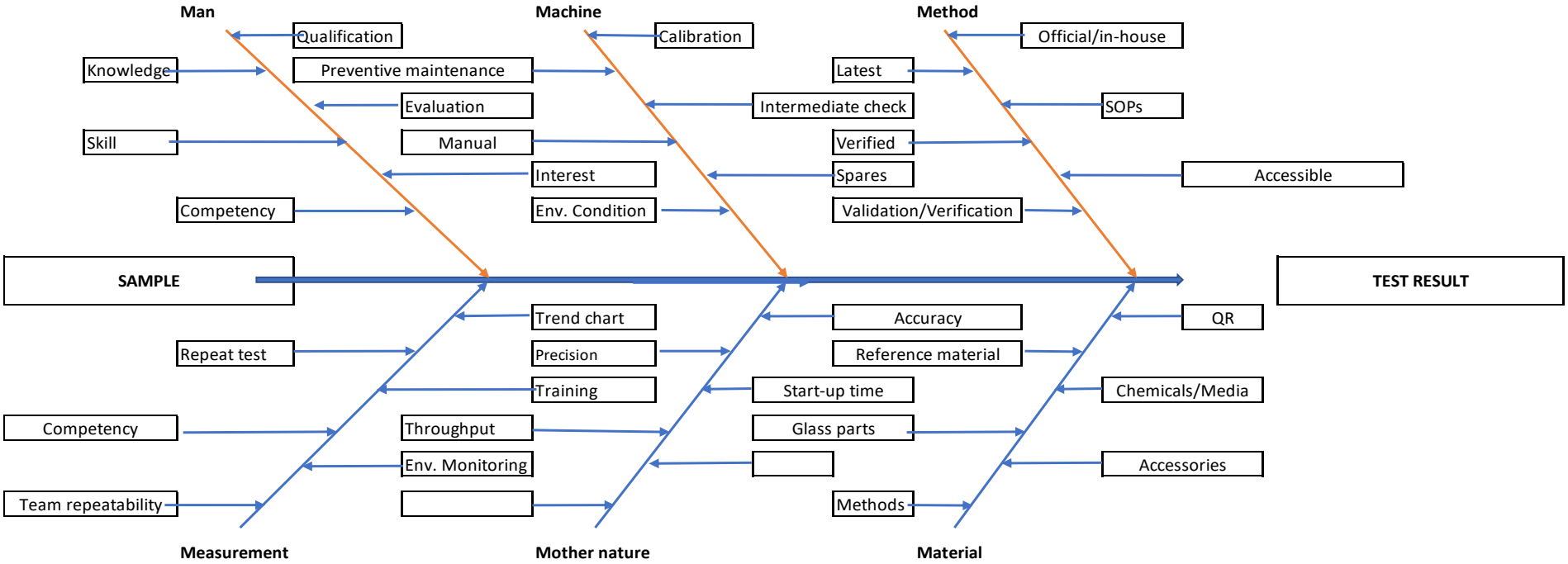
CTP:	**CTQ:**	**Monitor:**
Sample receipt time	Load per staff	Load on staff & instrument
Jobsheet entry and distribution	Calibration record	TAT for analysis – test wise
Work plan	CRM/COA record	CCV trend chart
Readiness for analysis	Quality Control record	Repeat analysis variation
	Analysis TAT	DPU
		Instrument response variation
		Sample load – test wise
		Variation of QC blind sample
		Variation of retained sample analysis
		Positive & negative control

Issue No.: 25-26-01; Abhijit.bhar@outlook.com; Mobile/whatsap: +91 9867423453

Analytical Hub
Technical Bulletin

Fish-bone (Ishikawa diagram)

Processing - Chemistry & Microbiology



Analytical Hub
Technical Bulletin

Factors extracted from Fish-bone:

Factors	CTP	Notes
Man	Qualification	The chemist / microbiologist should have minimum qualification for the respective activities
	Knowledge	Along with qualification, basic knowledge is needed and time to time updating of knowledge and information needed
	Evaluation	Periodical evaluation needed to ensure that skill and competency is up to the mark
	Skill	With time skill improves or reduce, due to several physical and medical reasons
	Interest	Person should have interest for the respective work
	Competency	Competency improves after periodical training
Machine	Calibration	Periodical calibration of instruments ensures that machine is fit for the intended purposes
	Preventive maintenance	To keep the instrument working, periodical and planned maintenance is must. It reduce the chances of sudden break-down
	Intermediate check	Intermediate check periodically as per plan helps to understand the instrument condition
	Manual	Operation manual needs to accessible by the users as lots of information on trouble shooting are available to solve small issues
	Spares	Some major spares need to maintain in stock to avoid any delay to resolve major break-down
	Env. condition	Temperature, humidity and effective partition needs as per the working principle of different equipment
Method	Official/in-house	The method adopted should be official methods or can be in-house developed method (evaluated and verified)
	Latest	All the method should be latest as time to time method changes as per requirement of regulatory bodies

	Verify	Each method needs to be verified to ensure that laboratory environment and facilities can repeat the same as per guide line
	SOPs	SOPs for each method helps to perform analysis referring it, as most of the methods elaborates each steps which may not needed for continuous analysis for a long time. That time only need to follow the steps
	Validation/verification	Official methods needs to verify after a periodic interval as different related factors may change over time (e.g., instrument sensitivity reduces, user changed permanently, major part of instrument changed which have direct or indirect impact on output)
	Accessible	All controlled copies of methods should be accessible to the users
Measurement	Trend chart	Trend chart of instrument response, consumption of chemicals/test, spares, consumables, etc. helps to identify the cause of errors easily
	Repeat test	Periodical repeat test ensures that obtained result is valid. It can be done by different ways (e.g., same test two times, same test by different persons, pooled the retained sample which already analyzed earlier, analysis on CRM after each 10 test, spiked sample, etc)
	Training	Monitoring the activities and identify the training helps to improve the quality of work as a whole
	Competency	Periodical check the competency helps to ensure that the person performing the test is competent (specially after a long break due to medical or natural calamities)
	Team repeatability	Team repeatability ensures that the test allotted to different person will produce the results within an acceptable tolerance
	Env. condition	Temperature, humidity at different stage of test have direct or indirect impact. Ensure there is no cross contamination

Mother nature	Accuracy	Accuracy depends on multiple factors which may not be avoided at particular time (e.g. method bias, matrix interferences, etc.)
	Precision	Precision depends on multiple factors which may not be avoided at particular time (e.g. electronic noise)
	Start-up time	Different instruments takes different warm-up time and the test plan to be done considering this delay
	Throughput	Throughput is technology dependent and unavoidable
Material	QR	Proper controlled format to maintain record ensures traceability
	Reference material	Ensure the authenticity of result
	Chemical/media	Shelf life and quality have direct impact on test
	Glass parts	Which are using for measurement, needs to be "A" class or calibrated in case of class "B"
	Accessories	Availability of different accessories have direct impact on analysis throughput
	Methods	Test methods needs to be accessible to the users

CTQ (Critical to Quality)

Sr. No.	CTQ
1	Qualification of personnel
2	Experience of personnel
3	Knowledge of personnel
4	Competency of personnel
5	Training and evaluation
6	Individual repeatability
7	Team repeatability
8	Trend chart of CCV, response, consumption
9	Validation/verification of method
10	Updated external document

11	Shelf life of reagents, media plate
12	Instrument performance
13	Environmental conditions
14	Effective partition in work area
15	Access to internet
16	Certified Reference Material

Analytical Hub
Technical Bulletin

SIPOC

Supplier	Input	Process Requirement	Process	Output	Customer Requirement	Customer
Processing team	Job sheet with sample	1. Job sheet and sample received 2. Job sheet entry 3. Job distribution	1. Job sheet and sample received before 10:00am 2. Job sheet entered in register 3. Job equally distributed	Work plan	1.	Processing team members
Processing team members	Work plan with job sheet and sample	1. Instrument 2. Chemicals & reagents 3. Glass parts 4. Accessories 5. CRM/RM 6. Methods	1. Check instrument performance 2. Ensure preventive maintenance done. 3. Ensure CRM available 4. Ensure COA available 5. Ensure all glass parts are calibrated 6. Perform analysis 7. Perform analysis of one known sample every after 10 samples 8. Ensure to update data in trend chart 9. Ensure raw data updated	Analysis result. Trend chart. Consumption record.	1. Error free result. 2. Supporting raw data and record 3. Records including instrument record, calculation record	QC

			10. Ensure sample analyzed as per TAT			

FMEA (Chemical)

	FMEA #:	2020-1	**Process Responsibility:**	Dr. Karunakara							**Core Team:**	Abhijit Bhar						
	Process Name:	Processing-Chemistry	**Prepared by:**									Karunakara						
	Affected Products:	Test Report										Nirmala, Kavya						
	FMEA Key Date:	4.4.2020	**FMEA Origin date:**	4.4.2020								Jacob, Ullas						
			FMEA Rev date:															

Sr. No.	*Process Function*	*Potential Failure Mode*	*Potential Failure Effects (KPOVs)*	*SEV*	*CLASS*	*Potential Causes of Failure (KPIVs)*	*OCC*	*Current Process Controls*	*DET*	*RPN*	*Recommended Actions*	*Responsible Person & Target date*	*Taken Actions*	*SEV*	*OCC*	*DET*	*RPN*
1	Jobsheet/sample received	Sample not sufficient	Result cannot be generated			Physical verification not done				0							0
2		Received late	Delay in analysis			Delay from lab-admin				0							0
3	Chemicals/reagents	Delay in reagent preparation	Delay in analysis			No forecast from lab-admin				0							0
4		Not available	Delay in analysis			Stock not updated				0							0
5						Delay in procurement				0							0
6		Reagent not proper	Delay in analysis			COA not available				0							0
7						Critical testing not done				0							0
8						Glass part not calibrated				0							0
9						Instrument not calibrated				0							0
10						Traning not proper				0							0
11	Instruments	Not working properly	Wrong result			Calibration not done				0							0
12						Preventive maintenance not done				0							0
13						Intermediate testing not done				0							0
14						Service contract not given				0							0
15	Analysis	Wrong analysis	Wrong result			Not trained properly				0							0
16						Verification not done				0							0
17						Competency not established				0							0
18	Quality Control	QC failed	Repeat analysis			QC blind failed				0							0
19						Repeat analysis not within tolerance				0							0
20						Recovery of spiked sample not within tolerance				0							0
21						Retained sample analysis report not within tolerance				0							0
22						CCV trend chart out of limit				0							0

Analytical Hub
Technical Bulletin

Quantitative data of each CTQ:

Sr. No.	CTQ	Discrete data	Continuous data
1	Number of sample rejected from process		
2	Number of sample received 15 minutes after inward time		
3	Number of days process did not receive forecast		
4	Number of repeat analysis due to problem with reagent		
5	Number instrument for which calibration date expired		
6	No. of training conducted per person		
7	No. of training conducted against which has no improvement observed		
8	Instrument preventive maintenance record available (Y.N)		
9	Intermediate testing record available (Y/N)		
10	No. of instrument without service contract		
11	No. of records without verification		
12	No. of test failed in QC		
13	No. of repeat test not within acceptable tolerance		
14	No. of days where value out of the control limit in trend chart		

Analytical Hub
Technical Bulletin

FMEA #:	2020-1	**Process Responsibility:**	Miss. Aindrila	**Core Team:**	Abhijit Bhar
Process Name:	Processing-Microbiology	**Prepared by:**			Karunakara
Affected Products:	Test Report				Aindrila
FMEA Key Date:	4.4.2020	**FMEA Origin date:**	4.4.2020		
		FMEA Rev date:			

Sr. No.	*Process Function*	*Potential Failure Mode*	*Potential Failure Effects (KPOVs)*	*SEV*	*CLASS*	*Potential Causes of Failure (KPIVs)*	*OCC*	*Current Process Controls*	*DET*	*RPN*	*Recommended Actions*	*Responsible Person & Target date*	*Taken Actions*	*SEV*	*OCC*	*DET*	*RPN*
1	Jobsheet/sample received	Sample not sufficient	Result cannot be generated			Physical verification not done				0							0
2		Received late	Delay in analysis			Delay from lab-admin				0							0
3	Media	Delay in media preparation	Delay in analysis			No forecast from lab-admin				0							0
4		Not available	Delay in analysis			Stock not updated				0							0
5						Delay in procurement				0							0
6		Media not proper	Delay in analysis			COA not available				0							0
7						Critical testing not done				0							0
8						Glass part not calibrated				0							0
9						Instrument not calibrated				0							0
10						Traning not proper				0							0
11	Instruments	Not working properly	Wrong result			Calibration not done				0							0
12						Preventive maintenance not done				0							0
13						Intermediate testing not done				0							0
14						Service contract not given				0							0
15	Analysis	Wrong analysis	Wrong result			Not trained properly				0							0
16						Verification not done				0							0
17						Competency not established				0							0
18	Quality Control	QC failed	Repeat analysis			QC blind failed				0							0
19						Repeat analysis not within tolerance				0							0
20						Recovery of spiked sample not within tolerance				0							0
21						Retained sample analysis report not within tolerance				0							0
22						CCV trend chart out of limit				0							0
23		No growth of positive control	Repeat analysis			Media not proper				0							0
24						Culture not proper				0							0
25		Negative control have presence of mcirobes	Repeat analysis			Sterilization not proper				0							0
26						Cross contamination during process				0							0
27						Environment not clean				0							0

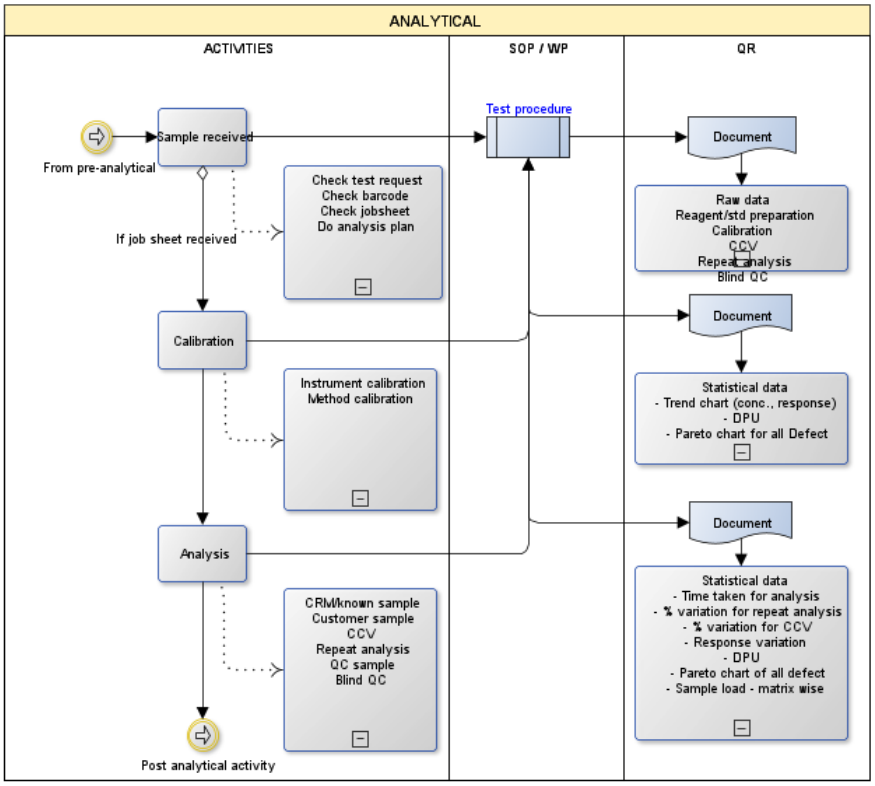
Analytical Hub
Technical Bulletin

Quantitative data of each CTQ:

Sr. No.	CTQ	Discrete data	Continuous data
1	Number of sample rejected from process		
2	Number of sample received 15 minutes after inward time		
3	Number of days process did not receive forecast		
4	Number of repeat analysis due to problem with media		
5	Number instrument for which calibration date expired		
6	No. of training conducted per person		
7	No. of training conducted against which has no improvement observed		
8	Instrument preventive maintenance record available (Y/N)		
9	Intermediate testing record available (Y/N)		
10	No. of instrument without service contract		
11	No. of records without verification		
12	No. of test failed in QC		
13	No. of repeat test not within acceptable tolerance		
14	No. of days where value out of the control limit in trend chart		
15	No. of record not available for sterilization cycle		
16	Positive control sample analyzed with each batch (Y/N)		

17	Negative control sample analyzed with each batch (Y/N)		
18	Work place environment monitoring perform for each batch (Y/N)		

Flow chart for Quality Control (QA & QC section)

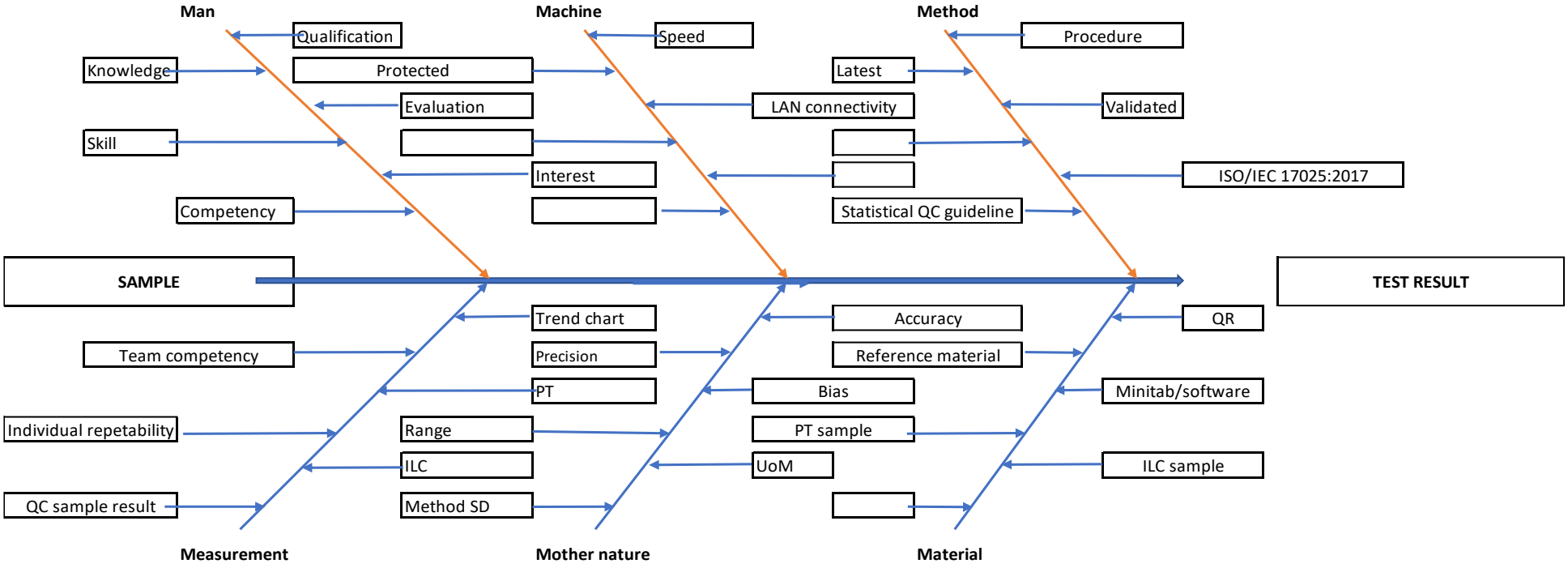


CTP:	**CTQ:**	**Monitor:**
- Quality control plan - Method evaluation - Instrument performance - Chemist/microbiologist evaluation - Using CRM	- Implementation of plan - Evaluation the result - Participation in ILC and PT - Instrument maintenance - Evaluation and training of chemist/microbiologist - Shelf life of CRM - Preparation of standard sample - Set the control limit and warning limit for trend chart from at least 30 data points	- QC activities as per plan - "Z" score of ILC & PT - Training record - Performance with QC sample - Individual repeatability - Team repeatability - Deviation from actual value - Instrument response trend against a known sample for sufficient time period

Analytical Hub
Technical Bulletin

Fish-bone (Ishikawa diagram)

QA & QC



Analytical Hub
Technical Bulletin

Factors extracted from Fish-bone:

Factors	CTP	Notes
Man	Qualification	The QA person should at least B.Sc. in any stream
	Knowledge	Should have enough knowledge about all the test performed, ISO/IEC 17025;2017, basic about statistics
	Evaluation	Periodical evaluation needed to ensure that skill and competency is up to the mark
	Skill	With time skill improves or reduce, due to several physical and medical reasons
	Interest	Person should have interest for the respective work
	Competency	Competency improves after periodical training
Machine	Speed	The computer should have enough speed to handle big data base
	Protected	The computer should be pass word protected to avoid access by unauthorised person
	LAN connectivity	The computer should be connected to LAN for data pooling from instruments which support LAN
Method	Procedure	The written procedure to perform QC activities helps to plan the schedules of multiple activities
	Latest	The procedure and other external reference documents should be latest
	Validated	The QC parameters should be validated before taking into consideration
	ISO/IEC 17025:2017	The copy should be accessible and to be referred time to time to ensure that QC activities covered all required clauses
	Statistical QC guide line	To analyze the trend chart, need to refer the guide line
	LQM, QP, SOPs	Ensure that Laboratory quality manuals, procedures and SOPs referred and followed in entire process

Measurement	Trend chart	Trend chart of instrument response, consumption of chemicals/test, spares, consumables, etc. helps to identify the cause of errors easily
	Team competency	Ensure that there is always back-up for all activities
	Individual repeatability	Individual evaluation after regular interval for continual improvement
	ILC "Z" score	Help to identify the current performance and scope of improvement, ensure the quality
	PT "Z" score	Help to identify the current performance and scope of improvement, ensure the quality
	QC sample results	Help to identify the current performance and scope of improvement, ensure the quality
Mother nature	Accuracy	Current process capability to maintain and find out the area to improve further
	Precision	Current process capability to maintain and find out the area to improve further
	Bias	The current method may have Bias during validation. Time to time monitor the bias if increased, if there is any opportunity to reduce/eliminate the bias
	Range	The range of acceptable deviation based on standard deviation obtained during validation/verification and subsequently pooled day by day
	UoM	Estimated UoM during verification
	Method SD	Use to decide the control limit and warning limit for trend chart
Material	QR	Proper controlled format to maintain record ensures traceability
	Reference material	To prepare QC sample
	Minitab/Statistical software	Need to calculate the histogram, ANOVA, etc.
	PT sample	To evaluate the current performance
	ILC sample	To evaluate the current performance

Analytical Hub
Technical Bulletin

CTQ (Critical to Quality)

Sr. No.	CTQ
1	Qualification of personnel
2	Experience of personnel
3	Knowledge of personnel
4	Tools using for statistical analysis
5	SOP for Quality control and quality assurance
6	Reference books, guidelines
7	Quality control plan
8	Method validation/verification record
9	CRM
10	Trend chart
11	Repeat analysis record
12	Repeat analysis of retained sample record
13	Spiked sample analysis record
14	Team repeatability record
15	PT record
16	ILC record
17	Instrument calibration record
18	Training record

Analytical Hub
Technical Bulletin

SIPOC

Supplier	Input	Process Requirement	Process	Output	Customer Requirement	Customer
QC	1. Blind QC 2. Intermediate sample 3. Retest request 4. Retained sample for analysis 5. ILC sample 6. PT sample	1. QC sample 2. CRM 3. Retained sample	1. Give QC sample as unknown 2. Give CRM for intermediate testing 3. Give one sample for repeat analysis Give one retained sample as unknown to process	1. Analysis result of QC sample 2. Analysis result of CRM 3. Analysis result of retained sample 4. Analysis result of a sample in duplicate	1. Result of QC sample within ± 10% of actual value. 2. Result of CRM sample within ± 10% of actual value. 3. Result of retained sample analysis within ± 10% deviation with earlier result. 4. Result within ± 10% deviation.	QC
QC	Analysis result	Raw data obtained from analysis. Approval from authority.	1. Check all data and verify if result within acceptable range. 2. Approve to prepare report. 3. Check the CCV trend chart, if not within range, send sample back to process for repeat analysis. 4. Check blind QC report, if not satisfied, do RCA. Sample to be reprocessed. 5. Check intermediate report, if not satisfied, verification needed. Stop analysis and	Final value in job sheet to lab-admin to prepare report	All parameters of QC activities to be satisfied to release report.	Lab-Admin

			resolve the problem. Inform lab-admin about the delay of reporting. 6. Check repeat analysis report, if not satisfied, do RCA. Reprocess of sample needed. 7. Check report of analysis of retained sample. If not satisfied, do RCA, hold the report.			

FMEA (QC)

FMEA #:	2020-0-1	**Process Responsibility:**	Dr. Karunakara	**Core Team:**	Abhijit Bhar
Process Name:	QA/QC	**Prepared by:**			Karunakara
Affected Products:	Test Report				
FMEA Key Date:	4.4.2020	**FMEA Origin date:**	4.4.2020		
		FMEA Rev date:			

Sr. No.	*Process Function*	*Potential Failure Mode*	*Potential Failure Effects (KPOVs)*	*SEV*	*CLASS*	*Potential Causes of Failure (KPIVs)*	*OCC*	*Current Process Controls*	*DET*	*RPN*	*Recommended Actions*	*Responsible Person & Target date*	*Taken Actions*	*SEV*	*OCC*	*DET*	*RPN*
1	Sample registration	Cancellation	Request to customer for fresh sample			Refer FMEA for Labadmin				0							0
2	Sample coding	Delay	Process delay			Refer FMEA for Labadmin				0							0
3	Processing	Delay	Delay in reporting			Refer FMEA for process				0							0
4	Repeat test	Variation out of limit	Delay in reporting			Chemist competency				0							0
5	Repeat analysis of retained sample	Variation out of limit	Authenticity of result issuing			Sample integrity				0							0
6						Chemist competency				0							0
7						Instrument not proper				0							0
8						Method changed and not validated before using				0							0
9	QC sample analysis	Variation out of limit	Authenticity of result issuing			Chemist competency				0							0
10						QC sample not proper				0							0
11						Instrument not proper				0							0
12	Team repeatability	Variation out of limit	Authenticity of result issuing			Chemist competency				0							0
13						Sample integrity				0							0
14	ILC	"Z" score	Authenticity of result issuing			Method not evaluated				0							0
15						Chemist competency				0							0
16						Instrument not proper				0							0
17	PT	"Z" score	Authenticity of result issuing			Method not evaluated				0							0
18						Chemist competency				0							0
19						Instrument not proper				0							0

Analytical Hub
Technical Bulletin

Quantitative data of each CTQ:

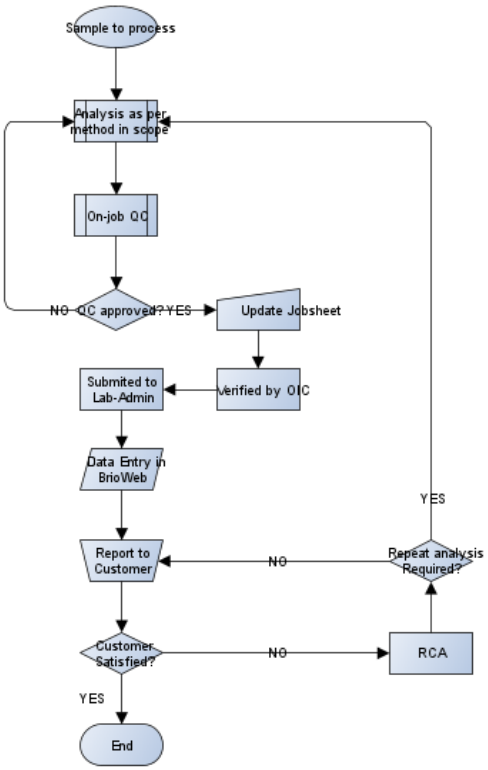
Sr. No.	CTQ	Discrete data	Continuous data
1	Number of sample cancelled/month		
2	Number of sample delayed to issue/month		
3	No. of sample delayed to report/month		
4	No. of repeat analysis conducted per month		
5	No. of repeat test out of limit/month		
6	No. of test for retained sample analyzed per month		
7	No. of repeat test for retained sample out of limit/month		
8	No. of test failed during team repeatability check/month		
9	"Z" score of test out of limit/ILC		
10	"Z" score of test out of limit/PT		
11	ILC participated per month		
12	PT participated per month		
13	No. of Error in TRF Vs. total TRF		
14	No. of report with error per month		

Analytical Hub
Technical Bulletin

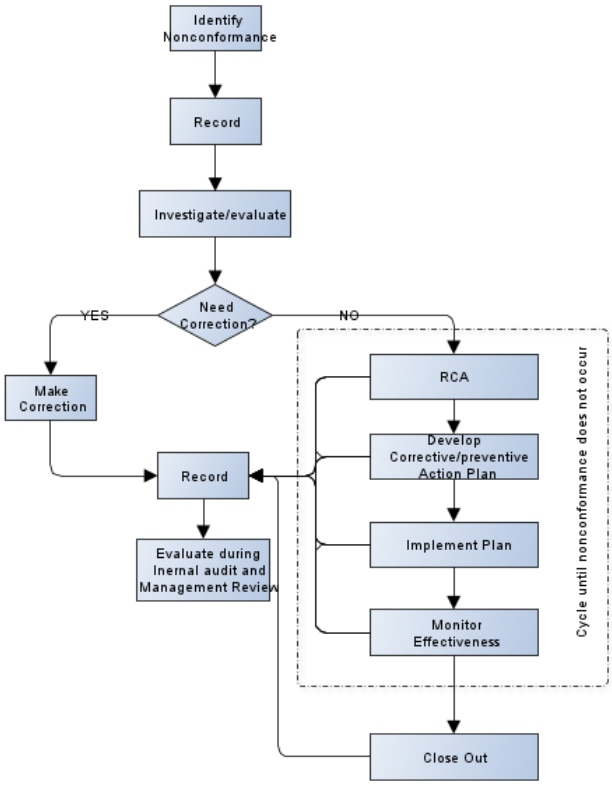
Ranking guide for FMEA

Ranking		Degree of Severity	Chances of occurrence	Detection Ability
10		May expose to loss, harm or major disruption - failure will occur without warning; government regulations violation	Very High: Failure is almost inevitable, more than one per day or >= 1 in 2	Almost impossible: No known control available to detect failure mode
9		May expose client loss, harm or major disruption - failure will occur with warning; government regulations violation	Very High: Failure is almost inevitable, once every 3-4 days or 1 in 3	Very remote: Very remote likelihood current controls will detect failure mode
8		Major disruption of service involving client interaction, resulting in either associte re-work or inconvenience to client, but without negative impact on safety or government regulations	High: Generally associted with processes similar to previous processes that have often failed, once every week or 1 in 8	Remote: Remote likelihood current controls will detect failure mode
7		Minor disruption of service involving client interaction, resulting in either associate re-work or inconvenience to clients	High: Generally associted with processes similar to previous processes that have often failed, once every month or 1 in 20	Very low: Very low likelihood current controls will detect failure mode
6		Major disruption of service not involving client interaction and resulting in either associate re-work or inconvenience to clients	Moderate: Generally associated with processes similar to previous processes which have experienced occational failures, but not in major proportions, once in every 3 months of 1 in 80	Low: Low likelihood current controls will detect failure mode
5		Minor disruption of service not involving client interaction and resulting in either associate re-work or inconvenience to clients	Moderate: Generally associated with processes similar to previous processes which have experienced occational failures, but not in major proportions, once in every 6 months of 1 in 400	Moderate: Moderate likelihood current controls will detect failure mode
4		Minor disruption of service involving client interaction that does not result in either associate re-work or inconvenience to clients	Moderate: Generally associated with processes similar to previous processes which have experienced occational failures, but not in major proportions, once a year or of 1 in 800	Moderately high: Moderately high likelihood current controls will detect failure mode
3		Minor disruption of service not involving client interaction and does not result in either associate re-work or inconvenience to clients	Low: Isolated failures associated with similar processes, once every 1 - 3 years or 1 in 1500	High: High likelihood current controls will detect failure mode
2		No disruption of service by the client in any capacity and does not result in either associate re-work or inconvenience to client	Low: Isolated failures associated with similar processes, once every 3 - 6 years or 1 in 3000	Veru high: Very high likelihood current controls will detect failure mode
1		No Effect	Low: Isolated failures associated with similar processes, once every 7+ years or 1 in 6000	Alomost certain: Current controls almost certain to detect the failure mode. Reliable detection controls are known with similar processes

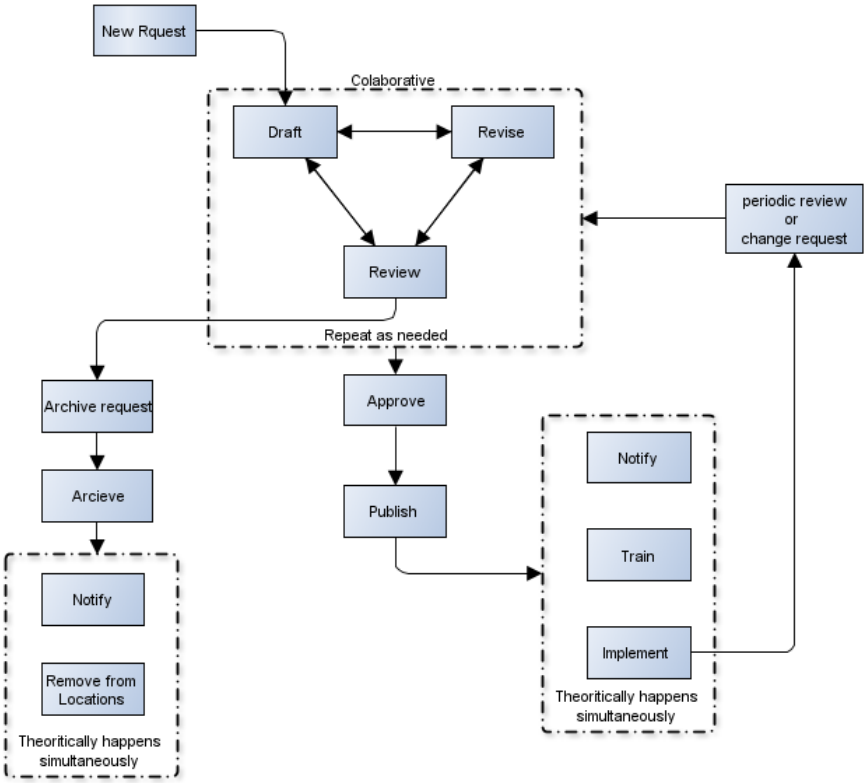
Report Release (Lab Admin Section)



Corrective action (QA & QC Department)

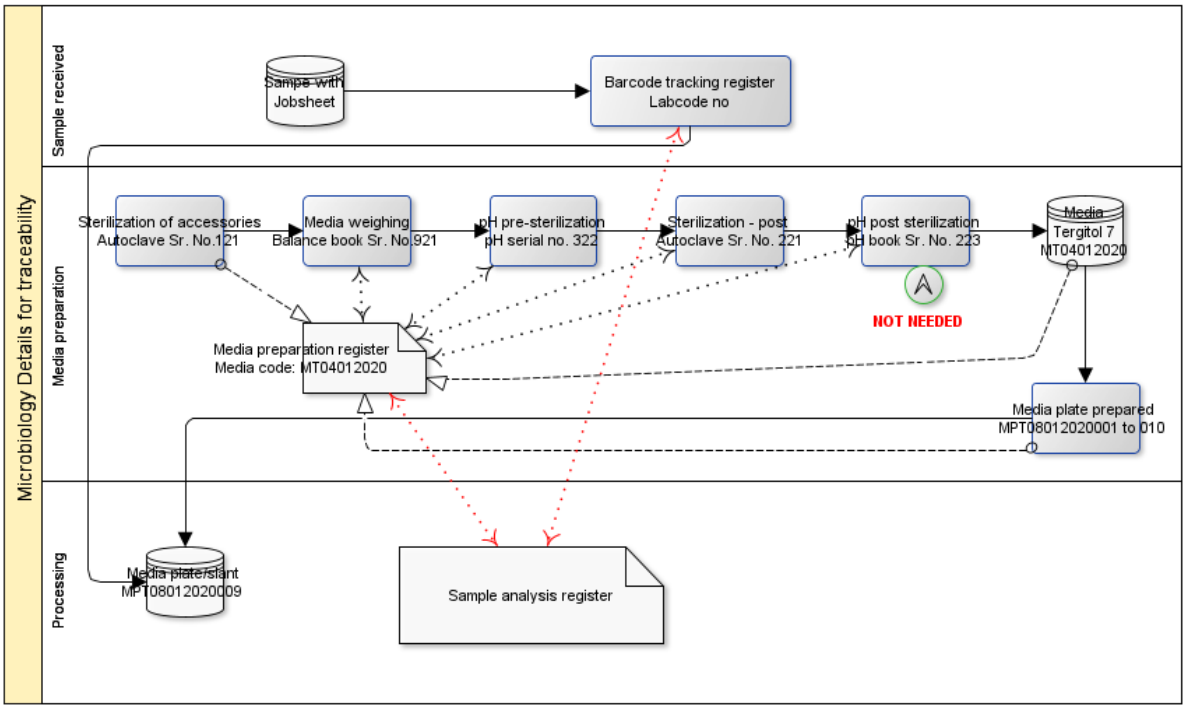


Document Control (All section)



Analytical Hub
Technical Bulletin

Traceability (Example with Microbiology section)



Please note, all above explanations are example only. You have to identify the CTP and CTQ of your organization yourself. Activity of each organization with similar works are different, and so the CTP and CTQ.

But 6M are common for any activities; if it is your personal or professional activities. For any thing we do, these 6Ms' should be the prime focus to find out the area of risk.

This document is only for the freshers and not for the champions. I have made this on the basis of problems I have faced in my carrier, and realization after recalled those failure and success for shelf evaluation.

All of the charts, data and materials enclosed are solely prepared by me time to time during practicing to learn the SQC.