

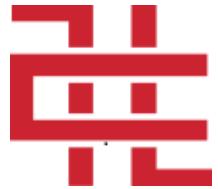


Chemo Test Laboratory

**commitment * consistency *credibility*



Pawane, Navi Mumbai



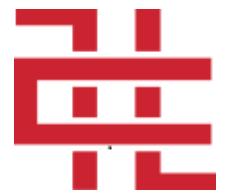
Introduction

- Government approved Public Testing Laboratory
- *Established in 1984*
- *Located at –*

Sewri – Mumbai

Pawane – Navi Mumbai

- *Chemical and Microbiological testing of Pharmaceutical, Chemicals, Drugs, Cosmetics, Herbal, Ayurvedic, Food & Agricultural product.*



Accreditations / Certifications



Food & Drug
Administration



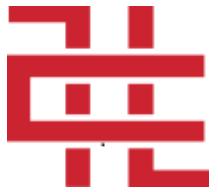
ISO/IEC 17025
NABL, India



ISO 9001
UNICERT, Germany



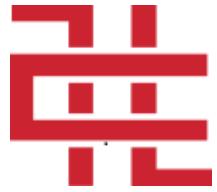
USFDA - REGISTERED
FEI – 3020879673
DUNS- 85-424-7369



Approvals

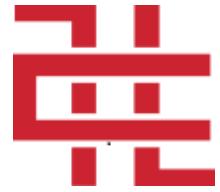
Approved testing facility in India for –

- *NAFDAC – Govt. of Nigeria*
- *Ministry of Health – Govt. of Mozambique*
- *Survieors France*
- *Govt. of Ukraine*
- *Govt. of The Gambia*



The Chemotest Way

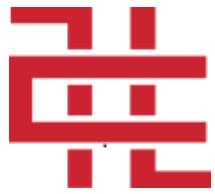
- *We at Chemo Test Laboratory are committed to serve the industry and the humanity at large.*
- *We are also committed to deliver authentic results and shall remain true to the professional ethics & law of the land.*
- *We follow the principle of 3C's :*
 - *C - Commitment*
 - *C - Consistency*
 - *C – Credibility*



The Chemotest Way

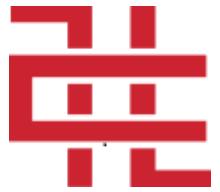
- *We are also committed :*

- *To constantly upgrade our skill & knowledge and managerial abilities to improve the quality of work.*
- *To follow verified & well documented procedures for analysis.*
- *To maintain valid records and documents for corroboration of the results.*
- *To maintain & implement Quality Management System as per ISO 9001:2015 & ISO 17025:2017.*
- *To maintain highest degree of confidentiality & impartiality.*



Services Offered

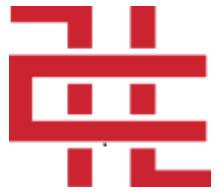
- *Pharmaceutical Testing*
- *Cosmetics Testing*
- *Food, Water & Agriculture Testing*
- *Herbal / Ayurvedic products Testing*
- *Impurity Profiling by LCMS-MS/GCMS-MS/ICPMS/ICPOES*
- *Analytical Method Development and Validation as per USFDA/ICH/WHO guidelines*
- *Stability Studies (Storage and/or Analysis as per ICH Guidelines)*
- *Elemental analysis by ICPMS/ICPOES/AAS*
- *Nitrosamine testing*
- *EG and DEG analysis*
- *Physical Inspection and Survey*
- *Sampling, Sealing and Container Stuffing*
- *Cleaning validation for Chemical/Antibiotic/Penicillin traces*
- *Cleaning validation for Microbial Contamination (Onsite Area validation)*
- *Microbial culture identification up to species level*
- *Sterility test*
- *Bacterial Endotoxin test*
- *Preservative Efficacy test*
- *Disinfectant efficacy test*
- *Antibiotic /Vitamin Assay (Microbiological)*
- *Pesticide residue/Aflatoxins*



Laboratory set up

Ground floor

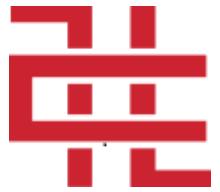
- *Changing room 1*
- *Changing room 2*
- *Reception area*
- *Conference room*
- *Stability room*
- *Server room*
- *Control Sample room*
- *Chemical Storage room*
- *Store room*
- *Sample receiving room*
- *Instrument room 1 – ICPOES/AAS room*
- *Instrument room 6 - ICPMS room*
- *Microbiology and Sterility section*



Laboratory set up

Microbiology and Sterility section

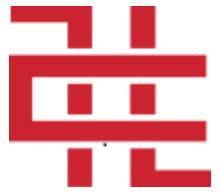
- *Sample receiving area*
- *Media preparation room*
- *Washing area*
- *Incubator room*
- *Autoclave room*
- *MLT room 1*
- *MLT room 2*
- *Assay room*
- *PST Culture room*
- *Sterility section*
- *Wide passage 1*
- *Wide passage 2*
- *Air lock 1 to 11*
- *Separate AHUs for each section*



Laboratory set up

First floor

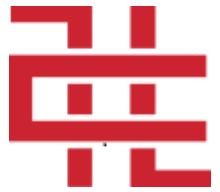
- *Instrument room 2 – Chemical instrument room*
- *Instrument room 3 – HPLC room*
- *Instrument room 4 – GC room*
- *Instrument room 5 – LCMS room*
- *Instrument room 7 – Dissolution room*
- *Instrument room 8 – IR/PS/PM room*
- *Wet lab*
- *Washing area*
- *Balance room*
- *Preparation room 1*
- *Preparation room 2*



Laboratory set up

Second floor

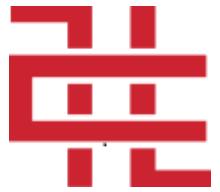
- *Cabin 1 – Dr. Atul Pusalkar*
- *Cabin 2 – Dr. Borna Basu*
- *Admin office*
- *QA department*
- *HR department*
- *Documentation room*
- *Accounts department*



Laboratory set up

Third floor

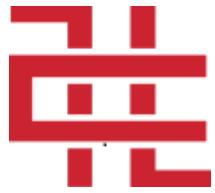
- *Water Purification system*
- *AHUs*
- *Canteen area*



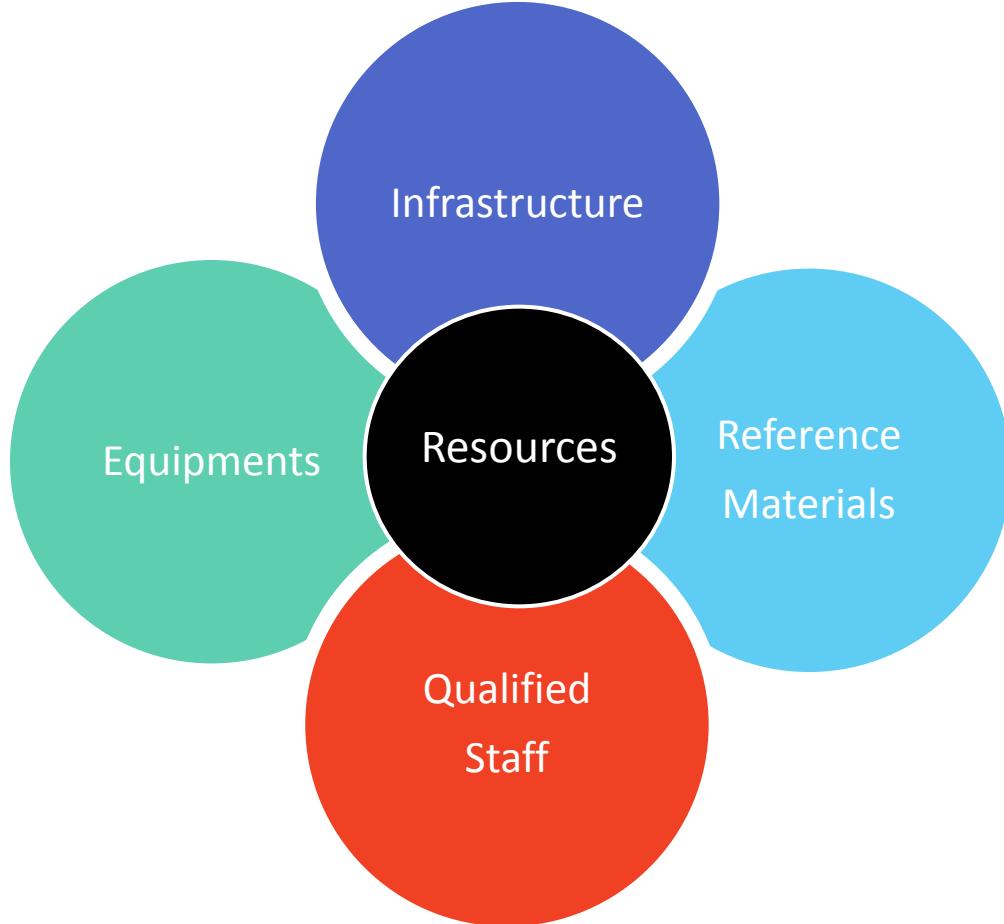
Laboratory set up

Ground floor – Outside area

- *UPS power backup room*
- *DG Generator*
- *ETP plant with Zero Liquid Discharge*
- *Electric board panels (MSEB)*
- *Fire and Municipality underground water tanks*
- *Security cabin*
- *Assembly area*



Resources



Infrastructure

Testing facility with appropriate area
Section wise segregated
Controlled environment and access
Separate AHU for each activity and air lock
Unidirectional man and material flow in microbiology department

Reference Materials

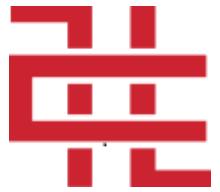
CRM, SRM, Primary standards, Impurities of National and International specifications (IP, BP, USP....), Cultures from Microbiologics, USA.

Qualified Staff

FDA and NABL approved Qualified testing staff,
Professional Managerial & Administrative staff

Equipments

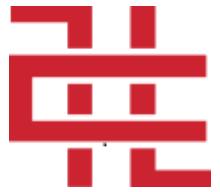
HPLC, GC, GCMSMS,
LCMSMS, ICPOES, ICPMS, AAS, UV-Vis, Spec, Particle size, analyzer,
FTIR/ATR, Ion, Chromatograph, Dissolution app, Biosafety,
Laminar Air Flow, Air Handling Unit, Stability Chambers etc



Sample & Report Flow

Sample Entry

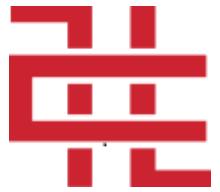
- *Sample receipt – Sample Inward, Physical condition verification, Feasibility check (4M)*
- *COA (Certificate of Analysis) Allocation – Entry of sample in software, COA No. allotment, protocol sheet generation*
- *Segregation of samples – Samples are segregated as samples for analysis and control sample. If control sample is not available, remnant sample is stored as control*
- *Transfer of samples to department: Department wise segregation of samples, sample distribution to analyst*



Sample & Report Flow

Sample Analysis

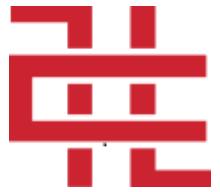
- *Tests of the sample are allocated to the analyst as per their analyst validation and qualification*
- *Method of analysis is reviewed by the HOD (Head of the department) and handed over to the analyst*
- *Tests as per the protocol sheet is performed*
- *Entry of the activity performed is made in the respective logbooks*
- *Raw data along with chromatograms, weight prints, validated excel sheets and relevant traceable records is attached to the protocol sheet*
- *Attached raw data is checked by the HOD for any discrepancy*



Sample & Report Flow

Data Review

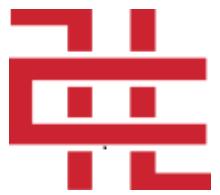
- *Data Review is done by QA reviewer*
- *A data review checklist is filled at each stage*
- *Appropriateness of method used for analysis is checked*
- *Method and database sequence is verified*
- *Validity of the equipment used is checked*
- *Validity of cultures/standards/media/reagents is checked*
- *Validated excel sheet is checked*
- *All the parameters performed are checked for their appropriateness and accuracy*



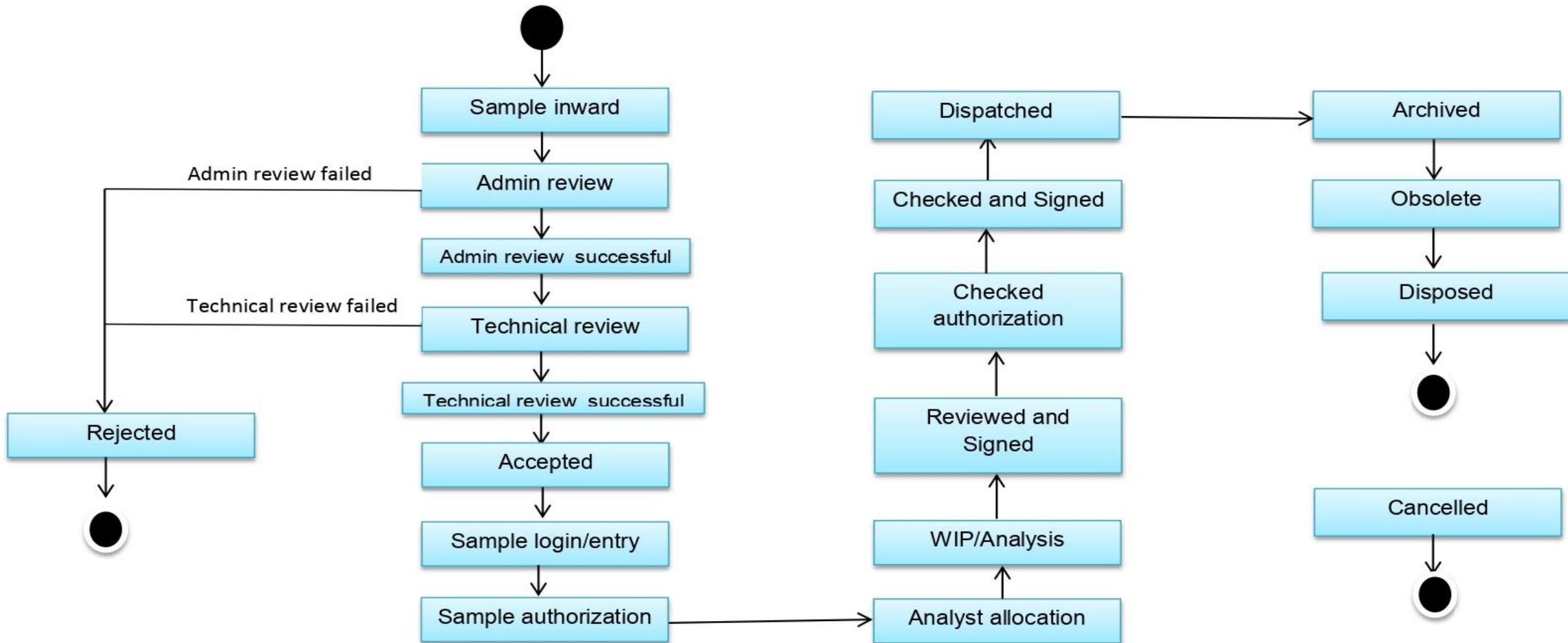
Sample & Report Flow

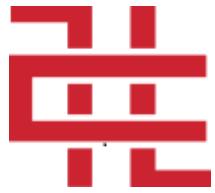
Report Authorization

- *QA Reviewer is responsible for authorization of report*
- *These personnel are FDA approved and NABL authorized staff*
- *A checklist issued to QA reviewer includes all the parameters for completion, accuracy, traceability and data integrity of analysis*
- *Only after satisfactory evaluation of the parameters listed the report is authorized by the authorized personnel*
- *A QR code is also available on the COA copy by which the customers can directly access their data*

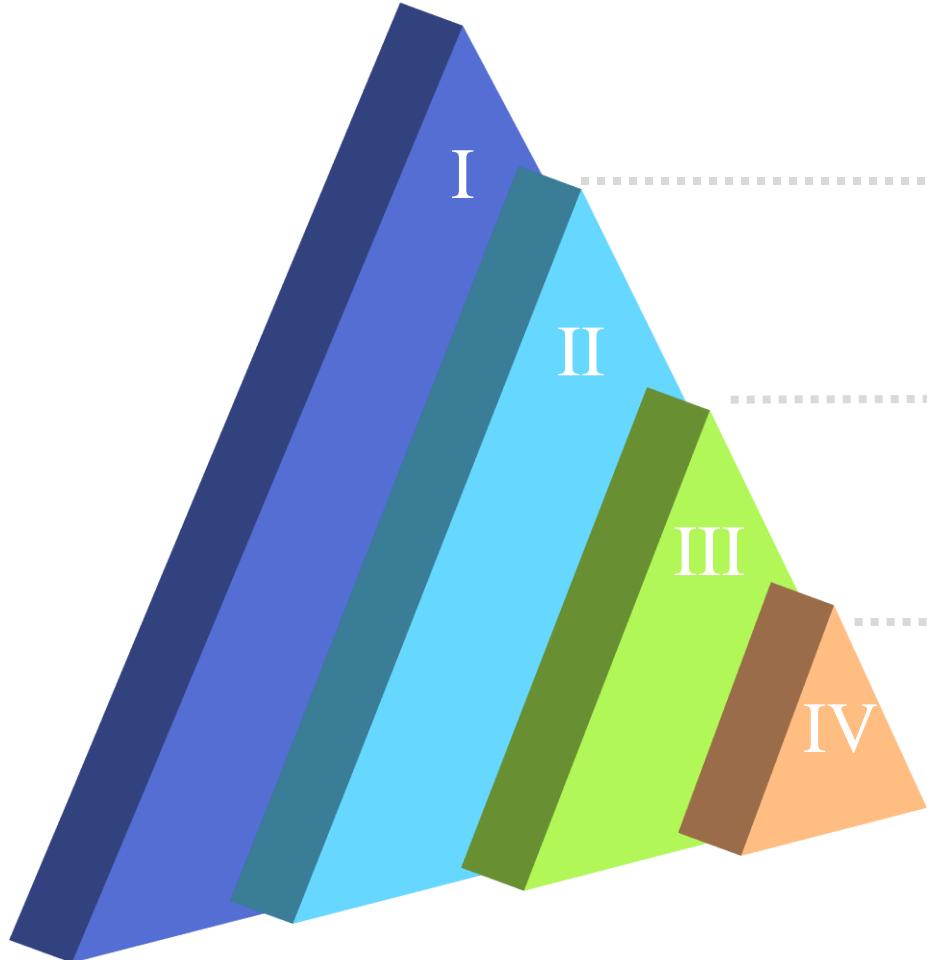


Sample & Report Flow - LIMS





Quality Management System



Level I – What lab will do? – Quality Manual, Site Master File



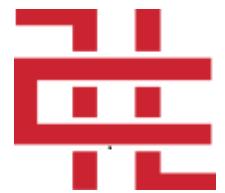
Level II – How lab will do? – Standard Operating Procedures, Validation Master Plan



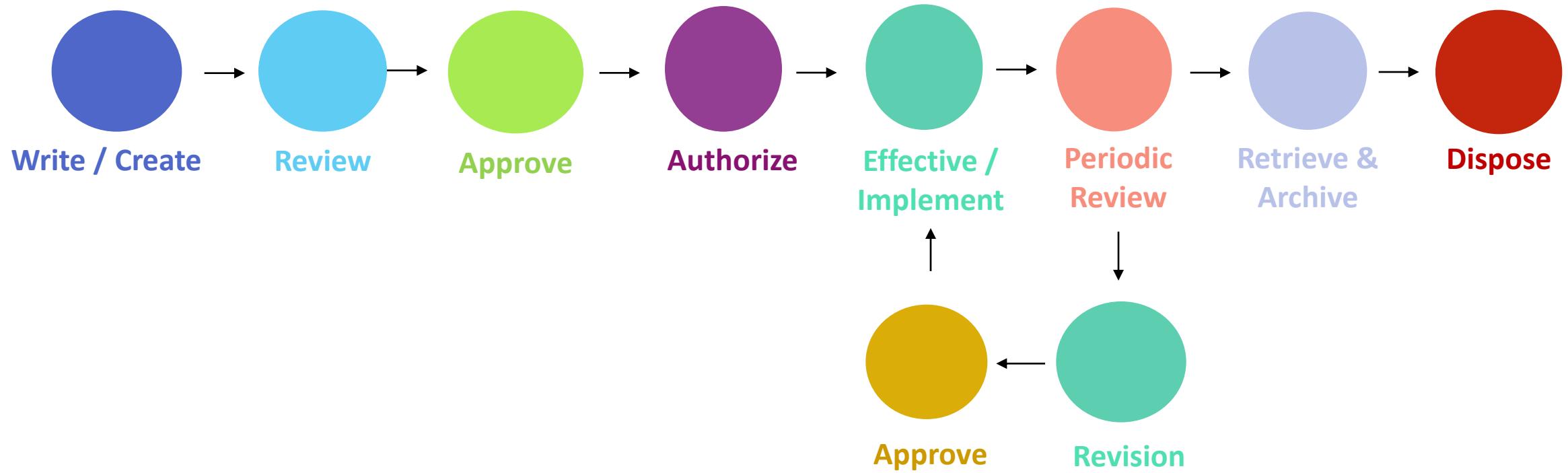
Level III – Where Will Lab record it?- Format, Lists, Annexures, Labels

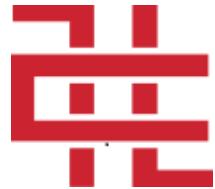


Level IV –What lab has done? – Evidences, Records, Raw Data, Chromatograms etc.

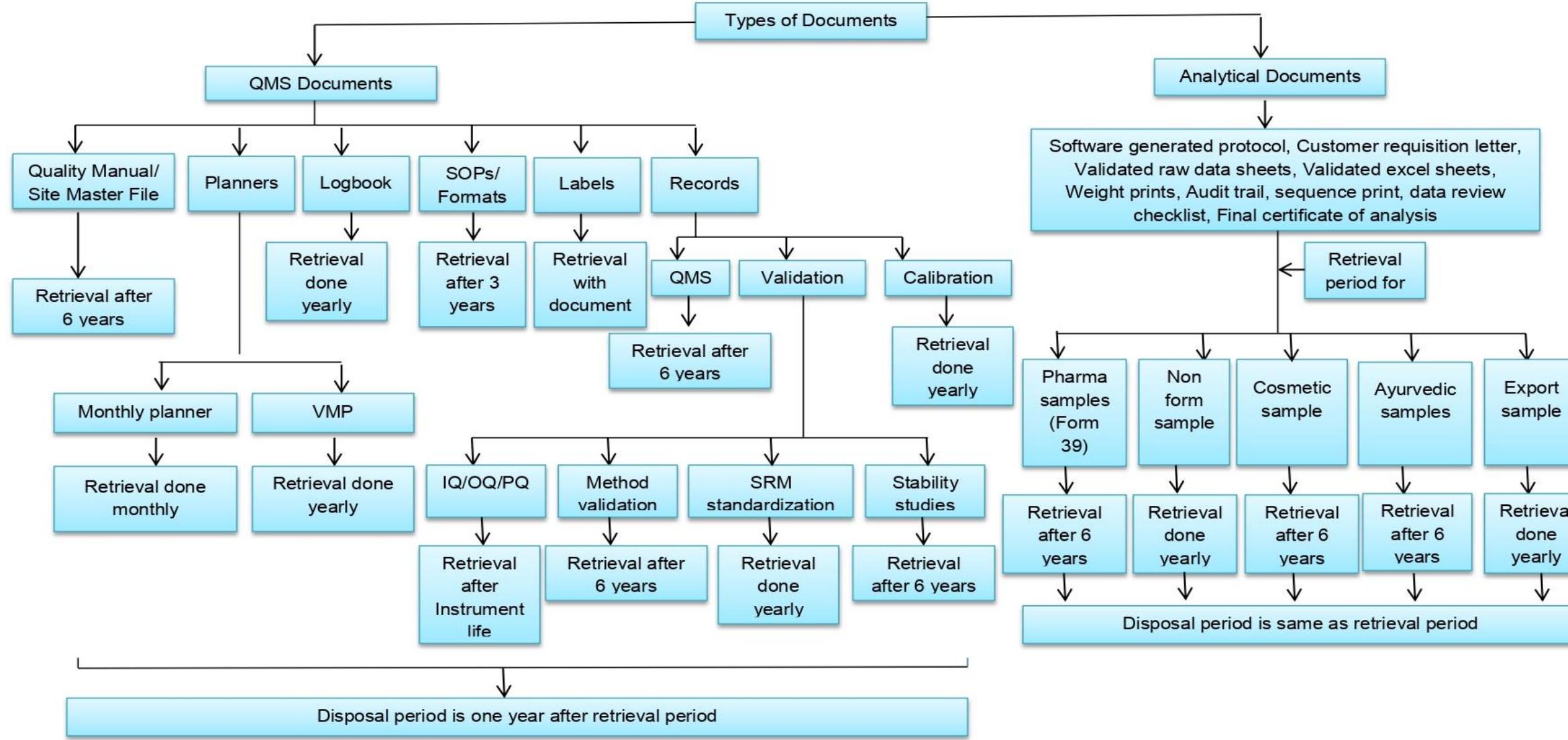


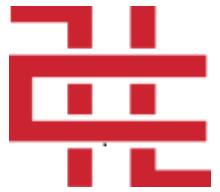
Document Life Cycle





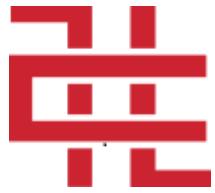
Document Control



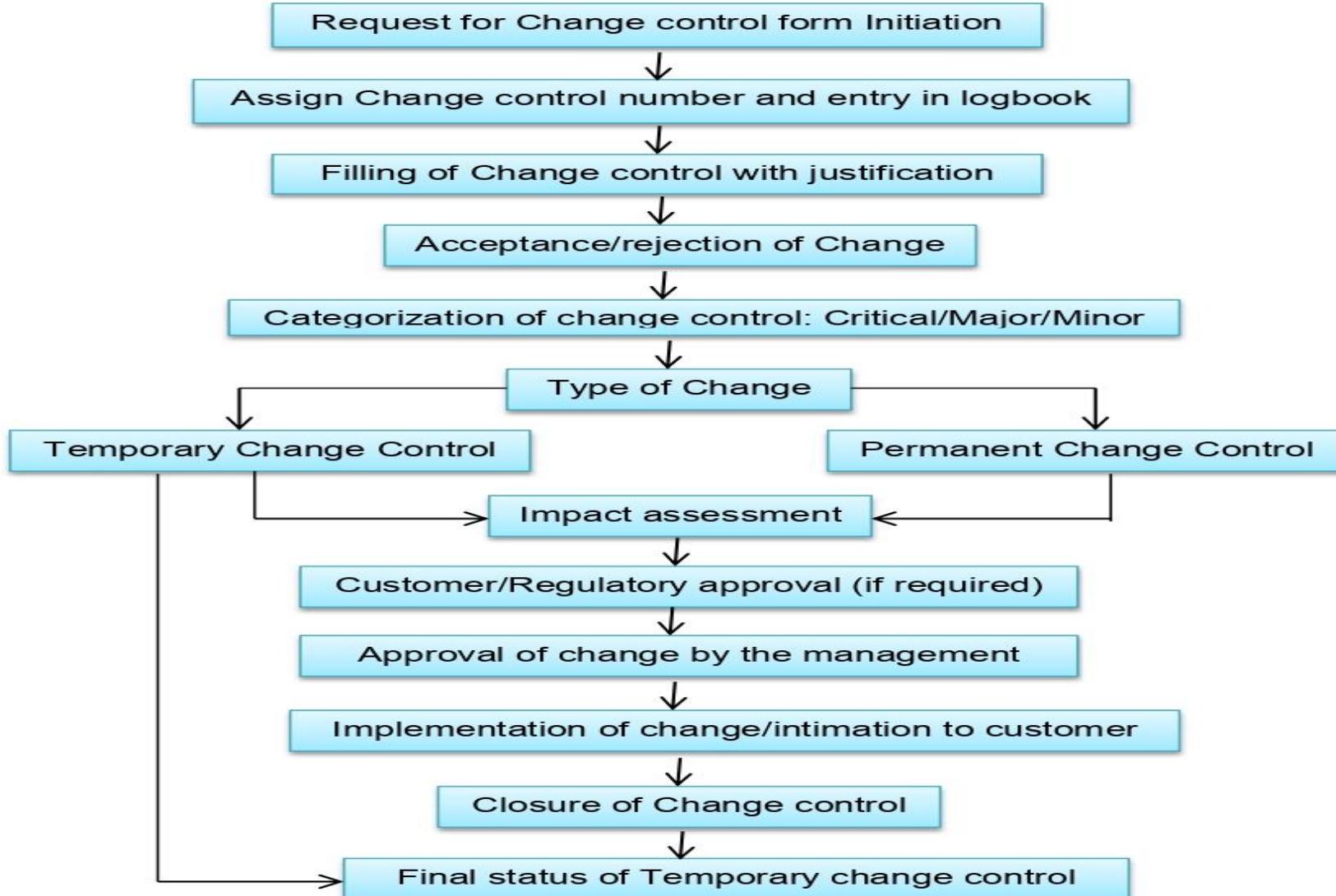


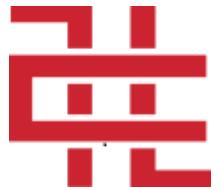
QMS Activities



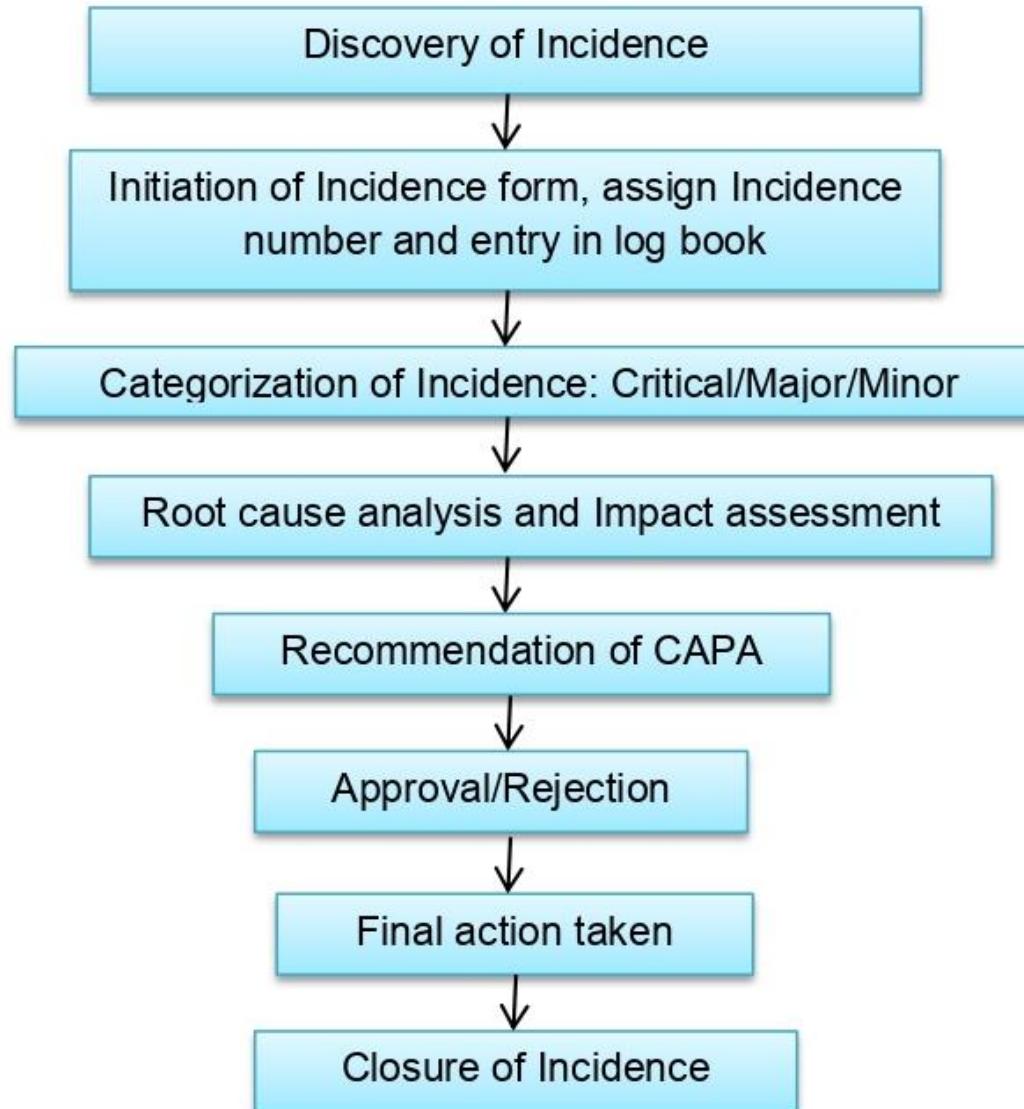


Change Control



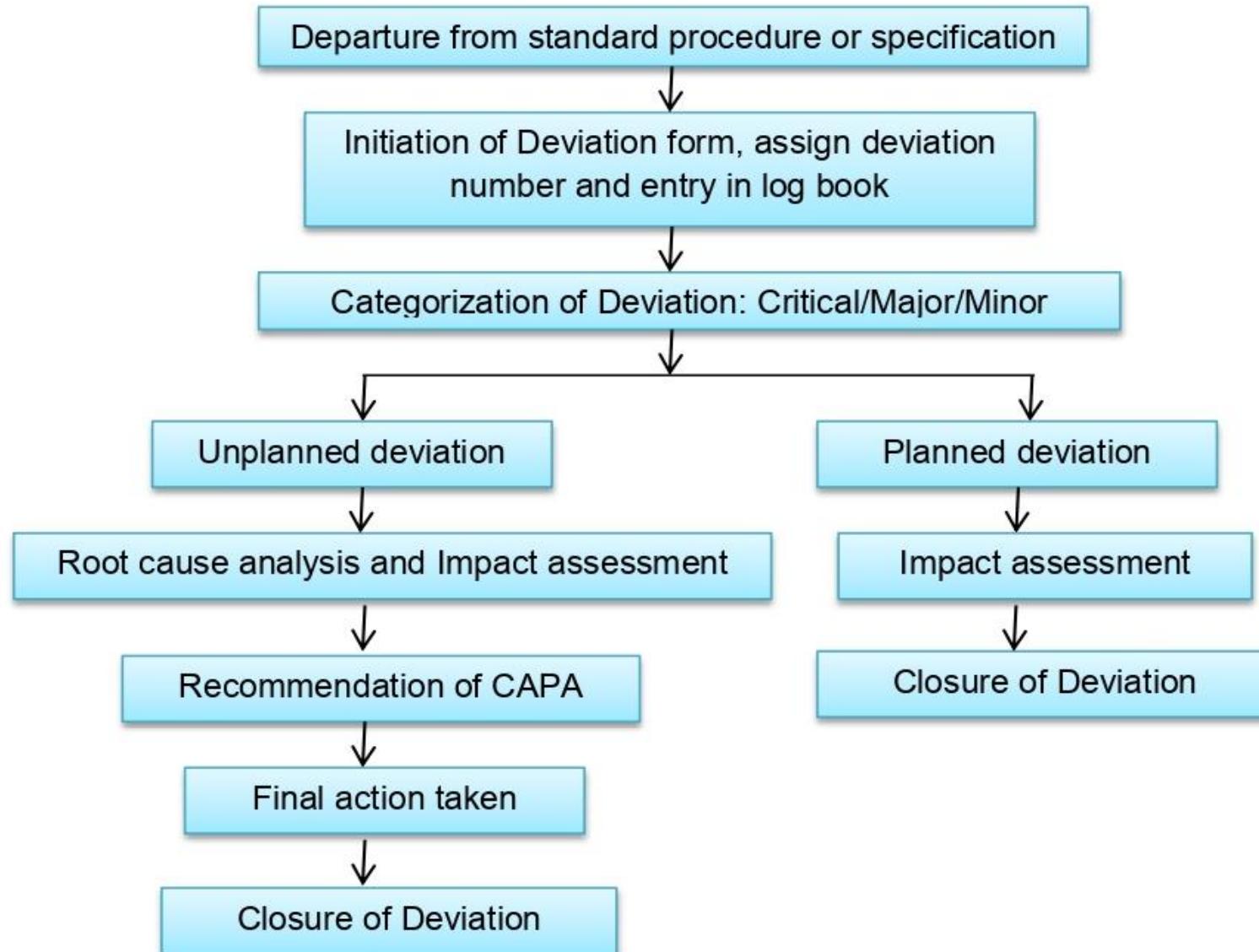


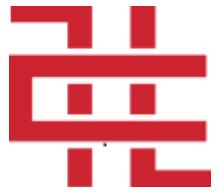
Incidence



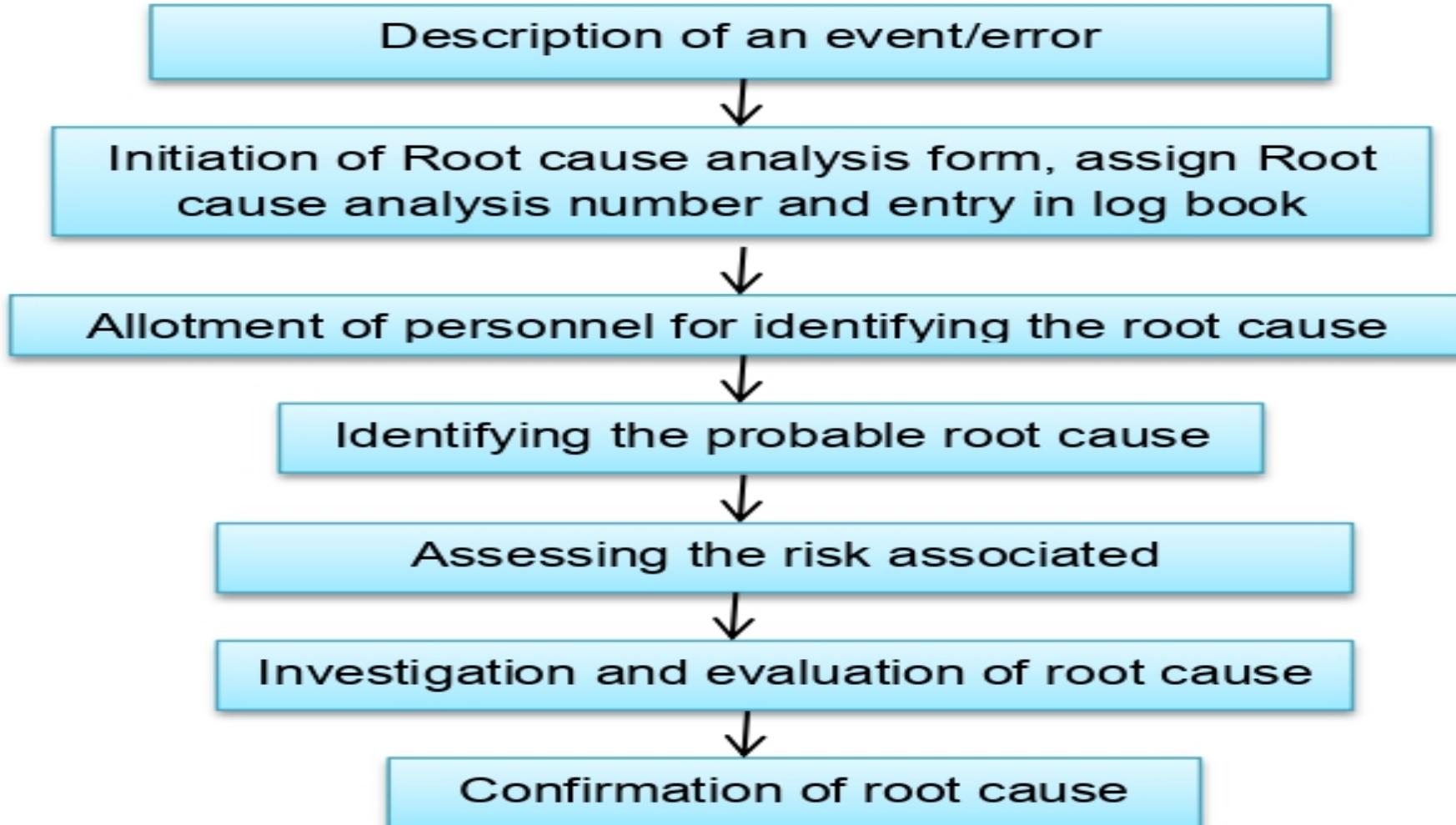


Deviation



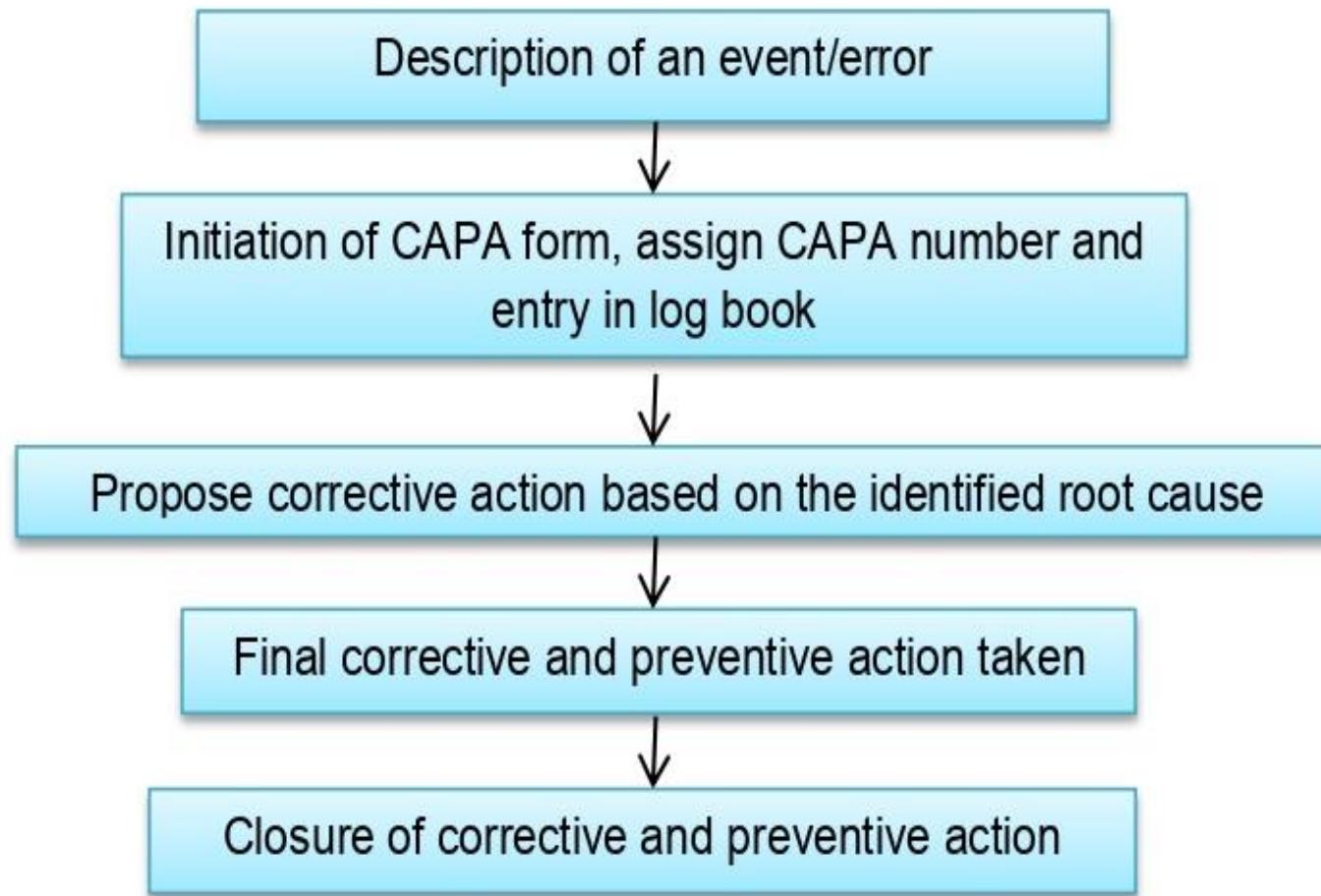


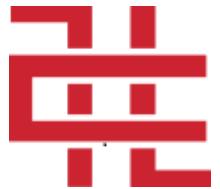
Root cause analysis



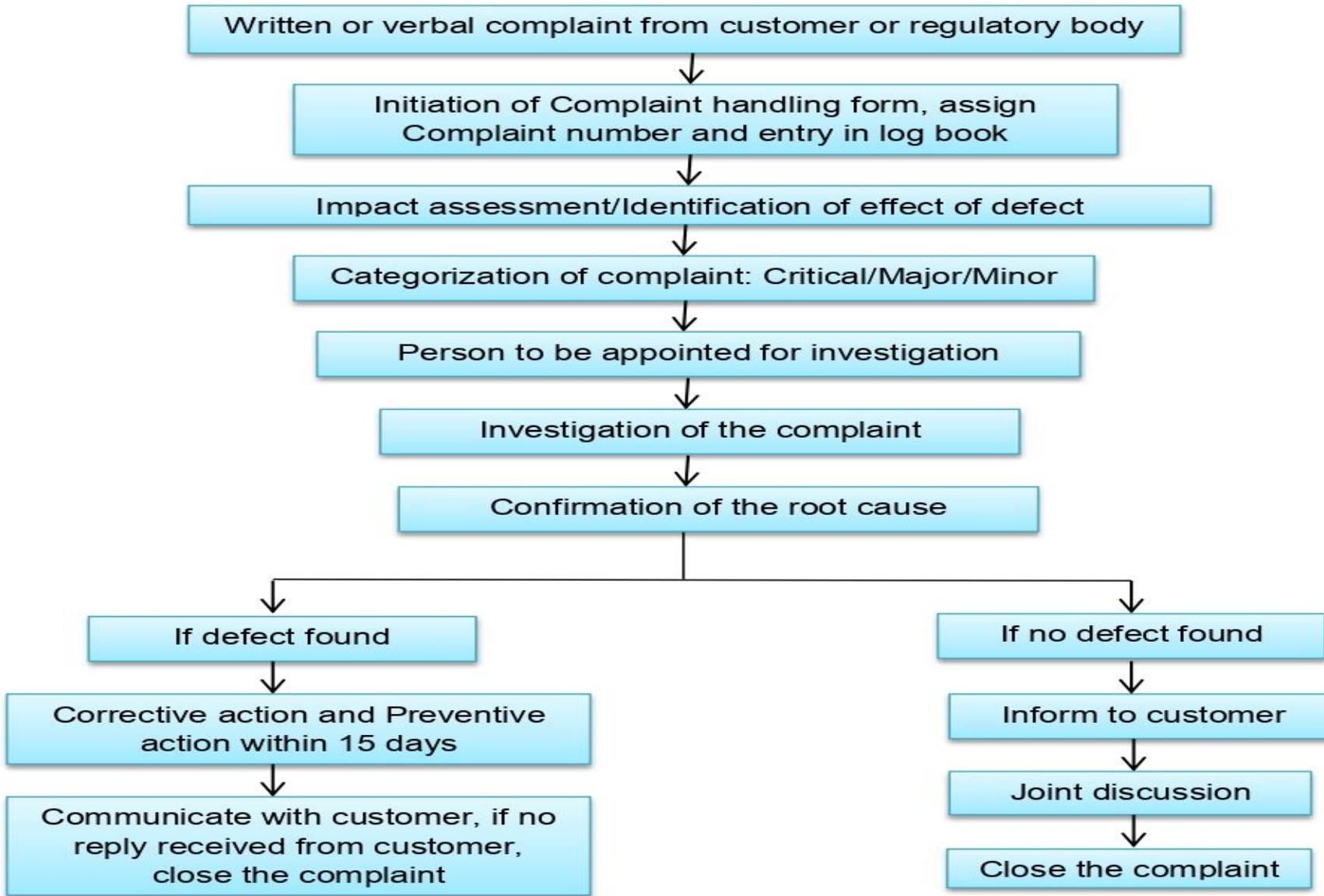


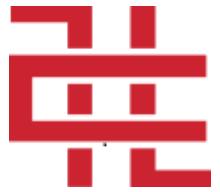
Corrective Action & Preventive Action



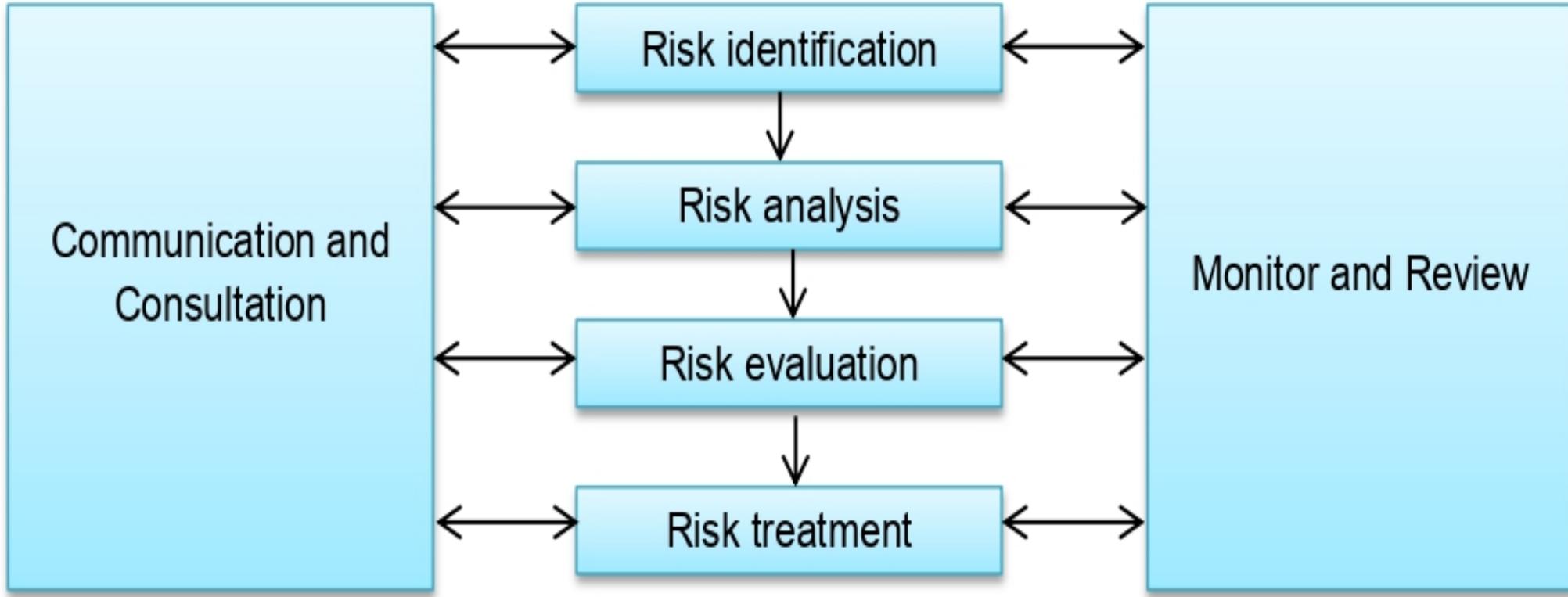


Complaint Handling





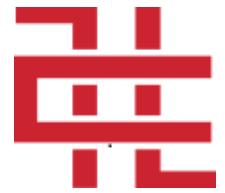
Risk Assessment





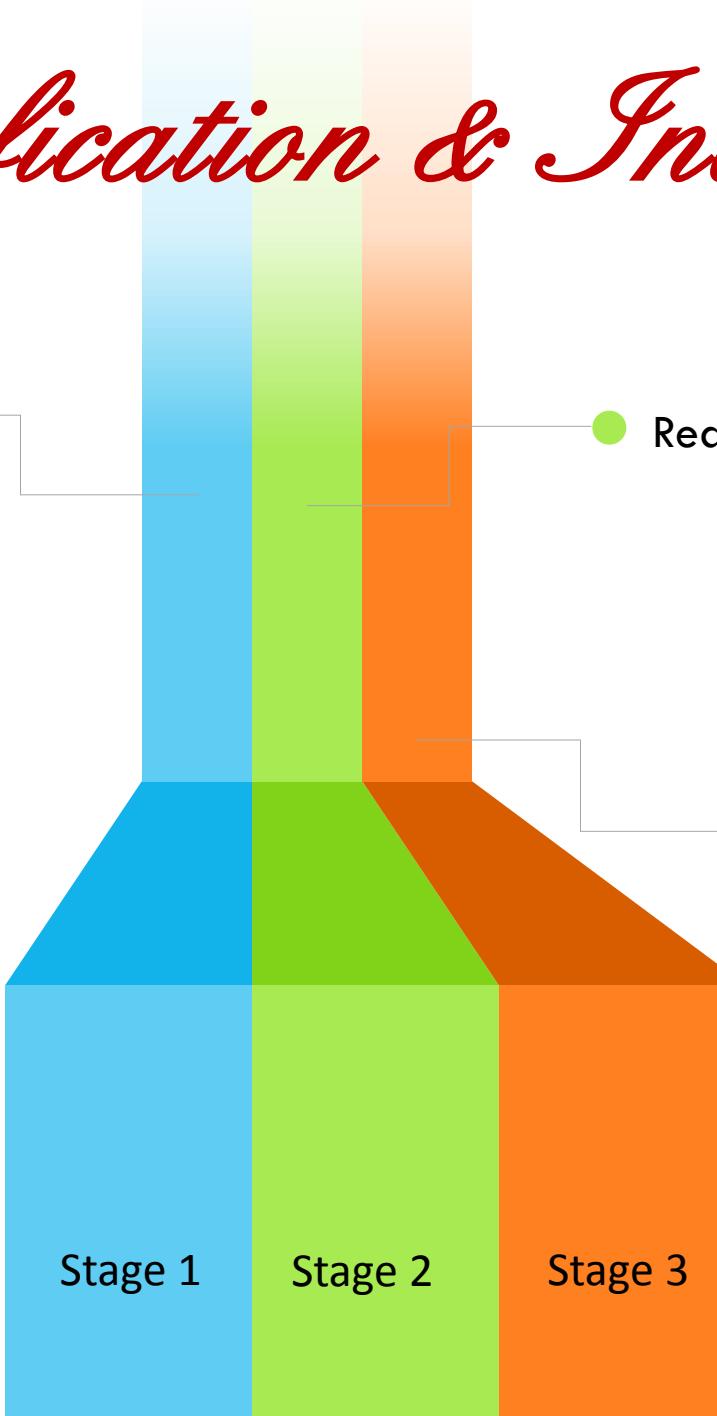
Improvement





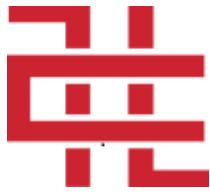
Out of specification & Investigation

Review of Original Testing for 6M –
Method, Material, Machinery &
Manpower, Measurement &
Environment



● Reanalysis of Sample by Senior Personnel

● Witness testing/Joint analysis (If required) & Release of Report.



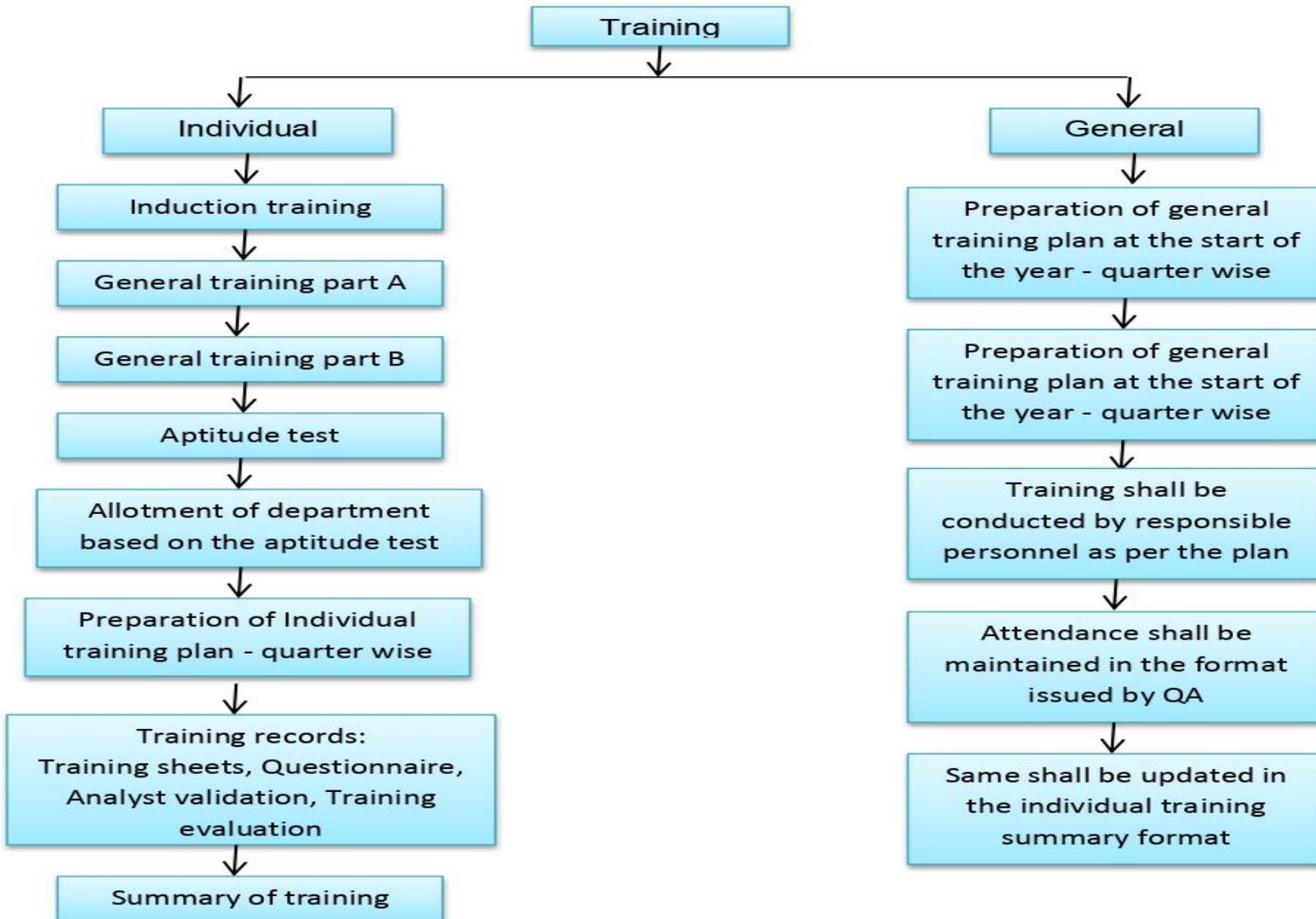
Keeping The Promise

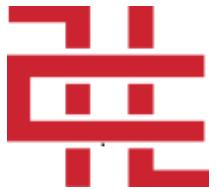
Quality Assurance

- *Equipment qualification/calibration*
- *Intermediate check*
- *Working standard and Volumetric solution standardization*
- *Growth promotion test*
- *Biochemical test*
- *Disinfectant efficacy test*
- *Analyst training and validation*
- *Logbooks*
- *Traceability of record*
- *Antibiotic potency verification*
- *Vertical and Internal audit*
- *Method verification and validation*
- *Inter Laboratory Comparison*
- *Proficiency testing*
- *Internal Quality Checks*



Training

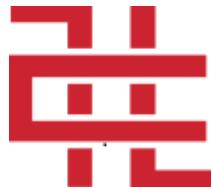




Data Integrity

- Separate logins for each user category
- User groups categorized as:
 - Administrator
 - QA Reviewer
 - Technical Reviewer
 - QC Reviewer
 - User/Analyst
- Rights and privileges well defined
- Audit trail/21CFR enabled
- Rights to add or delete any role/privilege is restricted to administrator only
- Password validity is set for 90 days





Data Storage

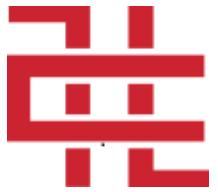


Date & Time block,
Internet Block, USB Block

Cloud Storage
For LIMS
NAS Oriented storage
User-Server Segregation
Agilent server - Chromaleon

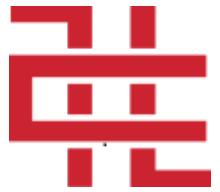
Regular Automatic Backup at daily &
weekly intervals. Disaster backup.

Password Policy, Audit Trails, Computer
System Validation,
User/Reviewer/Administrator Rights



Power backup

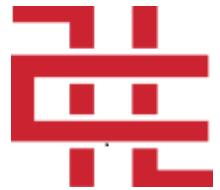
- *Power backup is enabled through UPS (100 kv)*
- *All the instruments are connected to UPS*
- *UPS is connected to DG generator which is again connected to main power supply unit*
- *Capacity of DG is of 120 kv and the switch over time is 30 seconds*
- *UPS power backup is also available for electricity supply other than the supply for instruments*



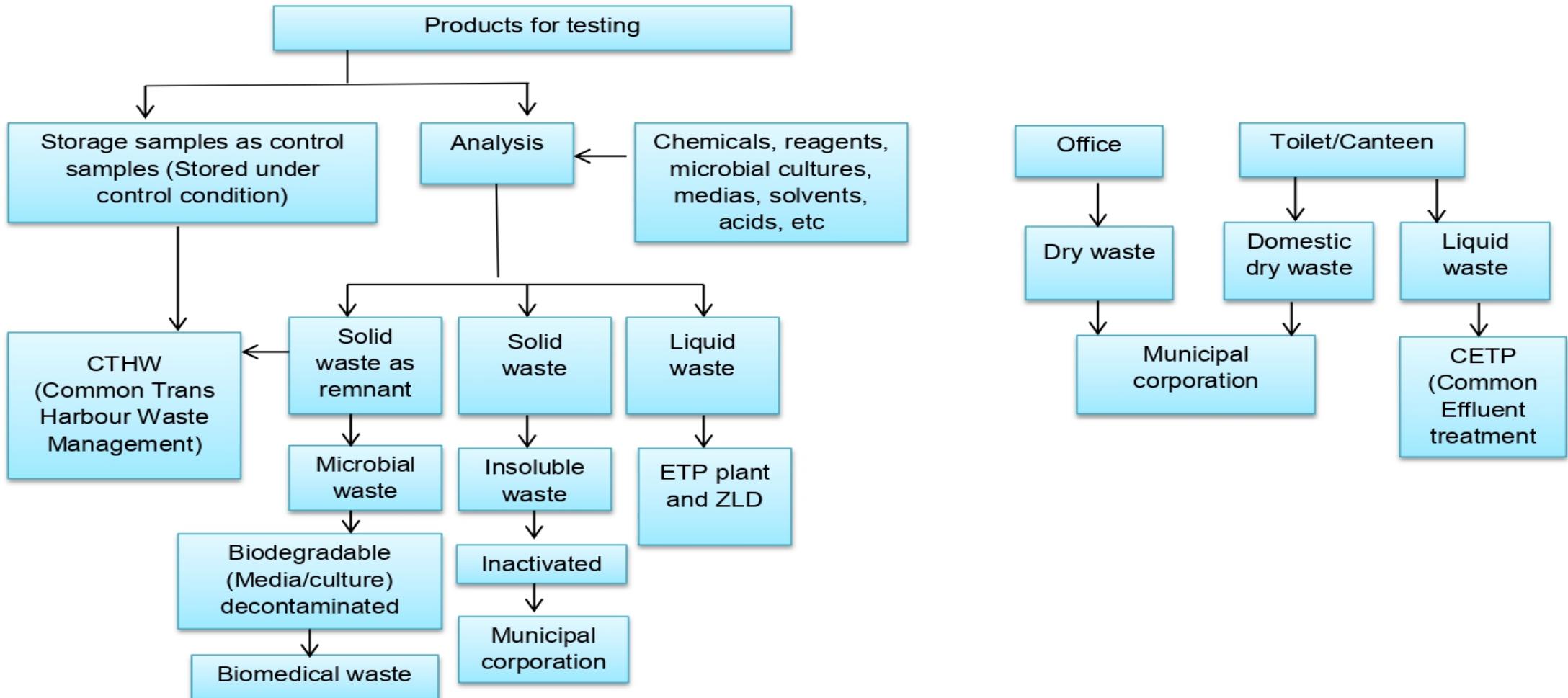
Laboratory Safety

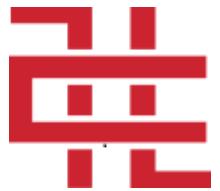
- NOC by Fire Safety MIDC
- Separate water tank (Capacity 40,000 L)
- Fire hydrant
- Smoke detectors
- Fire alarms
- Modular fire extinguisher
- Emergency exit
- Spillage kit
- Safety shower/Eye washer/Biological safety
- Microbial spillage kit
- PPE kit
- Fume hood
- Hazardous chemicals under controlled access



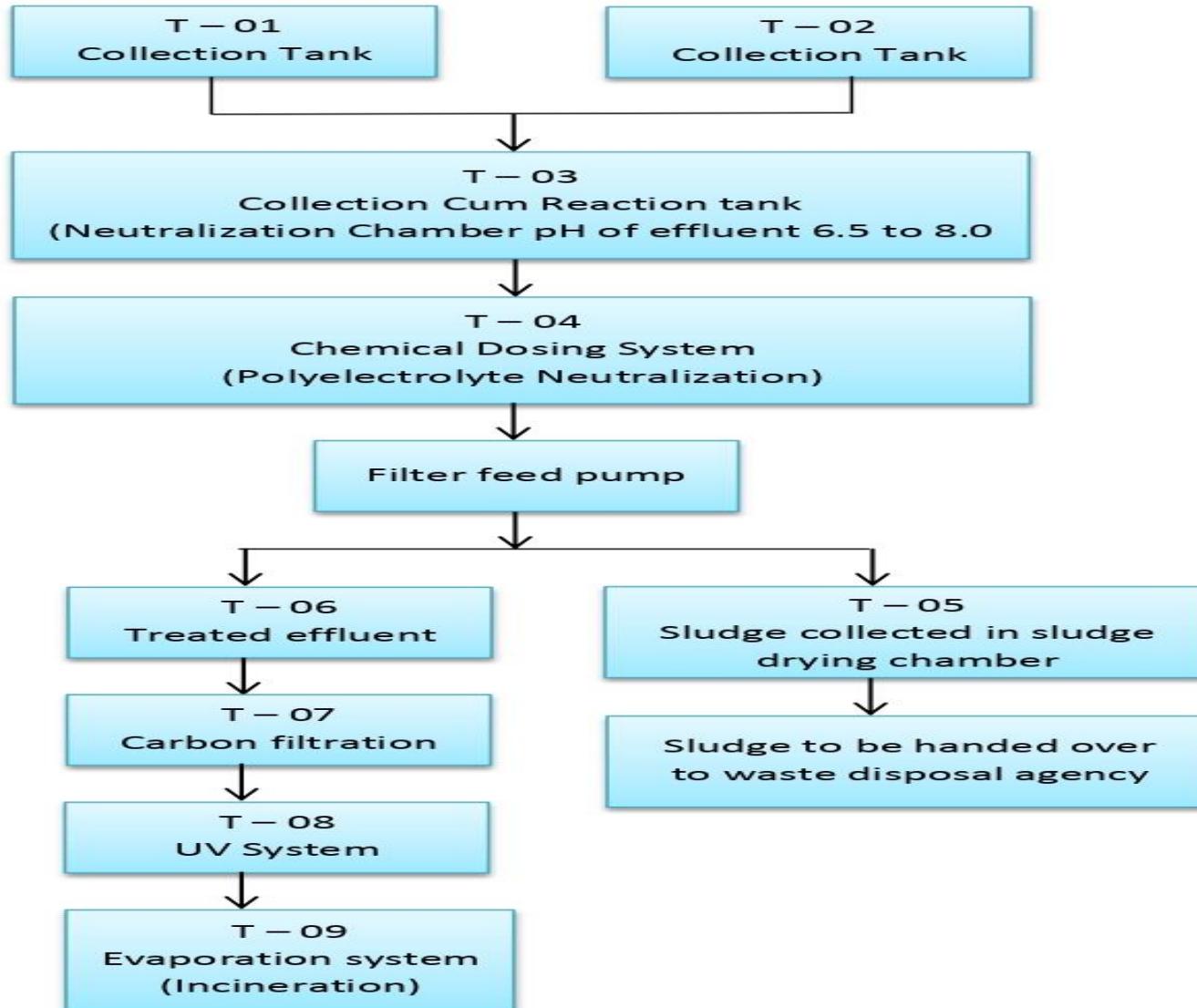


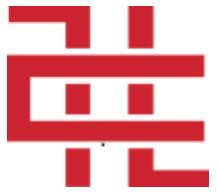
Waste management & Pollution control





Effluent Treatment Plant





Journey

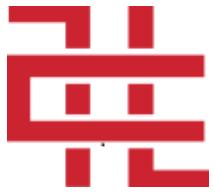
1984- Laboratory established in Mumbai, Approval from FDA

1990 - Instrumental analysis on HPLC and GC

1996 - Sterility and BET testing for parenteral preparations

2000 - Started serving the international market for analytical testing services

2003 - Certified as per ISO 9001 for QMS. Approval from NAFDAC, Govt of Nigeria



Journey

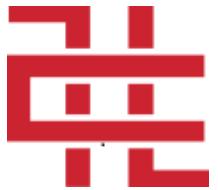
2005 - Accredited by
NABL as per ISO
17025:2005

2007- Expansion of
Sewri unit ground floor
for a more spacious
Microbiology and
Sterility section

2010 – There was a
growth in sales more
than 40%

2012 – Growth in sales
more than 50%.
A vision for a new
setup

2014 - New testing
facility established in
Navi Mumbai



Journey

2015 - Approval from FDA and CDSCO for Drugs and cosmetics at Navi Mumbai.
Started Stability studies

2016 - Accredited by NABL as per ISO 17025:2017 at Navi Mumbai.
Recognized by Ministry of Health, Ukraine, Mozambique and Surveyors France for testing

2017 - Started Analytical Method Development and Validation projects as per ICH, WHO, Geneva and USFDA guidelines

2018 - Analysis on LCMS-MS, GCMS-MS, ICP-OES, Ion Chromatograph

2019 - Analytical Method Validation for Pesticide residue, Aflatoxins, Sudan dyes in food products

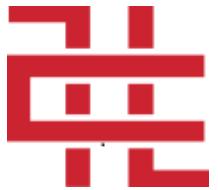


Journey

**2020 - Analytical method validation
for Nitrosamines**
**New QMS documentation introduced.
CQA status established**

**2021 - Accredited by NABL as per ISO
17025:2017 at Navi Mumbai for food and
agricultural commodities.**
**Pawane unit registered for USFDA. DUNS
Number: 85-424-7369 FEI: 3020879673**

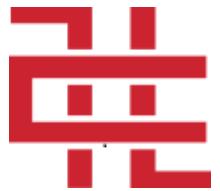
**2022 - Expansion of facility at Navi Mumbai
with state of art Microbiology and Sterility
section**
**TCD detector procurement for propylene
glycol assay test**



Journey

**2023 – Certification of FDA for Microbiology and Sterility section by CDSCO,
EG and DEG method validation on GCMSMS for cough syrups
Procurement of new LCMSMS, ICPMS and AAS for metal analysis
Approved by The Ministry of Gambia
NABL scope expansion for Food, Pharma & Cosmetics**

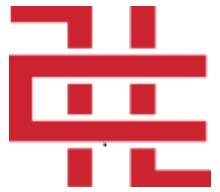
**2024 – Procurement and Installation
of Agilent server Chromaleon
Applied for testing of medical
devices
Applied for FSSAI approval for food
testing**



Future Plans

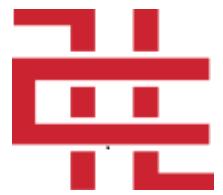
- *USFDA audit*
- *Bureau of Indian Standards (BIS) license for Water testing*
- *Food Safety and Standards Authority of India (FSSAI) license for testing of food products*
- *License for testing of Medical devices*
- *WHO certification for GLP*





Reception area

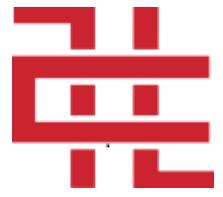




Conference room

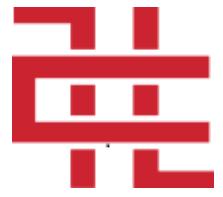


reenhatch
RENTAL SERVICES



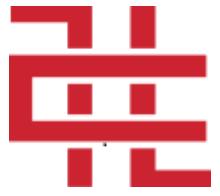
Entrance corridor





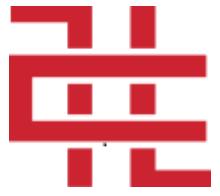
Instrument section





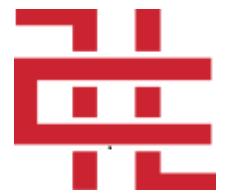
Instrument section





Instrument section

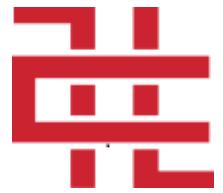




Instrument section - Corridor

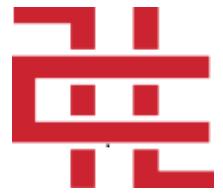


greenhatch
ARCHITECTS



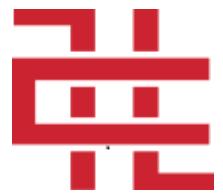
Lab area entrance





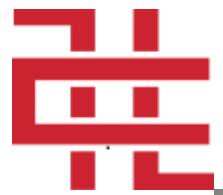
Admin area





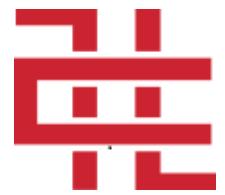
Microbiology section





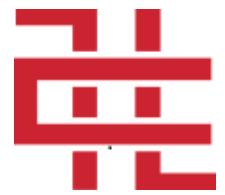
Microbiology section





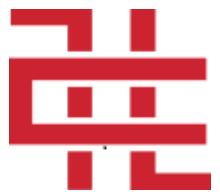
Microbiology section





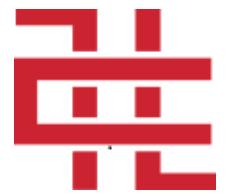
Microbiology section



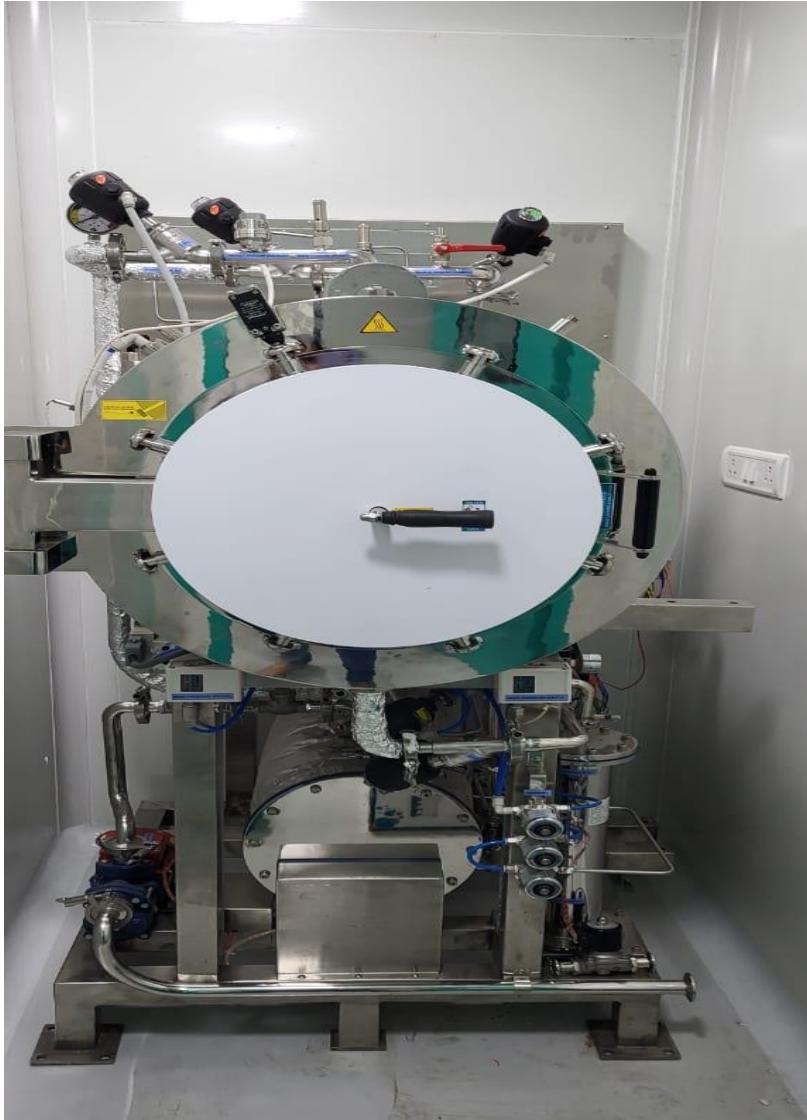


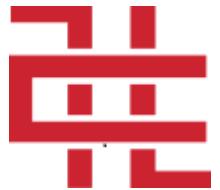
Microbiology section





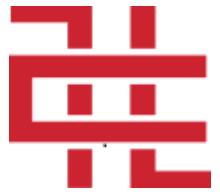
Microbiology section





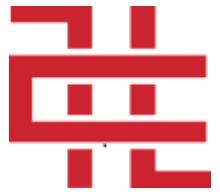
Visitors from Sierra Leone





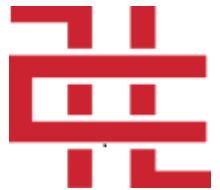
Visitors from Angola





Auditors from Ukraine





Auditors from Gambia





THANK YOU!