# Product Certification & Investigation Program

Stabicon

## 1. Introduction

Stabicon product certification process management strives to improve processes and align the needs of regulatory with Client objectives on quality product distribution channel. This gives transparency to the process making it more efficient.

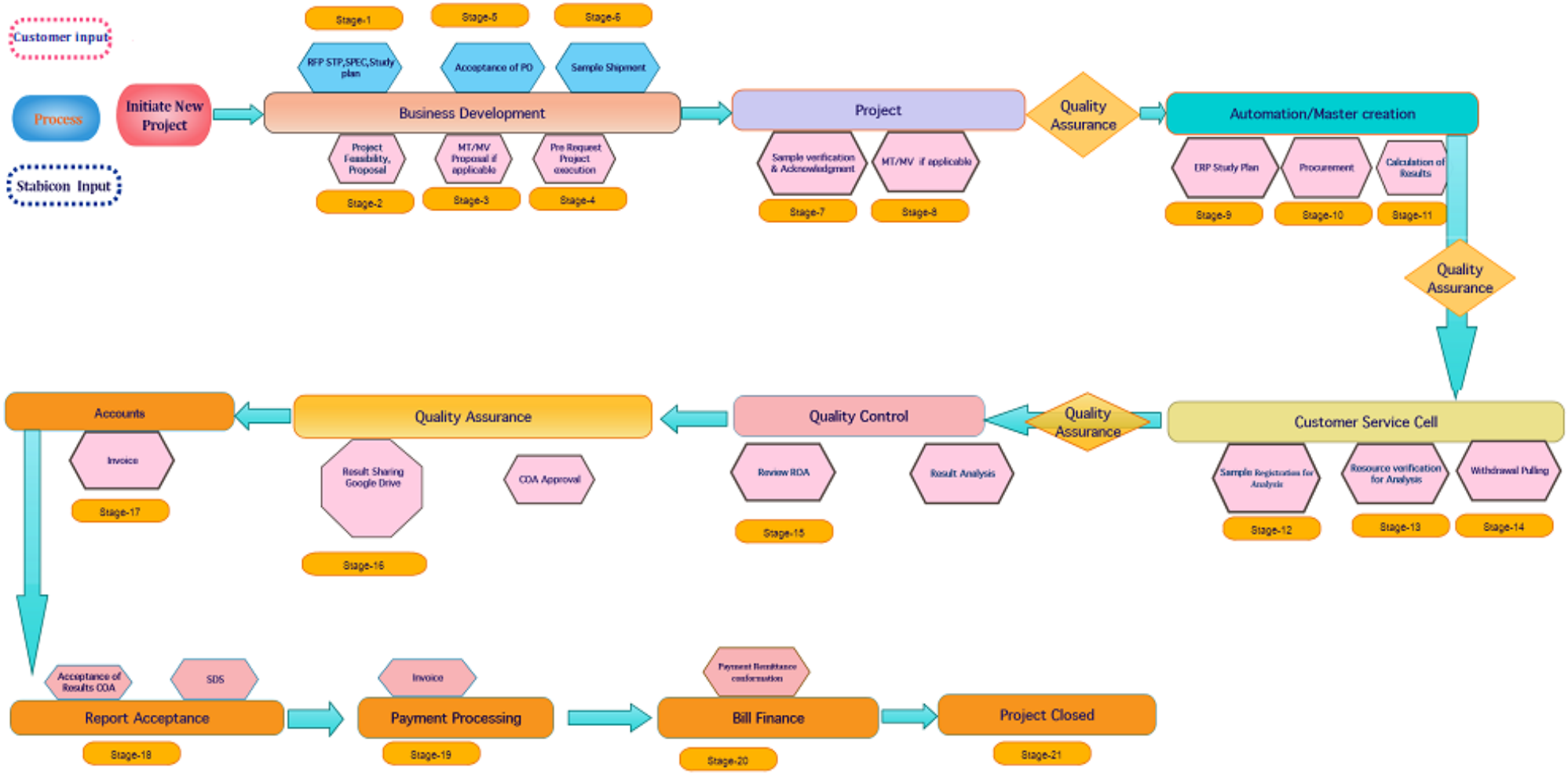
It Includes review and testing process to validate that the certified products meet certain standards and comply with a stated designed specification/requirement. Product certification process works towards improving efficiency across the various project stakeholders by helping product evaluation and implement best practices.

## Product Certification & Investigation Program

## 2. Experience & Diversity - Laboratory Business Segment

| Section – 2 Experience & Diversity - Laboratory Business Segment | | | | | |
|---|---|---|---|---|---|
| | Method Development | Method Validation/Verification | Stability Program | Product Certification for WHO & India Market Release | Spurious & Substandard product Investigation |
| **Experience** | 9 years | 9 years | 9 years | 9 years | 5 years |
| **Dosage** | Solid, Liquid, Topical, Parenteral (Internal & External Application) | Solid, Liquid, Topical, Parenteral (Internal & External Application) | Solid, Liquid, Topical, Parenteral (Internal & External Application) | Solid, Liquid, Topical, Parenteral (Internal & External Application) | Solid, Liquid, Topical, Parenteral |
| **Volume** | 100 - 200 | 300 - 500 | 500 - 700 | 1000 - 1200 | 250 - 400 |
| **Diversity** | Pharmaceutical Rx & OTC, Hygiene, Dietary, Compounding, Biological, Medical Device | Pharmaceutical Rx & OTC, Hygiene, Dietary, Compounding, Biological, Medical Device | Pharmaceutical Rx & OTC, Hygiene, Dietary, Compounding, Biological, Medical Device | Pharmaceutical Rx & OTC, Hygiene, Dietary, Compounding, Biological, Medical Device | Dietary , Pharmaceutical Rx & OTC |
| **Category** | Chemical, Enzyme, Peptide, Medical Device, Natural, Probiotics based products | Chemical, Enzyme, Peptide, Medical Device, Natural, Probiotics based products | Chemical, Enzyme, Peptide, Medical Device, Natural, Probiotics based products | Chemical, Enzyme, Peptide, Medical Device, Natural, Probiotics based products | Chemical, Enzyme, Peptide based products |
| **Market** | America, Europe, Asia, Australia, Africa, Canada, Middle east | America, Europe, Asia, Australia, Africa | America, Europe, Asia, Australia, Africa | America, Europe, Asia, Australia, Africa | Asia |

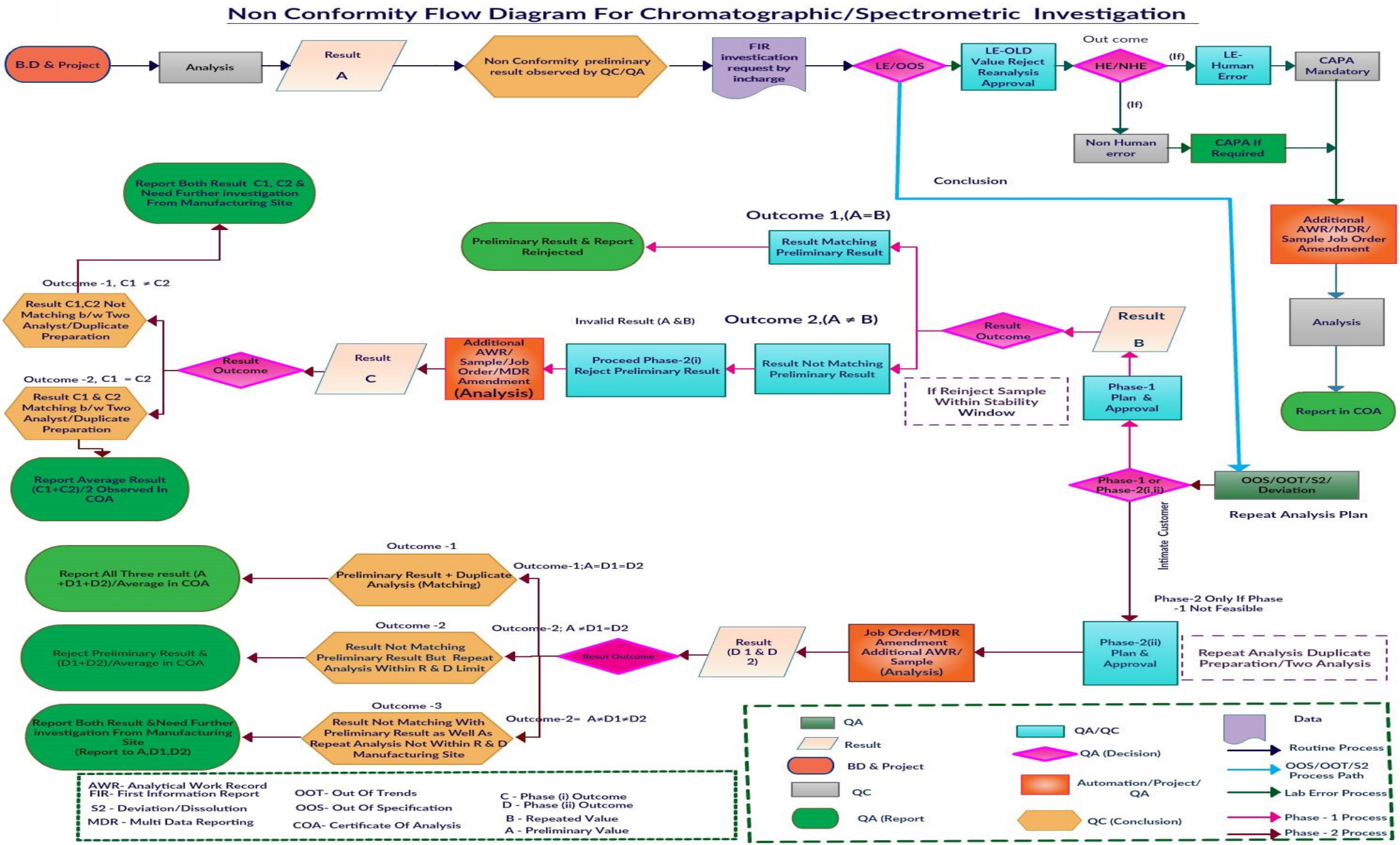
# Product Certification & Investigation Program




**Note :**

In case of Non Conformity observed Please refer Non Conformity work flow Diagram

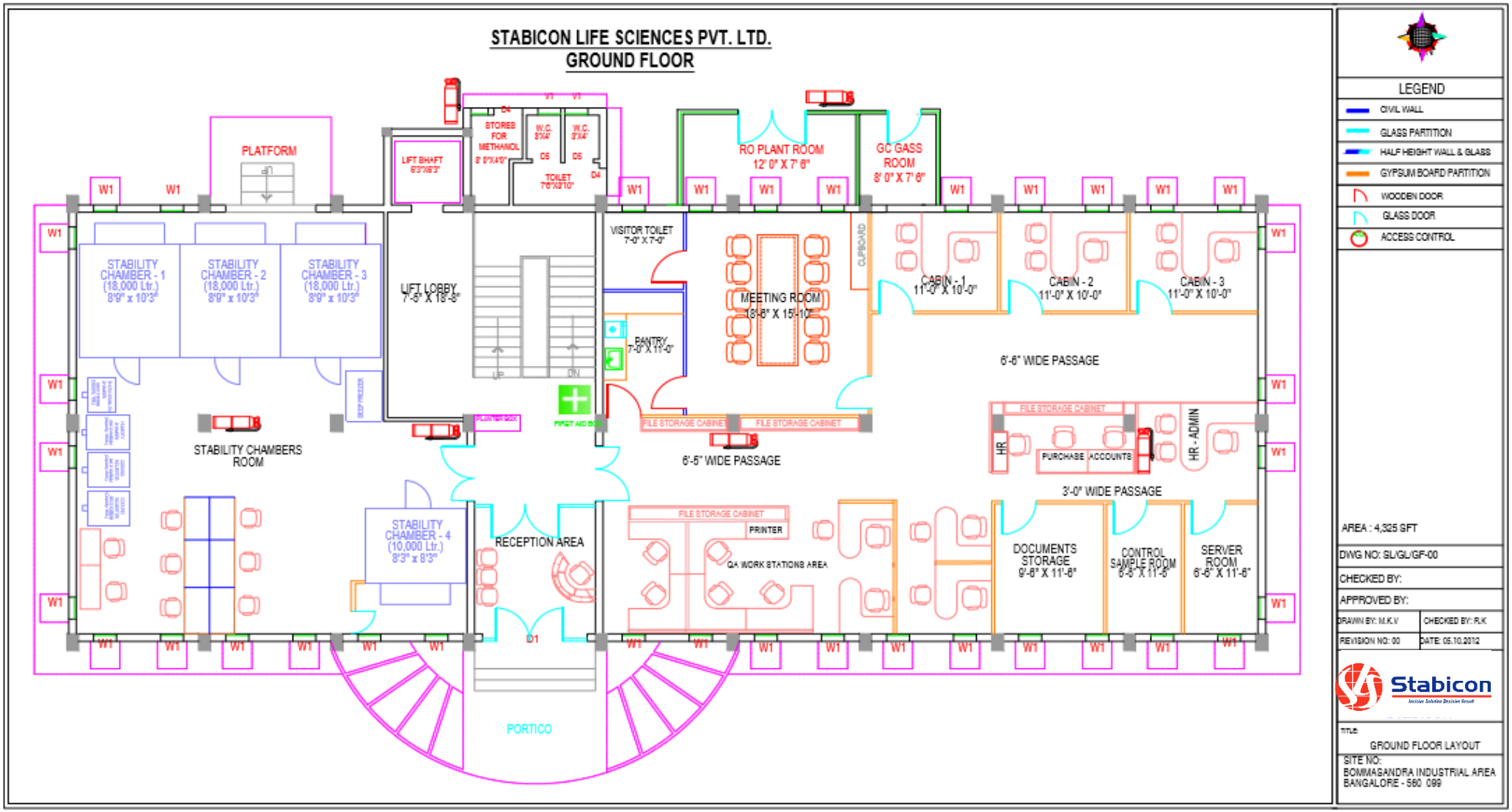
# Product Certification & Investigation Program



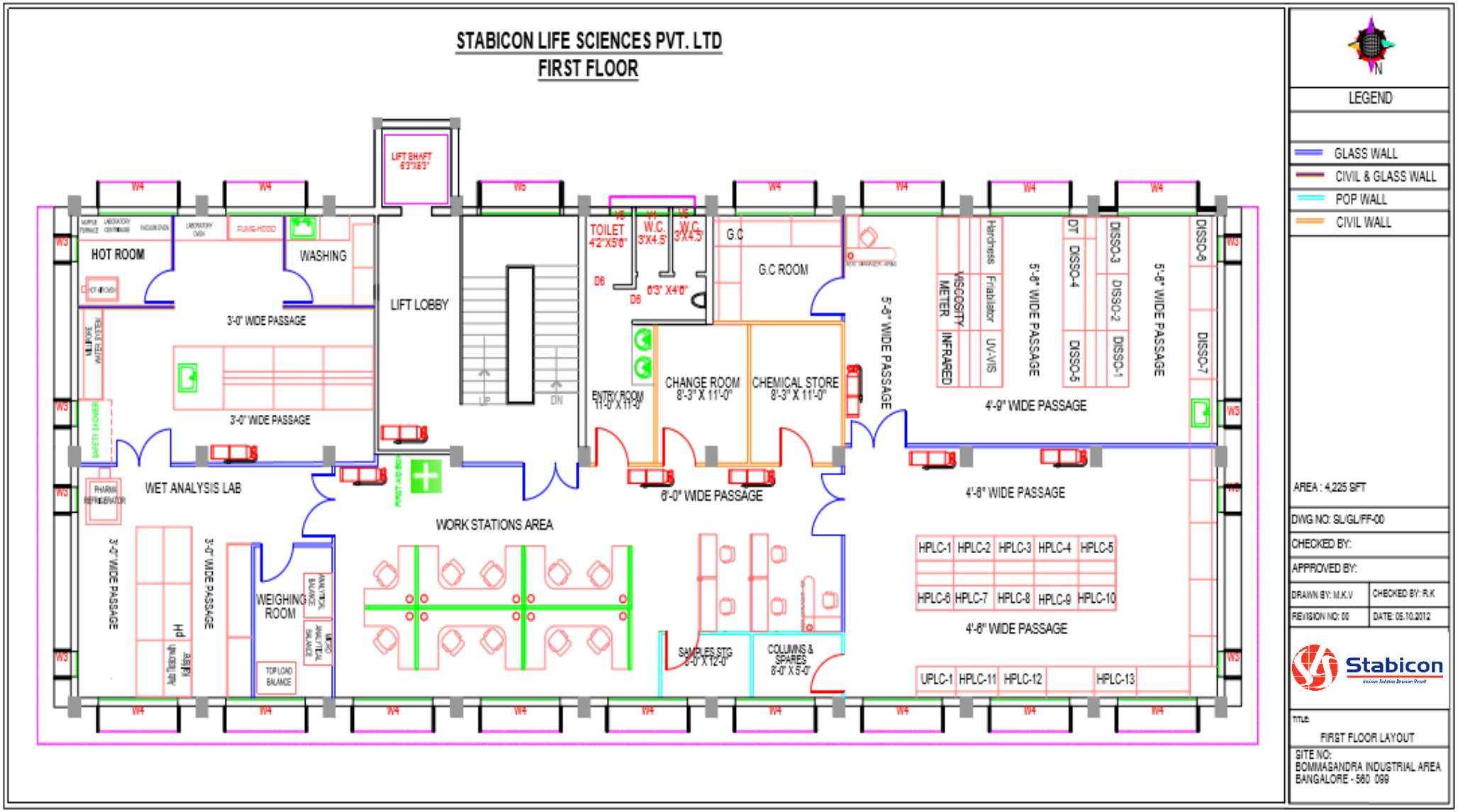
## 3. Regulatory Status & Agency view

- Approved by Health Canada
- Accredited by laboratory Assessment was done by NABL (National Accreditation Board for Testing & Calibration Laboratories) – India as per **ISO / IEC 17025:2005**
- Approved by **WHO, Geneva**; under Prequalification Medicine Program – Procedure for Assessing the Acceptability, in Principle of QC Laboratory for use by UN agencies; vide **LIF No.: L 1108**
- Registered with USFDA & DSIR
- Audited & approved by CDSCO (India FDA)

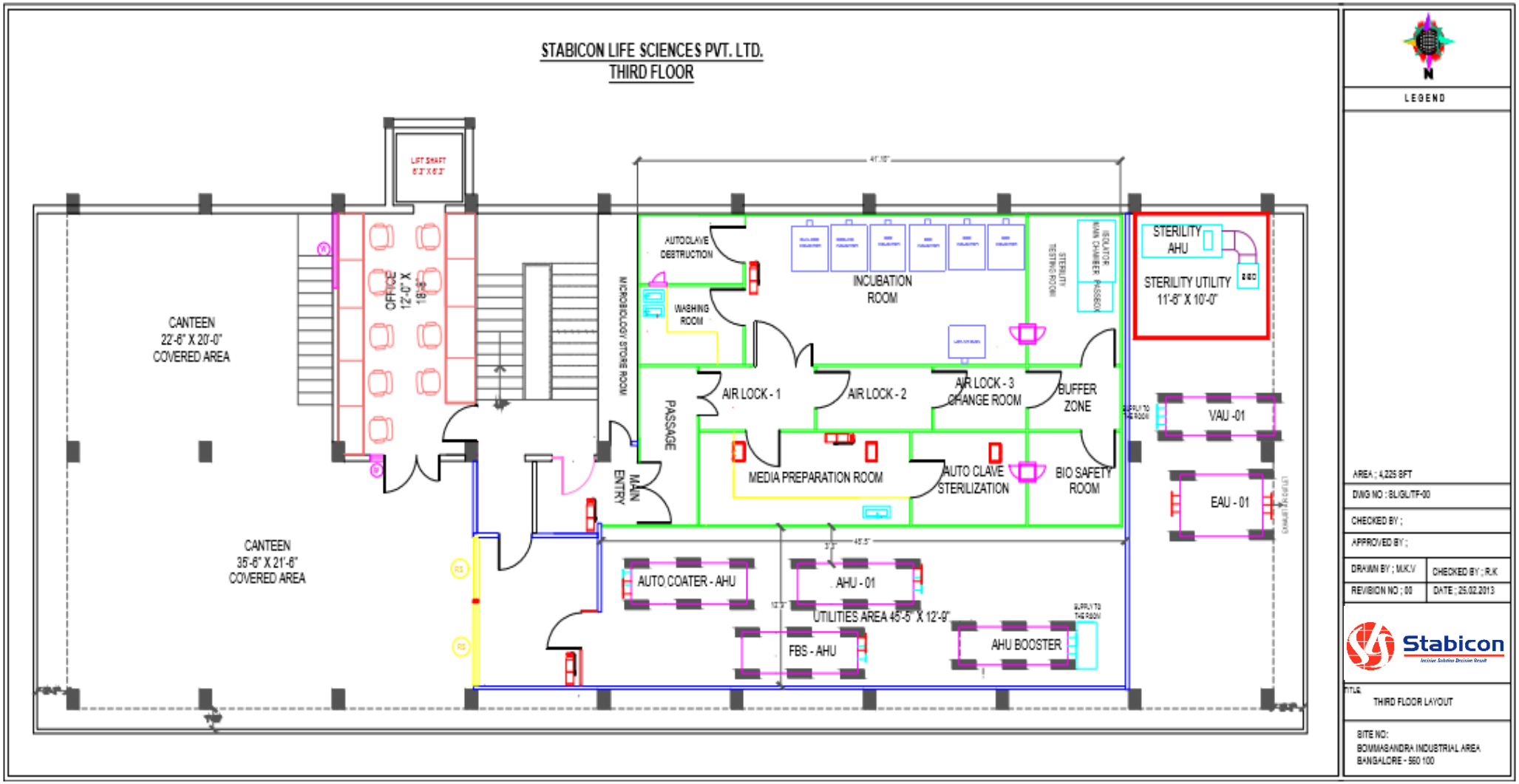
## 4. i)Storage facility – Administration, Quality Assurance & Sample Storage facility



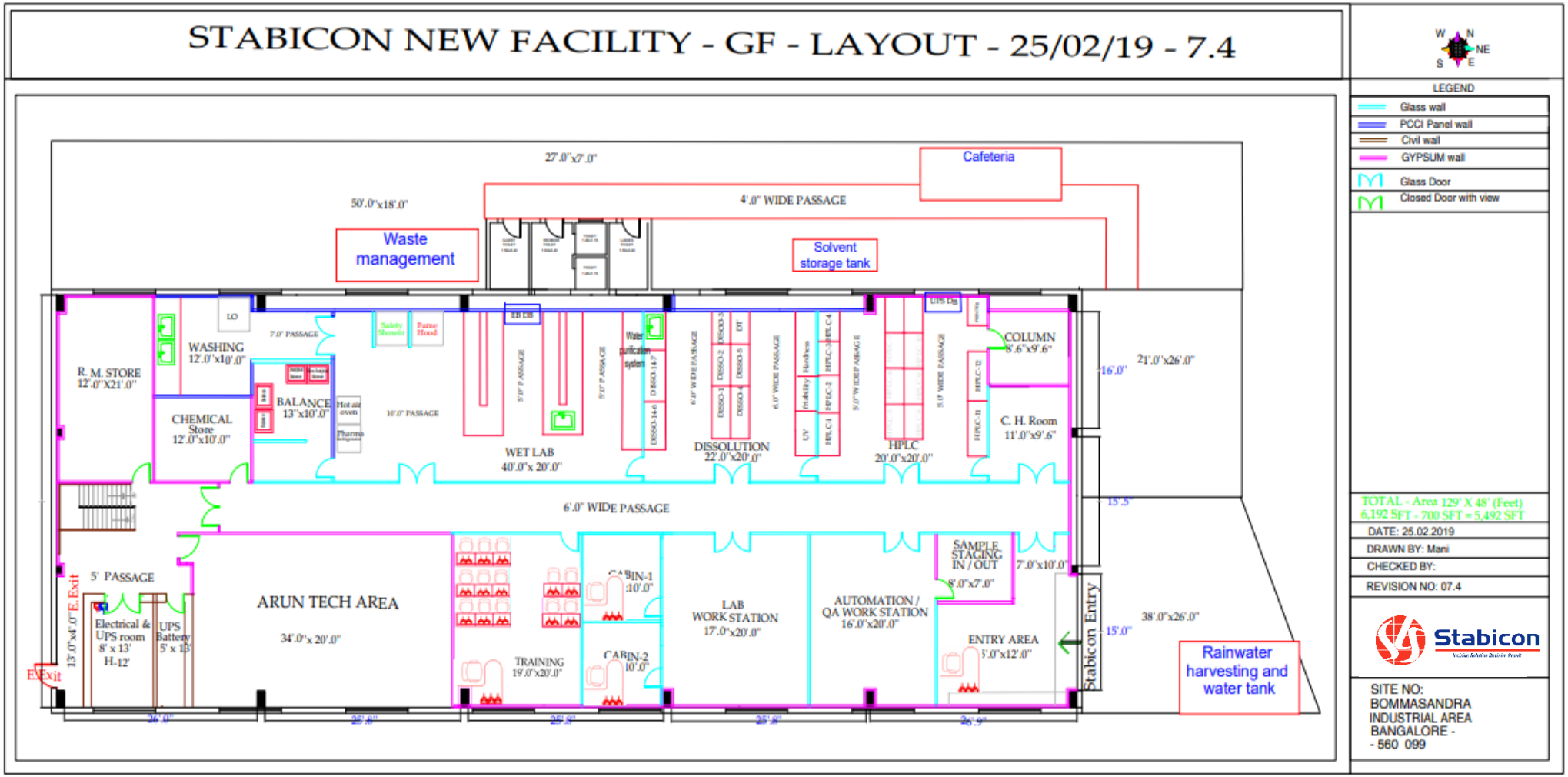
## ii) Analytical Lab Facility



## iii) Microbiology Lab facility



## iv) Analytical research & development facility



# 5. Capability & Capacity

| Table No 1 - Chemical Test in Number of Batches<br>Table No 2 - Microbiology sample analysis | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Validation | | | | Verification | | | |
| | **Sterility & BET** | | Assay | | Stability and BET | | PET | |
| | Present Capacity | Infrastructure Available for Expansion | Present Capacity | Infrastructure Available for Expansion | Present Capacity | Infrastructure Available for Expansion | Present Capacity | Infrastructure Available for Expansion |
| Week | NA | NA | NA | NA | NA | NA | NA | NA |
| Month | 10 | 5 | 20 | 10 | 10 | 5 | 10 | 5 |
| Yearly | 120 | 60 | 240 | 120 | 120 | 60 | 120 | 120 |

| Table No 3 – UPLC, HPLC & GC Chromatographic Sample Analysis | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Routine Analysis Project | | Method Development & Validation Project | | Stability Analysis Segment Project | | AR&D Analysis Segment Project | |
| | Present Capacity | Infrastructure Available for Expansion | Present Capacity | Infrastructure Available for Expansion | Present Capacity | Infrastructure Available for Expansion | Present Capacity | Infrastructure Available for Expansion |
| Week | 90 | 144 | 10 | 30 | 12 | 36 | 3 | 4 |
| Month | 300 | 576 | 40 | 120 | 48 | 144 | 12 | 16 |
| Yearly | 2880 | 2304 | 480 | 480 | 576 | 576 | 144 | 192 |

# Product Certification & Investigation Program

| Table No 4 Microbiology Sample Analysis | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Microbial Limit Test** | | Assay | | Stability and BET | | PET | |
| | Present Capacity | Infrastructure Available for Expansion | Present Capacity | Infrastructure Available for Expansion | Present Capacity | Infrastructure Available for Expansion | Present Capacity | Infrastructure Available for Expansion |
| Week | 100 | 50 | 50 | 25 | 60 | 30 | NA | NA |
| Month | 400 | 200 | 200 | 100 | 240 | 120 | 5 | 10 |
| Yearly | 4800 | 2400 | 2400 | 1200 | 2800 | 1440 | 60 | 120 |

## 6. Team Structure

| Table -1 Project Key Stake Holders' Team | | | | | |
|---|---|---|---|---|---|
| **Section** | **Name** | **Position** | **Role in project** | **Email id** | **Contact number** |
| *Operation Team* | | Business Development Officer | Handling new enquiries and Proposing proposal | | |
| | | Customer Support Cell Executive | Sample receipt and acknowledgement | | |
| | | Team Leader | One point contact for update on resources, specifications, status of upcoming project and ongoing projects | | |
| | | Manager-Project | In charge of techno commercial matters | | |
| | | Manager-Quality Assurance | Study report, Investigation | | |
| | | | | | |
| | | Senior Executive-Accounts | Invoicing, Proforma invoice, Remittance | | |
| *Escalation Team* | | Assistant General Manager | Techno-Commercial: Project | | |
| | | Senior Manager-Finance | Team Attitude -Administrator & Finance | | |
| | | Managing Director | Unethical Issues | | |

## 7. Communication plan - frequency calendar

| From | Task | Frequency Schedule | MIS Templates |
|---|---|---|---|
| Stabicon | Business development - Summary proposal status | 15 days | Refer Table No -1 |
| Stabicon | Post quote prerequisite summary for project execution | 15 days | Refer Table No -2 |
| Stabicon | Order book summary for invoicing | 30 days | Refer Table No -3 |
| Stabicon | Ongoing project status | 15 days | Refer Table No -4 |
| Client | Project forecast | 30 days | Refer Table No -5 |
| Stabicon | Non conformity | 15 days | Refer Table No -6 |
| Stabicon | Escalation operation review -skype/Telecom | 90 days | Refer Table No -7 |

# Communication plan - MIS Templates

| Table -1 Business Development - (Month) 2019 for (Client) | | | | | | |
|---|---|---|---|---|---|---|
| **Contact Person** | **Enquiry date** | **Feasibility** | **Quote submitted date** | **PO date** | **PO number** | **Date of execution** |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| Table -2 Post Quote Prerequisite summary for Project Execution | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Quote Number** | **Name of the Project** | **Type of Quote** | **Study Plan Document (Yes/NO)** | **Method Transfer (Yes/NO)** | **Placebo provided by Client (Yes/NO)** | **Standard to be provided from Stabicon/Client** | **Impurity to be provided from Stabicon/Client** | **Sample Estimate Date** | **Tracking Details** |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

| Table -3 Order Book Summary For Invoicing-(Month) 2019 for (Client) | | | | |
|---|---|---|---|---|
| Project type | PO number | PO value | Invoiced details | Balance/Open order |
| | | | | |
| | | | | |

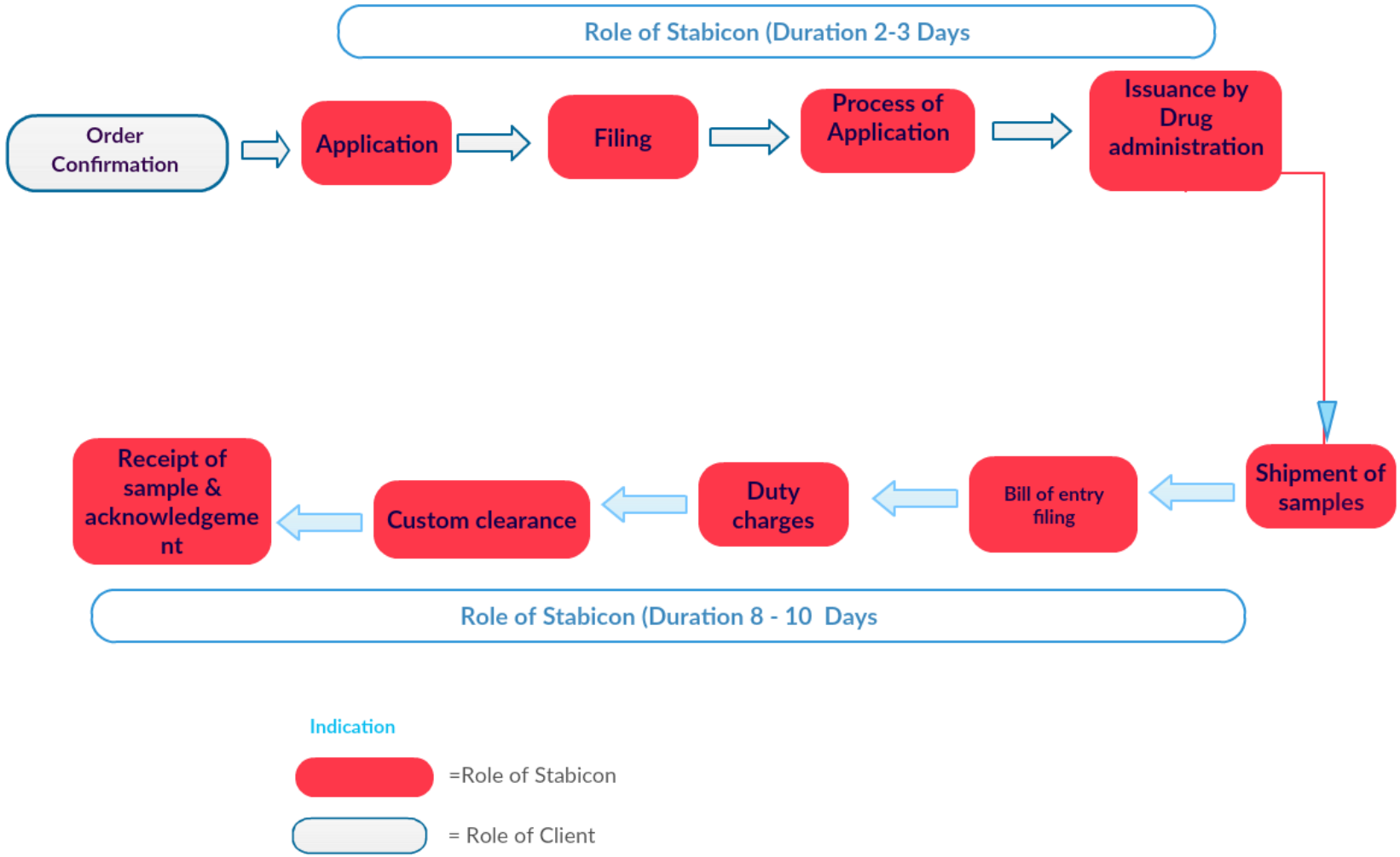
| Table -4 Project Report - (Month) 2019 for (Client) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| PO number | Name of project | No. of batches registered | Resources available | Resources to be procured (from vendor) | Resources to be arranged (from Client) | Analysis start date | Analysis completion date | COA release date |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

| Table -5 Project Forecast (Month) 2019 for (Client) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Plan | Project Name | Project Type | Status | Assignee From Client | Start Date From Client | End Date By Stabicon | Duration In Days | Comments |
| | | | | | | | | |
| | | | | | | | | |

| Table – 6 Nonconformity-(Month) 2019 for (Client) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Name of project | Batch number | AR Number | Non conformity type | Test parameter | Investigation report number | Next action | Conclusion |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| Table – 7 Escalation Team Review - (Month) 2019 for (Client) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Grievance for | Action Plan | Issue (Technical /Commercial) | Support by Stabicon | Support by Client | Skype date & Participants | Skype/Telecon Agenda | Next scheduled date for Skype/Telecon |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

## 8. Import Procedure - Overseas Health Samples



## 9.Training & Performance Management

Section 1: Auto Team Training Program

| Training SOP for Each Level | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Level | QC | | | | QA | | | | | AR & D | FR & D | IT | Automation | Invitro | HR | Finance | Account | Purchase | Project | CSC |
| | | | | | Issuance | | Monitoring | | Distribution | | | | | | | | | | | |
| | RS | SS | DY | Microbiology | AVR | Doc(OOS/OOT/SOP) | Audit | GLP | | | | | | | | | | | | |
| Manager | 145 | 86 | 90 | 125 | 95 | 15 | 07 | 11 | 72 | 148 | 110 | 30 | 90 | 105 | 15 | 25 | 12 | 12 | 85 | 70 |
| Asst.Manager | 135 | 69 | 71 | 101 | 71 | 09 | 04 | 08 | 60 | 132 | 96 | 25 | 74 | 83 | 10 | 17 | 07 | 08 | 70 | 64 |
| Sr. Team Leader | 122 | 48 | 57 | 87 | 62 | 05 | 02 | 05 | 55 | 122 | 80 | 20 | 57 | 70 | 07 | 10 | 04 | 04 | 63 | 57 |

## Section 2: Competency in Stabicon

| Competency in Stabicon | | | | | | | |
|---|---|---|---|---|---|---|---|
| SL. No | Department | Current Position | Name | No of year & specialization in Stabicon and Other | Duration of work in Stabicon | Current User | |
| | | | | | | HPLC | Non-HPLC |
| 1 | Quality Control | Manager | | 20 years experiences in the area of Quality Control and Analytical R&D in Drugs and pharmaceutical industry. Chemical, Instrumental testing in drugs & pharmaceutical and R&D, ISO / IEC 17025:2005 ,ISO 9001 WHO, and MHRA | 01 year 04 months | Yes | |
| 2 | | Asst. Manager | | 12 years experiences in the area of Quality Control in Pharmaceutical Industry. | 04 years 06 months | Yes | |
| 5 | | Team Leader | | 05.5 years experiences in the area of Quality Control in Pharmaceutical Industry. | 02 year 00 months | Yes | |
| 6 | | Executive | | 3 years experiences in the area of Quality Control in Pharmaceutical Industry. | 03 years 02 Months | Yes | |
| 10 | | Senior Officer | | 3 years experiences in R&D and Quality control in Pharmaceutical Industry | 01 year 03 months | Yes | |
| 15 | | Research Associate | | 10 months experiences in the area of Quality Control in Pharmaceutical Industry. | 10 Months | Yes | |
| 23 | | Officer | | 2.5 years experiences in the area of Quality Control in Pharmaceutical Industry. | 10 Months | Yes | |
| 29 | | Trainee | | Fresher | Fresher | | Yes |

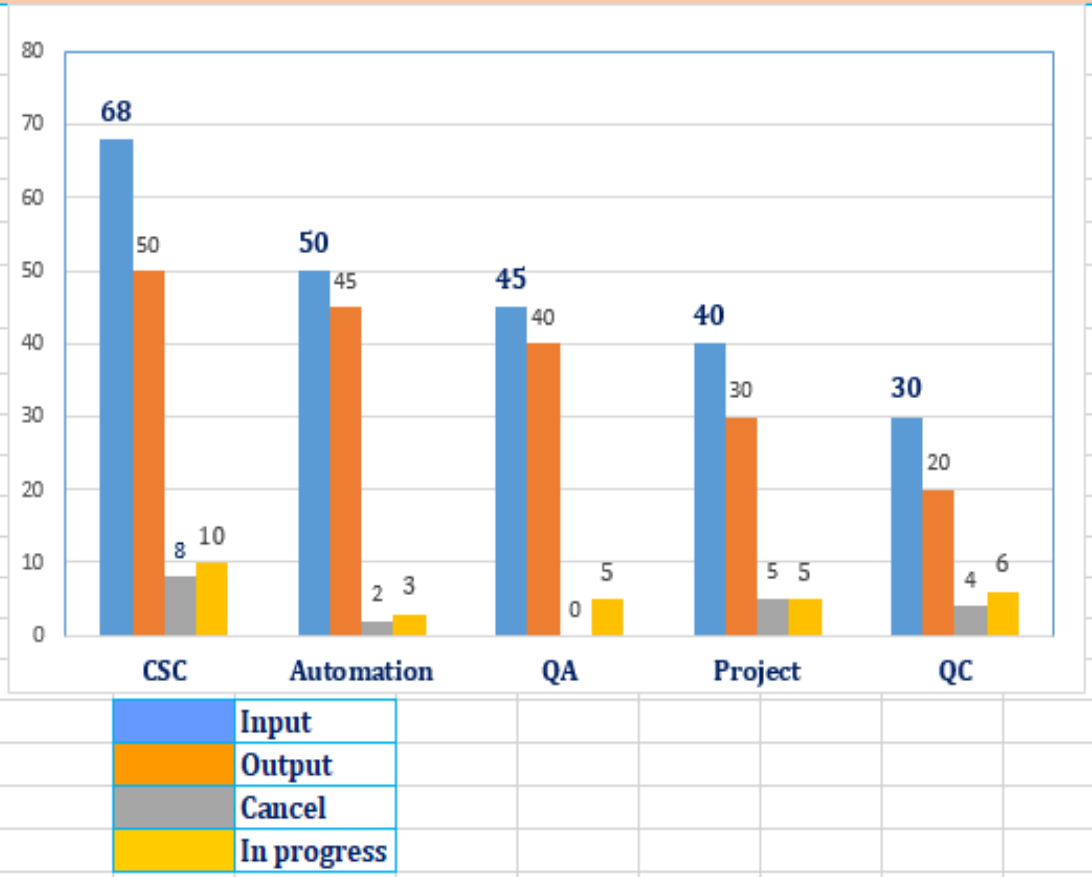
**Product Certification & Investigation Program**

## Section -3 Projects – Department KRA – KPI

### Stability Project

| Projects | Department Performance | | | | |
|---|---|---|---|---|---|
| | CSC | Automation | QA | Project | QC |
| Input | 68 | 50 | 45 | 40 | 30 |
| Output | 50 | 45 | 40 | 30 | 20 |
| Cancel/Hold | 8 | 2 | 0 | 5 | 4 |
| Inprogress | 10 | 3 | 5 | 5 | 6 |

### Graph of KRA - KPI




**Note : Data for example only**

## 10. Strength for our Alliance

- All process mapped & automated.
- All project process & training can be viewed online on each application software – complete transparency, traceable & easily accessible to various stakeholders globally.
- Complete transparency, traceable & easily accessible to various stakeholders globally.
- Centralized center for stability & method validation.
- Lean Management, Flexible to adapt for new technology & System.
- Synchronize operation as per global time zone.

## 11. Other Related Businesses:

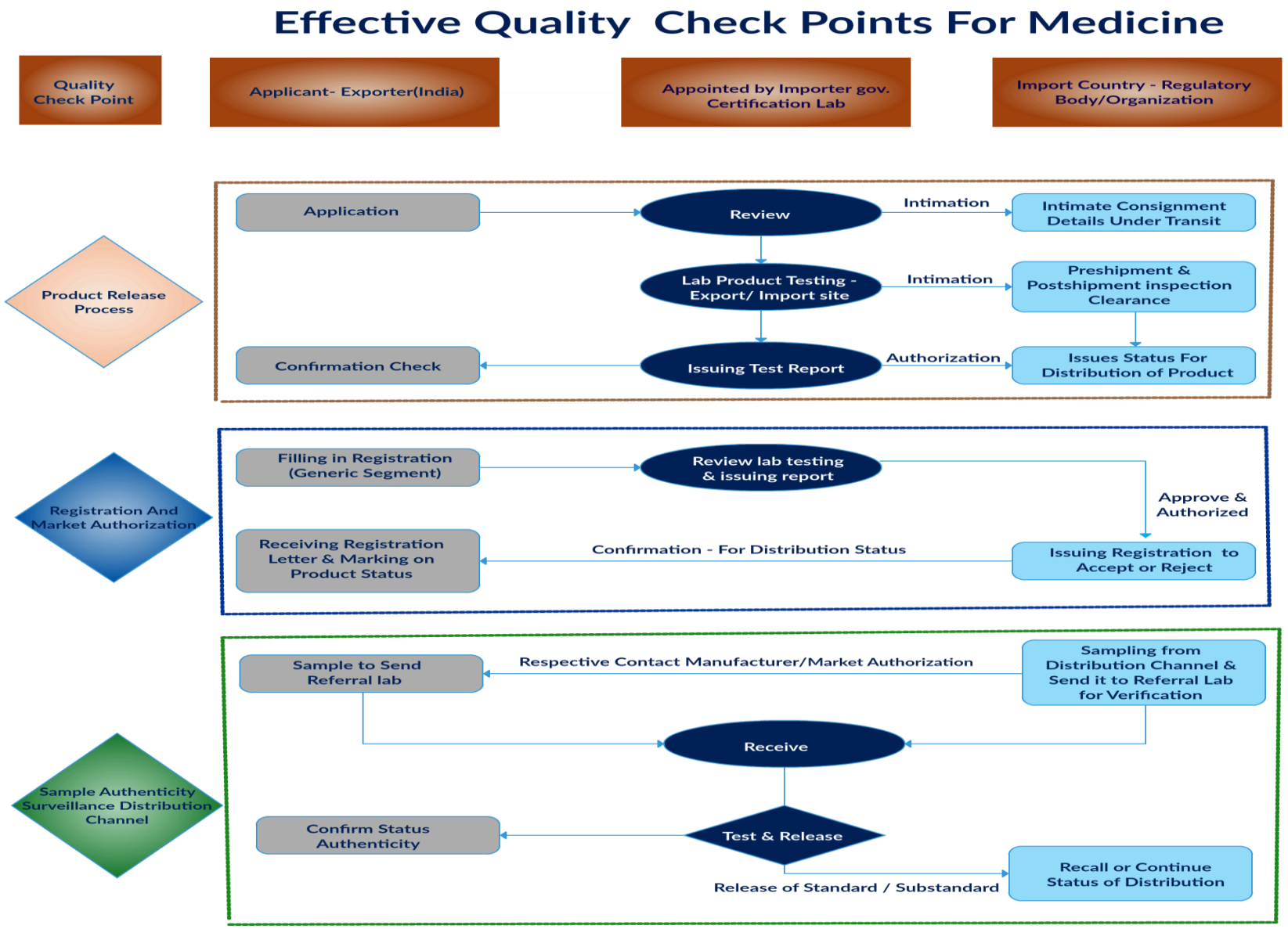
## Turnkey & Training Portfolio:

We provide concept-to-completion design laboratory for pharmaceutical industry. Our experts will understand your business, possess experience implementing best practices, and will leverage that expertise to enhance your lab's and R&D efficiency. Whether it's for research or routine testing, we can recommend and provide the right solution to address laboratory and development process challenges, helping you drive decisions, maximize resources, and increase productivity.

| Sl No | Capabilities |
|---|---|
| 1 | Needs Assessment |
| 2 | Process improvement |
| 3 | Complete automation of process |
| 4 | Plan and setting up operation centre |
| 5 | Multicentre integration process |
| 6 | Training programs Onsite & offsite Program |
| 7 | Expert Laboratory Personnel training |

## Referral Lab:

Poor medicine quality can sometimes lead to serious health consequence & death. Imported or Locally Manufactured Medicines without proper pre & post inspection may be rendered substandard at any point along the medical supply chain, from the point of manufacture through the point of distribution. Substandard medicines undermine governments' investments in health delivery systems. Regulatory body/ Organization Partnering with Stabicon support assist to can address the above challenges by following approaches


Effective Quality Check Points For Medicine
Quality Check Point
Applicant- Exporter(India)
Appointed by Importer gov. Certification Lab
Import Country - Regulatory Body/Organization
Product Release Process
Application
Review
Intimation
Intimate Consignment Details Under Transit
Lab Product Testing - Export/ Import site
Intimation
Preshipment & Postshipment inspection Clearance
Confirmation Check
Issuing Test Report
Authorization
Issues Status For Distribution of Product
Registration And Market Authorization
Filling in Registration (Generic Segment)
Review lab testing & issuing report
Approve & Authorized
Receiving Registration Letter & Marking on Product Status
Confirmation - For Distribution Status
Issuing Registration to Accept or Reject
Sample Authenticity Surveillance Distribution Channel
Sample to Send Referral lab
Respective Contact Manufacturer/Market Authorization
Sampling from Distribution Channel & Send it to Referral Lab for Verification
Receive
Confirm Status Authenticity
Test & Release
Release of Standard / Substandard
Recall or Continue Status of Distribution

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## For any queries /discussions, please contact us:

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Thank you