Stabicon Life Sciences Pvt. Ltd.

Corporate Presentation

Business Development Team

Year 2017

Overview

- Located in Bangalore, a Dedicated cGMP and cGLP Compliance Laboratory
- Established in September 2010
- Approved Contract research Organization by India FDA
- Approved by Health Canada since 2013
- Registered with USFDA & DSIR
- Managed by well experienced professionals from Multinational Companies and Contract research organization
- In the business of Formulation R&D, Invitro, Analytical Development, Validation & Stability Management Programs.

Management Team

Mr. Suresh Khanna **Founder Chairman**	❑ Over 35 years experience in the pharmaceuticals industry ❑ Set-up one of the largest contract manufacturing company in India and catering to customers like GSK Pharma, GSK Consumer, Novartis, J&J, Pfizer, Wyeth, etc….. ❑ Former member of the board of Millipore India ❑ Founder of KPO providing back-office regulatory services to MNC's in Europe
Mr. Vijay Kumar Ranka **Managing Director**	❑ Worked in area of transgenic using Micro-injection, Data curation in disease pathway identification, Bio-analysis, Impurity identification, Metabolite identification, Enzyme based assays, Characterization of biopharmaceuticals and Herbals marker identification. ❑ Past positions at NCBS, Jubilant Biosys, Synchron Research & Waters Corporation.

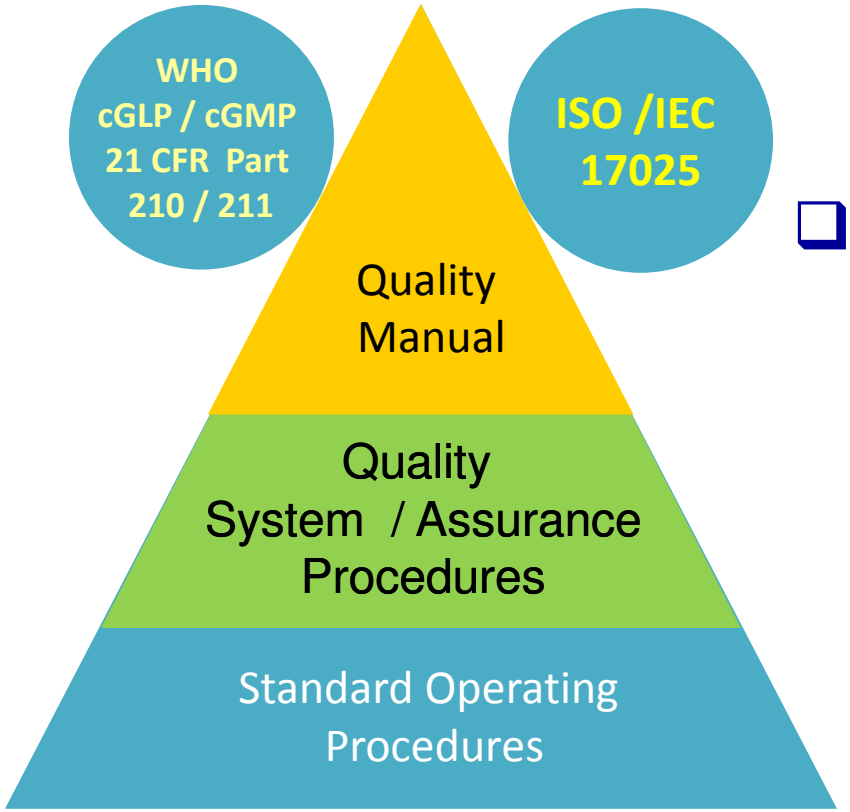
Regulatory Compliance Status

- Approved by Health Canada . Recently successful audited and awaiting for approval letter

- Accredited by NABL (National Accreditation Board for Testing & Calibration Laboratories) – India as per **ISO / IEC 17025:2005**

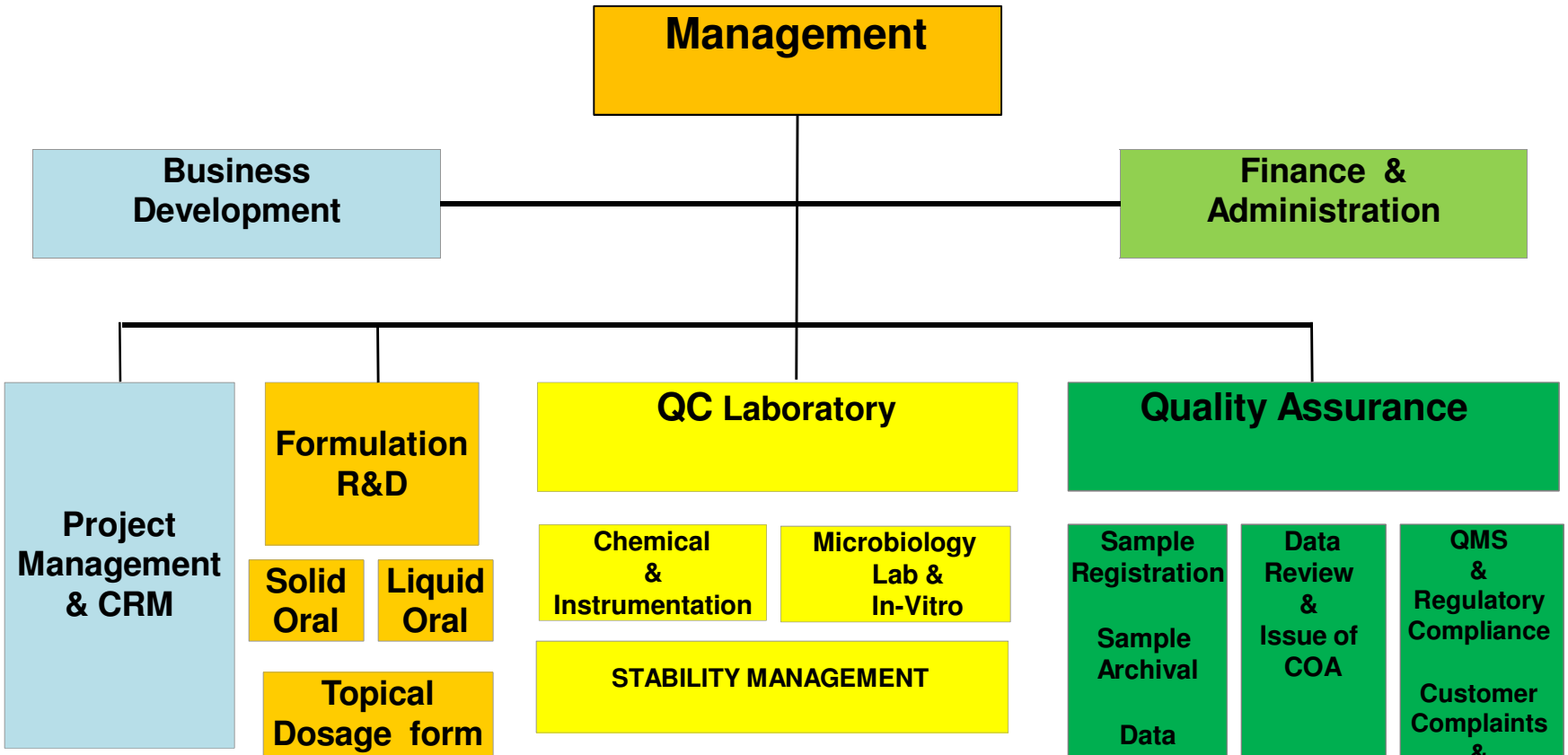
- Approved by **WHO, Geneva**; under Prequalification Medicine Program – Procedure for Assessing the Acceptability, in Principle of QC Laboratory

Quality Management System



- Quality Manual (QM) based on
  - ISO 17025 : 2005
  - WHO GPQCL
  - USFDA 21 CFR Part 210 / 211
  - MHRA / EMEA
  - Division – 2 of FDR, Health Canada
  - Our Quality Strategies
  - Our Businesses Process

Organogram


Management
Business Development
Finance & Administration
Project Management & CRM
Formulation R&D
Solid Oral
Liquid Oral
Topical Dosage form
QC Laboratory
Chemical & Instrumentation
Microbiology Lab & In-Vitro
STABILITY MANAGEMENT
Quality Assurance
Sample Registration
Sample Archival
Data Archival
Data Review & Issue of COA
QMS & Regulatory Compliance
Customer Complaints & Investigations

Facility Highlights

Independent building,

4 levels,

18,000 sq. ft.

Built-up area

Dedicated Facility for

Formulation Development

(Tablets, Capsules, Liquid Orals,etc..)

Segregated facilities for

Instrumentation,

Wet Chemistry,

Microbiology.

Stability Project Management

Captive Power Generation & Support

Fully Compliant with EHS Regulations

Product Development - Highlights

- Development & business Strategy
- Project Timelines and mile stones monitoring
- Administrative licensing activities
- API / Excipient / Packing materials sourcing and vendor screening
- Patent non infringement for formulation
- Formulation trials for robust composition as per QbD.
- Scale up and process optimization and stability
- Quality risk assessment and Quality attributes
- Process Validation
- Dossier documentation as per CTD requirements
- Customer communication and building transparency, confidence and buoyancy

Laboratory Highlights

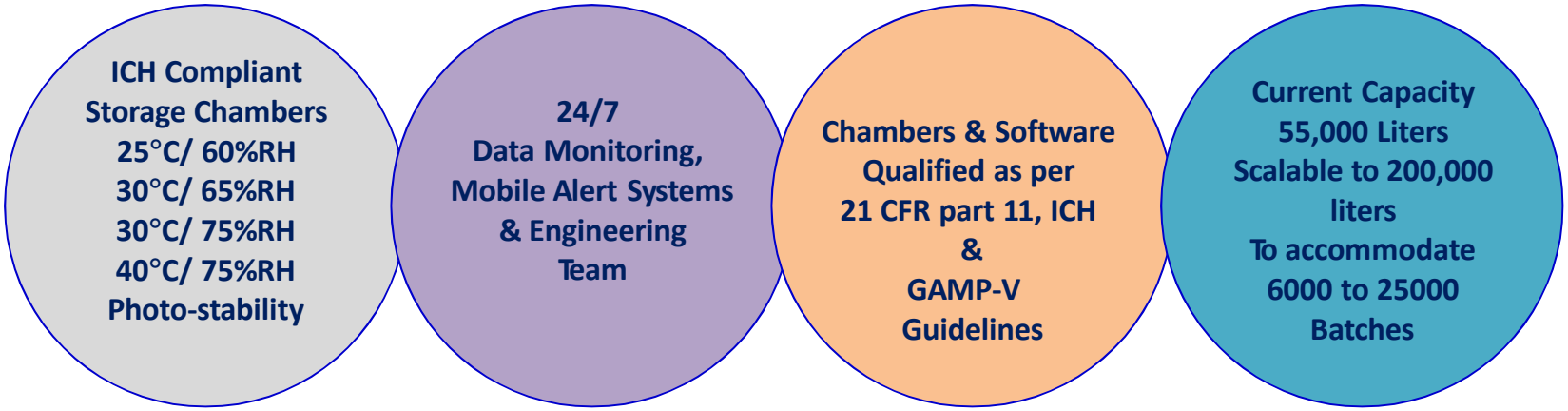
- Stability Projects are monitored & maintained using Validated LIMS Software
- HPLCs & UPLC are on Central Net-working Software in compliance with 21 CFR Part 11
- Stability Chambers & Incubators Data Monitoring using validated ICDAS Software
- All Analytical Equipment data back-up done periodically on Dedicated Server
- RO Water Purification System
- Access Control Systems
- Fire Alarm Systems
- Smoke Detection Systems

Laboratory Services Offered

- Stability Programs
- Analytical Development & Validation
- Bio-waiver Studies (Comparative Dissolution Profiles)
- Invitro Bio Equivalent studies
- Quality Control Testing
- Microbiological Testing
- Sterility Testing closed system (Isolator integrated with sterility test pump Millipore)

Stability Programs

- Long-term Stability Studies
- Accelerated Studies
- Photo-stability Testing
- Zone IV Conditions
- Freeze Thaw Stability
- Customized Study



Stability Programs

We undertake Stability Programs of

- R&D & Pilot Batches
- Process Optimization Batches
- Validation Batches
- Follow-up Batches
- Commercial Batches
- On-Going Batches

Method Development & Validation

- Verification of Accuracy & Adoptability of the Developed Method
- Development & Validation of Stability Indicating Methods
- Analytical Method Transfers
- Re-validations / Partial Validations As Per Customer Requirement
- As per requirements of ICH, USFDA, MHRA, MCC, WHO, ANVISA, etc..
- **Method Development & Validations for**
  - **Assay**
  - **Dissolution**
  - **Uniformity of Content**
  - **Related Substances**
  - **Degradation Products**
  - **Identification**
  - **Purity**
  - **Preservatives**
  - **Anti-oxidants**
  - **Colourants**

Biowaiver Studies

- Development of Discriminating Dissolution Methods
- Performing CDPs as per various Regulatory Requirements like WHO, USFDA, MHRA, TGA, MCC, ANVISA, etc…
- Conclusions based on Classification of Drug Molecules
- F1 / F2 calculations for acceptability of Bio-waivers

Pre-Despatch QC Testing

- Raw Materials (Exceipients / APIs)
- Oral Solid Dosage Forms
- Oral Liquid Dosage Forms
- Ointments / Creams / Gels / Soft Gels
- Sterile Products
- Ophthalmic Products
- Cosmetics Controlled By FDA
- Pharmaceutical Water Analysis




Microbiology

- Validation of Microbiological Tests
- Bio-burden Tests
- Bacterial Endotoxins by LAL
- Antibiotic Assay
- Preservative Efficacy Testing
- Efficacy Testing of Antibiotic Activity
- Efficacy of Chemical Disinfectants
- Environmental Monitoring





In-vitro Bioequivalence

In-Vitro Bioequivalence studies for following areas, but not limited to it. It is always open to discuss to new approaches and new challenges.

- In-vitro Binding Studies for Locally acting GI Resin Drugs
- Oral Generic Product with An Alternate Administration
- In-Vitro Quantitative Capsule Rupture Test (QCRT)

Clientele

Customer from Pharmaceutical industry & Health organization from highly regulated markets like USA, Canada, UK, EU Countries & South Africa.

a) South Korea,Russian, CIS, Middle East & Developing countries

- Approved by leading generic pharmaceutical and MNC's

Why Stabicon ?

- Conceptualized Project Management
- Robust Regulatory Documentation
- Assured Confidentiality on Product Technology & Data
- Well Experienced Professionals who add value to your thought process by understanding your needs during Product Development, Validations and Dossier Registration till receipt of MA
- We deliver to International Quality Standards at Competitive costs
- Open for Transparency like Data interface through Web-access

Thanks

For any query, Please contact us

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