CRAMSN Research Park

Delivering Excellence, Driven by Science

Dr. Manne Satyanarayana Reddy
Founder & Managing Director of MSN Group of Cos

"To serve the world by bringing affordable medicines within everyone's reach"

A One-Stop-Shop CRO & CDMO Solutions Partner for your Chemistry Needs

About CRAMSN Research Park

CRAMSN is a One-Stop-Shop CRO and CDMO service partner enabling pharmaceuticals, and consumer health companies **to accelerate drug development and delivery**.

Unlike many Service providers, CRAMSN differentiates its services by having expert capability in all areas to deliver affordable medicines to end patients **with high quality, speed and agility.**

Vision:

To be the **"Supplier of Choice"** :

- With **End-To-End Integrated** R&D and Manufacturing solutions delivered seamlessly, affordably and ethically
- To help our customers to **transform** their R&D operations with interactive, mobility and data
- To provide **accelerated value** to customers as a service

Business Model:

CRAMSN will be your **'Strategic Service Partner**' to support by providing Innovative and Novel chemistry solutions from Drug Discovery phase to Commercial phase.

CRAMSN ADVANTAGE

- Diversified expertise in Conventional, Complex & Niche Chemistries
- World class R&D centre and Huge manufacturing base
- Dedicated manufacturing facilities to handle high potent molecules
- Crystallization studies for Polymorph, Salts & Co- crystal screening
- Regulatory Compliance & support
- Digitally driven advanced tools & technologies
- Strong associations & wide client base
- Quality & On-time Deliverables
- Financial Stability

Global Regions:

We are based in the US, and the UK with Headquarters at India

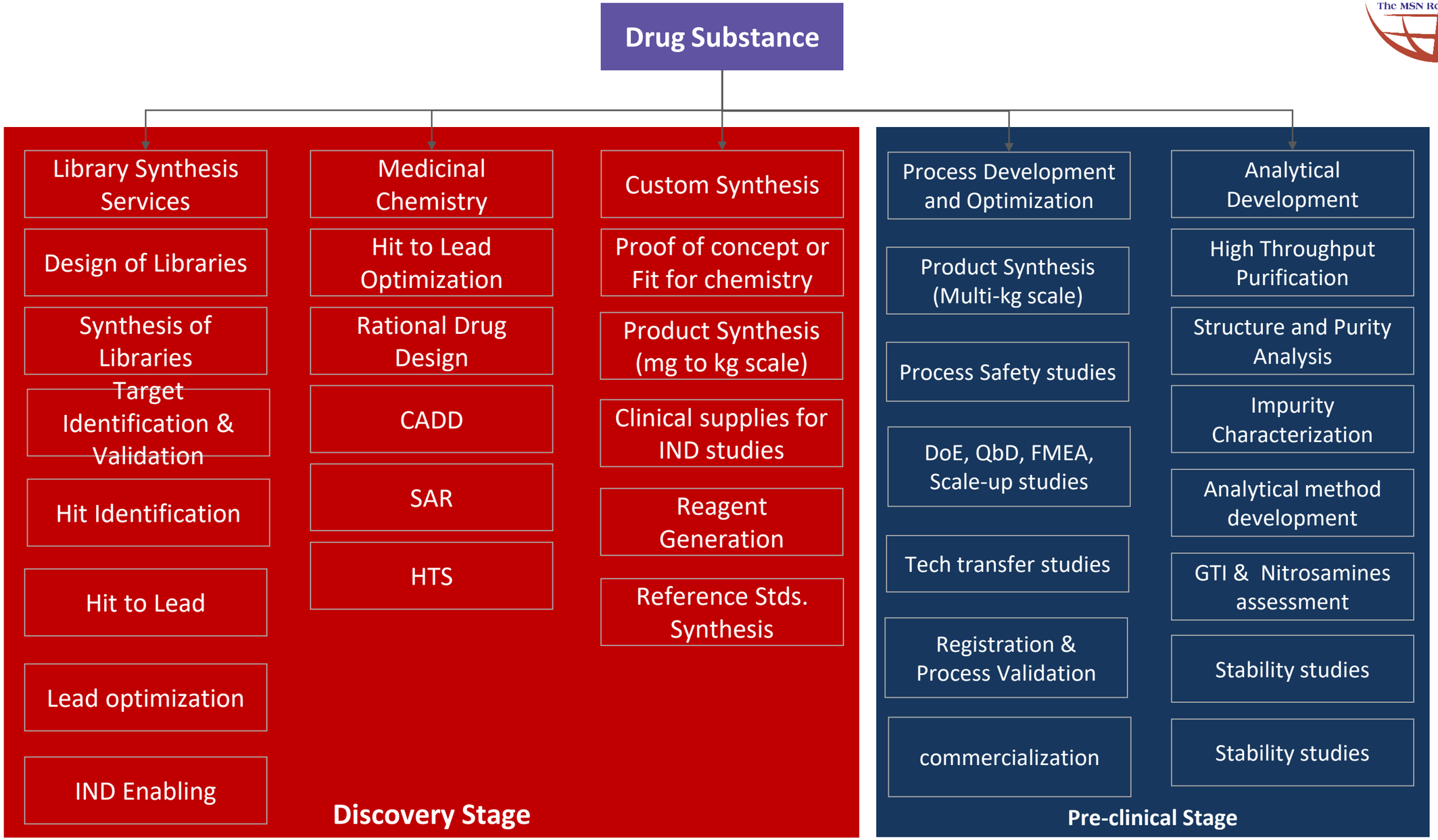
CRAMSN Solutions

- Route scouting
- Synthesis & Supply of preclinical quantities
- Hit to lead
- Library generation
- Milligrams to grams supply
- Lead optimization activity
- Synthesis and Supply of cGMP quantities for clinical studies
- IND enabling

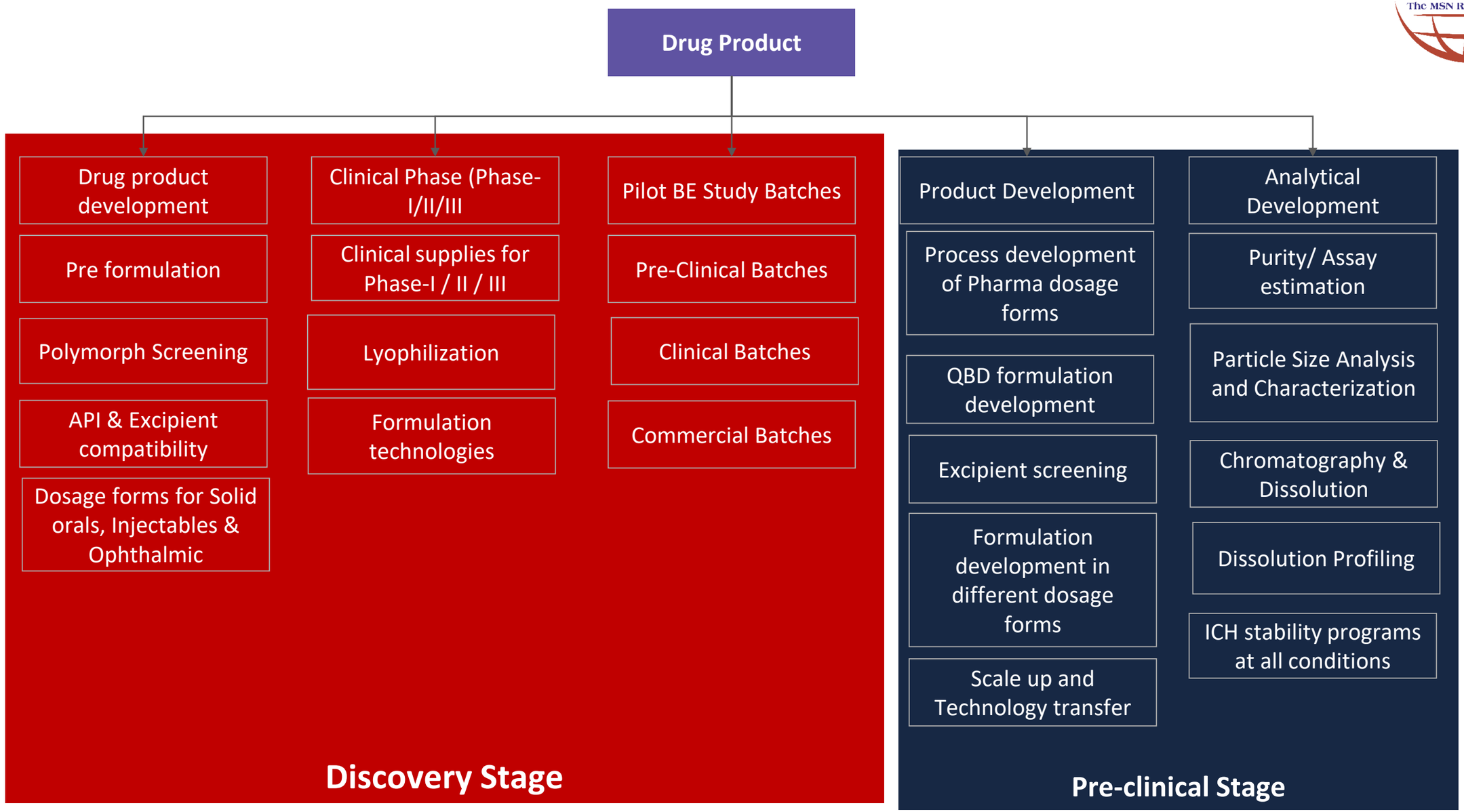
- Route assessments –CPR&D
- Process Feasibility/ Familiarization
- Process Optimization
- Management of Impurities
- Process engineering & Safety studies
- DOE & QbD Studies
- Salt &polymorph screening
- Technology Transfers
- Manufacturing of Target Compounds

- Technology Transfers
- Process familiarization & equipment suitability studies
- Commercial manufacturing up to multi MT scale
- Manufacturing units with FDA and other regulatory accreditations
- Project life cycle management support
- Address regulatory queries, I any

CRAMSN CRO & CDMO Solutions



CRAMSN CRO & CDMO Solutions



CRAMSN – R&D / AR&D Infrastructure and Capabilities

Scientific pool from reputed institutions

Expertise in > 35 therapeutic areas

Cost-effective & ecofriendly processes

Facility spread in 184,000 SFT (G+3 floors)

40 synthetic labs & 350 Fume Hoods

Standalone Analytical Services

Analytical Method development, and validations

AR&D spread over 45,000 SFT

CRAMSN
The MSN Research Park

DEDICATED LABORATORIES FOR

- Labelled Compounds
- Flow Chemistry Platforms
- Pol. Screening & Solid state Char.
- Peptides and Oligonucleotides
- Iron – Carbohydrate complexes
- Bio-catalysis
- HPAPIs/ Prostaglandins
- Process Safety & Engineering

MANUFACTURING - OVERVIEW

1 R&D Center	7 FDF Units	15 API Units

State-of-the-art & fully-integrated facilities

Kilo Lab – Infra To Supply Materials For Clinical Studies

cGMP kilo-lab for small scale projects (up to 10kg):

- ✓ Total reactors: 12
- ✓ Reactors range: 5L to 100L
- ✓ Clean room: All glass reactor set-up (class 100,000 area)
- ✓ Upstream & Downstream equipment
- ✓ Supply of cGMP material for clinical studies (grams to multi kilograms level)
- ✓ Synthesis and supply of Non-GMP material for preclinical studies (millgrams to 100s of grams)
- ✓ Scale-up studies and data generation
- ✓ Stability studies and packing conditions
- ✓ Addressing Polymorphism and solid state characteristics

API CAPACITIES

- Expansive manufacturing infrastructure
- Capability to deliver from grams to tonnes

2400
Reactors

10,000kl
Total Volume

1500+
MT / Annum

KILO LAB (R&D)

30
Reactors

5kl
Total Volume

FDF CAPACITIES (PER ANNUM)

Tablets **~ 12 Billion**	**Capsules** **~ 2.0 Billion**
Sachets **~ 100 Mn.**	**Parenterals** **~ 40 Mn.** (Lyo & Liquids)
Oral Suspensions **~ 7.0 Mn.**	**Granules** **~ 100 Tons**

CRAMSN – Manufacturing Strengths and Capabilities

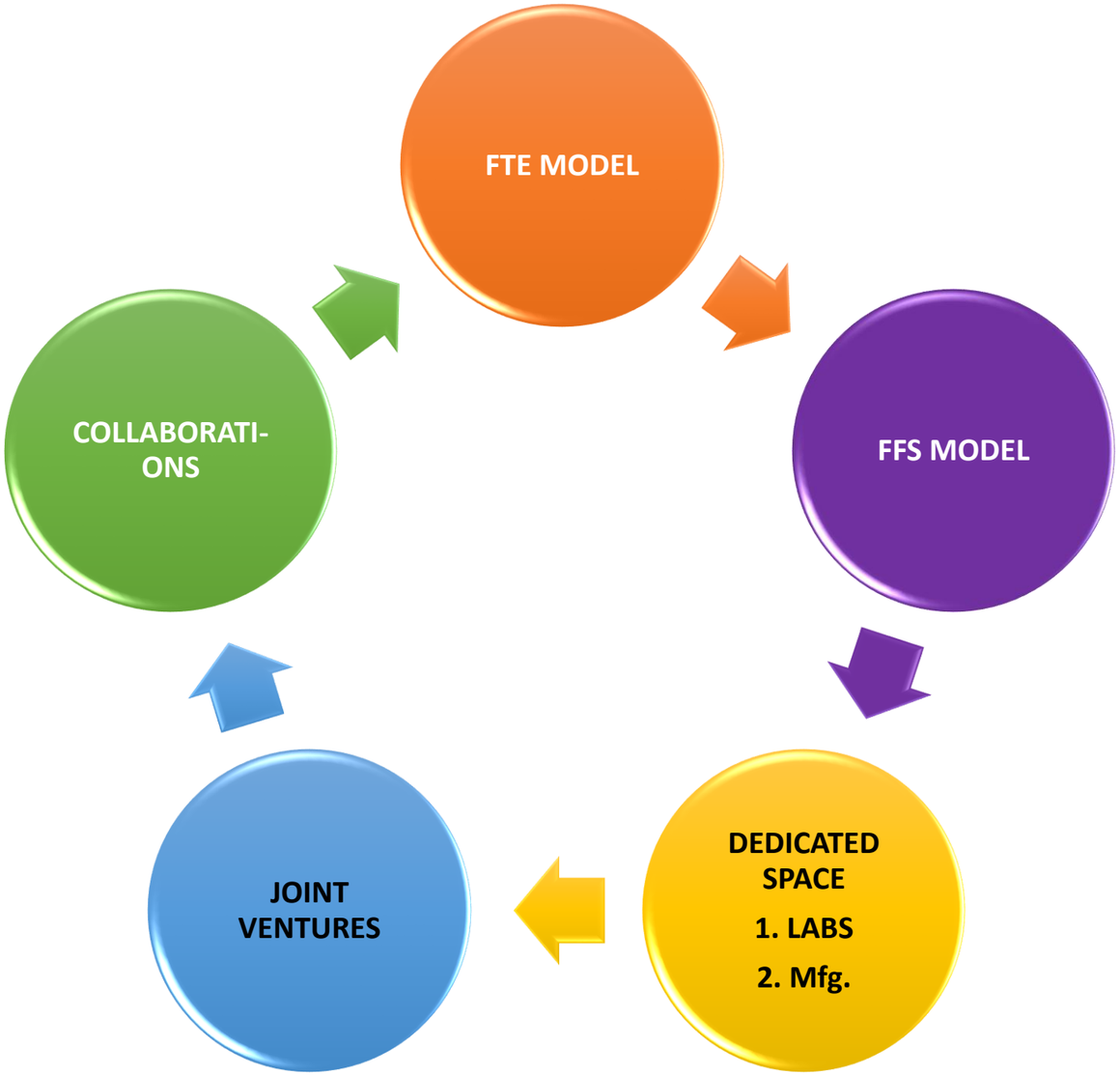
Manufacturing Strengths

- 15 API mfg. facilities with 10000 KL reactor volume
- Audited by FDA & other with zero observations
- Highly Skilled staff to handle Varieties of Chemistries
- Major reactions established on 100s of kilos
- Commercial scale process validations for various projects
- Two dedicated facilities to handle HPAPIs (up to 0.1 µg/m^3)

Engineering , Safety, Quality and Regulatory

- Customize Equipment prior to scale-up
- Particle engineering for consistent polymorph
- Strictly adhering to the EHS recommendations
- Following cGMP practices
- Facilities & people are in compliance with quality policies
- Address & resolve regulatory queries, if any

Business Models



- **Confidentiality:** CRAMSN respects the CDA with its customers and thus, all communications & information will be treated as confidential.
- **IP:** All information/ technology developed because of the foregoing work shall be the property of customer and is part of the CDA.

FACILITY AUDITS & CERTIFICATIONS

Country	Agency	Month of Inspection	Mfg. Block
ZAZIBONA	MOH	Mar.2018	C
Zimbabwe	MCAZ	Jun.2019	D
Gulf Health Council	GHC	Jun.2019	C & D
PERU	DIGEMID	Aug.2019	C & D
Hungary	NIP	Dec.2019	C & D (OSD)
Malta	MMA	Dec.2023	C, D & G (OSDs)
Slovakia	SUKL	Aug.2021	C & G (Sterile)
Russia	SIDGP	Jul.2022 #	D
Korea	KFDA	Feb.2022 #	C
EEU (Eurasian Economic Union)	EECC	Feb-Mar.2023	Entire Site
Taiwan	TFDA	Mar.2023	C & D
Chile	Chile ISP	Aug.2023	Entire Site
YEMEN	YMOH	Nov.2023	Entire Site

 # Desktop Audit

FACILITY AUDITS & CERTIFICATIONS

Country	Agency		Month of Inspection	Mfg. Block
USA		USFDA	Feb.2015, Feb.2016, July.2017 & Mar.2019	D
			Jan-Feb 2017 & Feb 2018	C
			Nov.2019	C & D
			Dec.2023	Entire Site
Germany		BGV	Mar.2016	C & D
Brazil		ANVISA	Jun.2016	C
Nepal		MOH	Jul.2016	C
Kenya		MOH	Sep.2016	C & D
Tanzania		TFDA	Dec.2016	C & D
WHO-GENEVA		WHO	Mar.2017 & May.2020 #	D
Czech Republic		SIDC	Apr.2017	C & D
UK		MHRA	Apr.2017 & Jul.2019	C (Sterile)
Uganda		UNCST	Jun.2017	C & D

FACILITY AUDITS & CERTIFICATIONS (Latest year of Audits)

Country	Agency	Month of Inspection	Mfg. Block
DESKTOP & VIRTUAL INSPECTIONS			
WHO-GENEVA	WHO	May. 2020 #	D
Philippines	RPHD	Jun. 2021 #	C & D
USA	US FDA	Sep. - Nov. 2020 #	D (PAI)
USA	US FDA	Mar. - Apr. 2021 #	D (PAI)
USA	US FDA	Mar. - Apr. 2021 #	G (PAI)
USA	US FDA	Jul. 2021 *	C (PAI)
USA	US FDA	Nov. 2022 *	C (PAI)
USA	US FDA	Sep. 2023 *	C (PAI)
USA	US FDA	Nov. 2023 #	D (PAI)
# Desktop Inspection	**** Virtual Inspection***		

Supporting Services

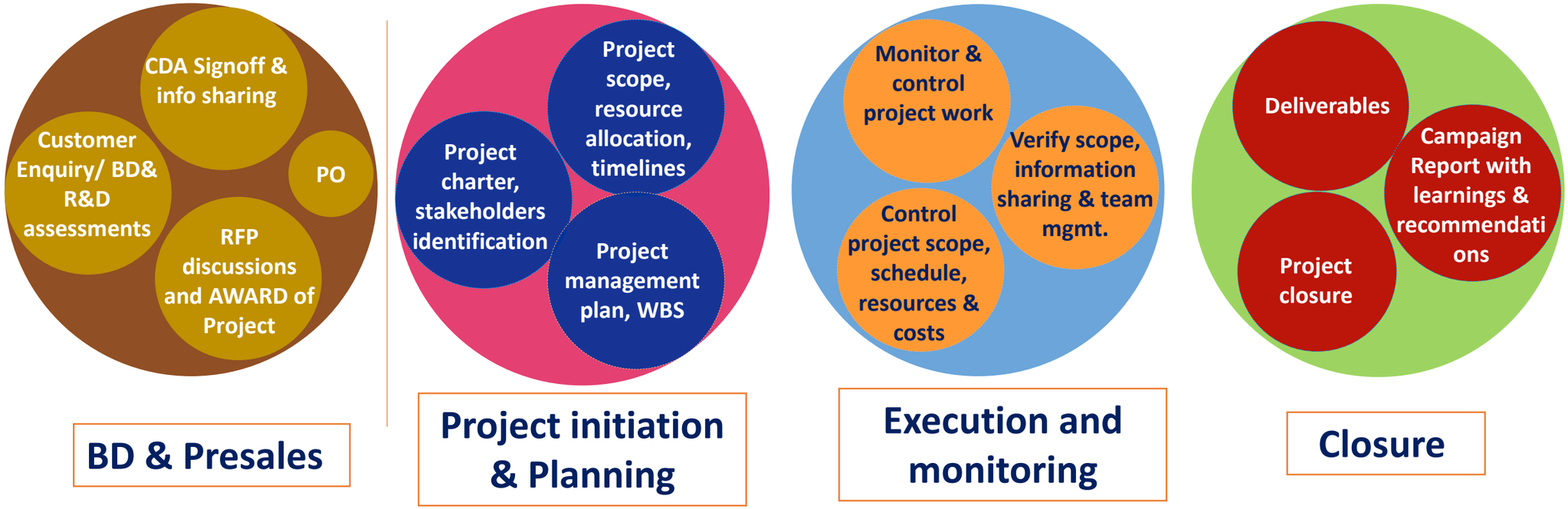
- Identification & mitigation of risks
- Process Hazard Assessment (PHA)
- HAZOP studies
- Promote Green Chemistry
- Ensure minimum disposal of hazardous waste
- Improve the carbon foot-print

- Process safety studies (RC1, DSC, TSU etc.)
- Process simulation study
- Equipment selection & mapping
- Support & execute scale-up / manufacturing campaigns

- Identification of reliable, cost-effective vendors
- Explore domestic vendors to avoid external dependency
- Strategic sourcing

- Compilation & review of documents with customer
- Document controls and archiving
- Ensure development as per guidelines and Tech transfers
- Analysis & release of raw materials & intermediates
- Method transfer & validations

Project Management



1) Implementing multiple gate ways at each stage of execution to control the project timelines
2) PM team and Marketing team are single point contact for all communications and activities

Our People – Our Strength

100+ employees with MSc / PhD / Engineering / Technical capabilities

Our utmost priority is to meet customers **ESG goals** by reducing greenhouse gas emissions

"**People** First" approach

CRAMSN Environmental and Social Governance

CRAMSN are commited to:

- Embracing green technologies & eco-friendly processes
- Ensuring 50% green cover at all manufacturing units
- Zero discharge facilities
- Efficient hazardous waste management systems
- Solar Power for a sustainable future
- Encouraging Community Afforestation Measures
- Community Health Initiatives
  - Distribution of free diabetes kits globally
  - Manufacture of Orphan Drugs at zero profit
- Community Empowerment Initiatives
  - Education
  - Infrastructure Projects – Roads and Water

Thank you

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