



An Introduction



Vision-Mission

“Grow by assisting the clients in attaining a competitive advantage by delivering quality Products & Services of unmatched value for any size of Pharmaceutical Companies globally.”

Sushen Medicamentos Pvt. Ltd.

Corporate Office & R&D Center

Ahmedabad-Gujarat-**INDIA**

CIS Office

Tashkent-**UZBEKISTAN**

Directors

Kaushik Shah

B.Pharm, MBA

Deepak Kulabkar

BSc. MBA(International Marketing)

Company promoted by highly qualified,
well experienced International
pharmaceutical experts

Technical Team of People

- PhDs
- M. Pharms & B. Pharms - Experts in
 - Manufacturing & Projects
 - QA & QC
 - F&D
- Chemists-Experts in QC
- Engineers –Experts in
 - Project, Maintenance & Design
- Designers- Experts in AutoCAD and Solid works
- Service Technicians
- Experts in Management & Finance



Collective team experience of >2 decades

Shop floor management

Manufacturing & Maintenance of
Formulations / APIs

Project management for pharmaceuticals

International audits

Faced numerous International
audits (GMP)

Product registrations



Pharmaceutical Services

Pharmaceutical Turnkey Projects

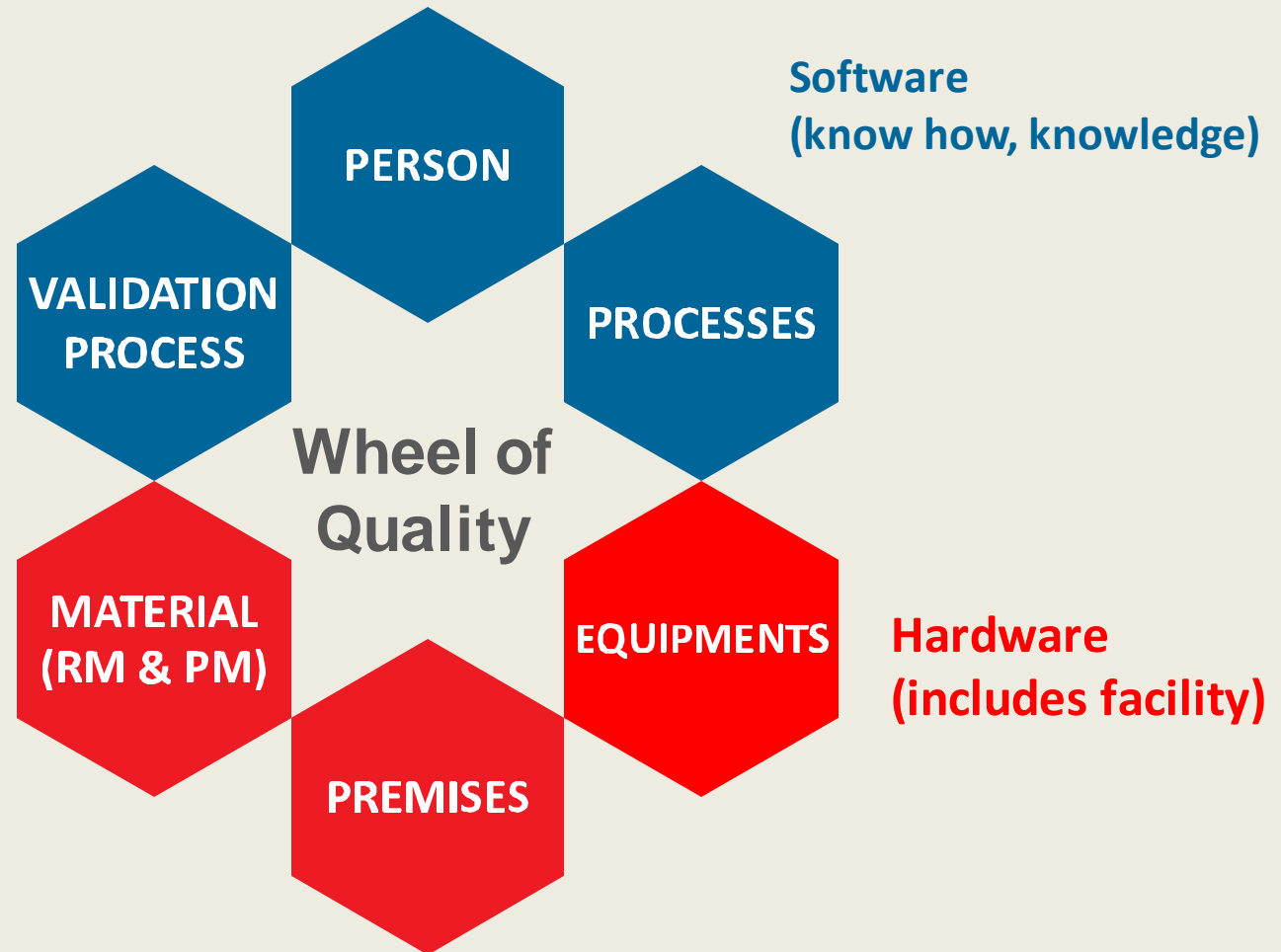
- Concept to Commissioning
- Design & Consultancy

Contract Research Activities

- Formulation & Development (FnD)
- Other Pharmaceutical Services
 - Analytical Services
 - Stability Studies Management



Any Pharmaceutical Business . . .





SUSHEN

The Project Management Company



Sushen - Project Implementation

1. Conceptualization
2. Designing
3. Procurement
4. Construction/Installation
5. Commissioning
6. Validation
7. Commercial Production

Step-1 Conceptualization

- **Product:** What?
- **Capacity:** How much?
- **Quality:** Type/Specifications (Product), Process, Facility, cGMP norms.....
- **Aesthetics**



Step-2 Project feasibility study

- Estimate the Cost of project-(Approximate)
- Market study and data analysis
- Estimates for manufacturing cost
- Profitability study
- Sensitivity analysis
- Risk analysis



Step-3 Data Compilation

- Study & finalize the Mfg. Process
 - Process flow charts ■ ■
 - List of equipments & their specifications
- Various Utilities required
- Space required ■



Step-4 Preliminary design

Prepare Preliminary design of plant

- Prepare various options
- Evaluate
- Zero upon a layout

- Personnel Flow
- Material Flow
- Site Layout



Step-5 Detailed designing

Civil

- Prepare detailed layout, model, drawings
- Structural Designs (Done locally)



Step-5 Detailed designing

Mechanical Engineering

- HVAC ■ ■ ■
- Prepare P & ID ■
- Prepare BOM ■



Step-5 Detailed designing

Electrical

- Prepare SLD (detailed Engineering Drawings) ■
- Prepare BOM



Our Approach to the project...(cont.)

- Step-6 Procurement
- Step-7 Commissioning
- Step-8 Validation
- Step-9 Commercial Production

Modular Clean Rooms **Sandwich Panels & Partition**

Top and Bottom Profiles are of Aluminum to avoid Rusting and have Long-term Durability

Demountable / Re-locatable. (Facility can be Dismantled and Shifted easily without Damage or Loss of Modules or Components)

Sheet Metal and Aluminum Profiles with Flush & Coved Powder Coated Panels does not allow Micro-organisms Growth.



Flush Doors

All Standard Door Frames are of Aluminum Profile Exclusively Provided to avoid Rusting and due to Special Design in Aluminum Profile for the Fitment of Rubber Gasket which Results Proper Sealing and Air Tightness of the Door.

All Doors are Insulated with Polyurethane / Rock Wool Insulation and as per Customer Requirement.



Vision Panels

Clean Room Application which is suitable for Masonry Walls and is flushed on one side of the wall.

The Smooth Surface of the Vision Panels ensures Cleanliness, Hygiene, Stability and Attractive Appearance.

We Develop and Prefabricate each Vision Panel to fit Customer Specific Requirements.



Walk On Ceiling



HVAC Application

Common problems of a wrongly designed cleanroom HVAC System:-

- Insufficient airflow
- Inadequate laminarity
- Fail to pressurize to specified pressure level
- Too high noise
- Temperature / Humidity variation



What can HVAC do?

- Control airborne particles, dust & micro-organism
- Maintain room pressure / temperature / Humidity
- Cleanliness & noise control
- Chemical exhaust
- Uniformity

Water Treatment Plant



Sr. No.	Name	Country	Project Detail
1	Core Pharmsnoat Limited	Uzbekistan	Project 1:- LVP (100-500ml) (WHO-GMP Geneva) Project 2:- Tablets & Capsules (WHO-GMP Geneva)
2	Nov o Pharma A Plus	Uzbekistan	Project 1:- SVP (1-10ml) (WHO-GMP Geneva) Project 2:- Tablets & Capsules (WHO-GMP Geneva)
3	Quick Stop – United Kingdom	Uzbekistan	LVP (100-500ml) (WHO-GMP Geneva)
4	Timur Med Farm	Uzbekistan	Project-1:- LVP (100-500ml) (WHO-GMP) Project-2:- Tablet & Capsules (WHO-GMP) FnD : 5 Products Technology Transfer
5	Sir Universal	Uzbekistan	Ampoule Injection (WHO-GMP)
6	Benta SAL	Lebanon	Project-1:- Pre-Filled Syringes 91-3ml) (USFDA Plant) Project-2:- Oral Liquid, Tablets & capsules (USFDA Plant)
7	TBK Nika Pharm	Uzbekistan	Tablet, Capsules & ORS Powder (6-30gm) (WHO-GMP Geneva) FnD : 2 Products with
8	Ayrton Drugs	Ghana	Oral Liquid & Tablets (WHO-GMP Geneva)
9	Industrial Chemical Laboratory	Ghana	Oral Liquid, Tablets & Capsules (WHO-GMP Geneva)
10	Kama Group Of Companies	Ghana	Oral Liquid (WHO-GMP Geneva)

Sr. No.	Name	Country	Project Detail
11	Tobinco Pharmaceuticals Ltd	Ghana	Project 1:- Beta Lactum:- Dry Syrup Powder, Tablet & Capsule Project 2:- Non Beta Lactum:- Tab/Cap/Liquid/Ointment/Powder Both (WHO-GMP Geneva) FnD : 2 Products with Technology Transfer
12	Fidson Healthcare PLC	Nigeria	LVP, Tablets, Capsules & Oral Liquids (WHO-GMP Geneva)
13	Emzor Pharmaceuticals Ltd	Nigeria	IV Fluids Injectable (WHO-GMP Geneva)
14	DHG Pharma	Vietnam	Technology Transfer (FND)
15	Oman Pharmaceutical Ltd	Ghana	FnD : 4 products Technology Transfer
16	DHG	Ghana	FnD : 4 Products with Technology Transfer
17	Institute of Chemical Pure Substance (ICPS)	Uzbekistan	Extraction plant (20 Products)
18	Universal Corporation Ltd	Kenya	Project I. Two (2) Product Development with Technology Transfer. Project II. Five (5) product development with Technology Transfer
17	Aram Kimya	Iran	SVP & LVP (WHO-GMP)
19	Zeera Group Of Companies	Ghana	Non Beta Lactam :- Liquid, Dry Syrup, Tablets, Capsules, Ophthalmics Eye Drops & Ointment, Sachets. (WHO-GMP Geneva)

Sr. No.	Name	Country	Project Detail
20	Kokand Pharmaceuticals LLC	Uzbekistan	IV Fluids Injectable (WHO-GMP Geneva)
21	MSJI Pharma	Sri Lanka	Upgradation to WHO-GMP & Validation & Design facility.
22	NPPL	Sri Lanka	SVP (Dry Powder Injection) (WHO-GMP/PICs) & GMP services for Documentation (SOP)
23	Montage Pharmaceuticals Pvt. Ltd	India	Project I. SVP (Injection vials) (WHO-GMP) Project II. Hormones
24	Swiss Sterile Pvt. Ltd	India	Vials & Ampoules (WHO –GMP)
25	State Pharmaceuticals Manufacturing Corporation of Sri Lanka	Sri Lanka	WHO-GMP Audit
26	Renown Pharmaceuticals Ltd	INDIA	Non Beta Lactam-Tablets, Capsules, Dry Syrup & ORS (WHO-GMP)
27	Soxa Formulations And Research Pvt. Ltd.	INDIA	WHO-GMP
28	Union Pharmaceutique Constantinoise	Algeria	3 Product Development with Technology Transfer
29	Bochem Parenterals Pvt. Ltd	India	LVP & SVP – WHO-GMP/PICs
30	Sami Pharma	Pakistan	Designing services for SVP, LVP Dry Powder Suspension, Topical Preparation & Tablets (In Process)

Sr. No.	Name	Country	Project Detail
31	Amico Laboratories Limited	Bangladesh	Project : Designing & GMP Services For Non Beta General Products
32	Bio Pharm	Algeria	FnD : 1 Product with Technology Transfer
33	Theramaf	Algeria	FnD : 8 Products with Technology Transfer
34	Saiph	Tunisia	FnD : 1 Product with Tech Transfer



SUSHEN

Pharmaceutical Services



Sushen – Pharmaceutical Services

- 43,000 sq. ft. Land & 38,000 sq. ft. of constructed area
- Well defined area with **WHO-GMP Certified** and in process for US FDA & UK MHRA approval.
- Facility holding all requisite license by **FDCA – Gandhinagar, Gujarat, Govt. of India**
- Facility recognized by **DSIR- Govt. of India, New Delhi, India**
- High quality equipments and instruments



Sushen – Pharmaceutical Services

Key Activities includes

- Formulation & Development (FnD) of Generic Drugs
- Analytical Services
 - Method development & validation
- Stability study management
- Validation & support activities
- Preparation of Registration Dossiers
- Pre-approval audits



Sushen – Pharmaceutical Services

Key Activities includes...

- Collaborative work
- Technical consultation with various MOH
- Storage, management and distribution of samples for various phases of Research & Development activities



Sushen – Pharmaceutical Services

Formulation & Development (FnD) of Drugs (Complete Development of ANDA / eCTD / ACTD Dossier)

- **Solid Oral Dosage form**

Tablets

- Orally Disintegrating Tablet
- Modified Release (MR)
 - Immediate Release (IR)
 - Controlled Release (CR) / Sustained Release (SR)
- Mono / Bi-layered Tablets
 - Immediate Release IR / CR Layered Matrix
 - Biphasic release Matrix
- Mouth Dissolving Tablets
- Chewable
- Enteric Coated (EC)



Sushen – Pharmaceutical Services

Analytical Services

- Method development
- Optimization
- Validation



Sushen

F&D Services (Facility)

Stability Study Management

- Sample storage at various conditions
- Continuous recording of storage parameters with 21 CFR compliance
- Timely retrieval of sample & Analysis
- Structural identification and quantification of impurities, if required
- Preparation of final report and documentation for submission
- Providing rental storage facility



Sushen

Pharmaceutical Services

Validation & support activities

- Validation Master Plan (VMP)
- Qualification protocols-DQ, IQ, OQ, PQ
- Validation protocol- Utility, systems, processes, cleaning, analytical methods
- Validation summary reports



Sushen - Pharmaceutical Services

Preparation of Registration Dossiers

- Compiled as per ICH guidelines
- Country specific requirements
- Assistance in preparation of DMF and 510k application
- Compile Dossier to submit ANDA and eCTD



FnD – In Images



FnD – In Images



FnD – In Images



FnD – In Images



FnD – In Images



FnD – In Images



FnD Scale Up – In Images



FnD Scale Up – In Images



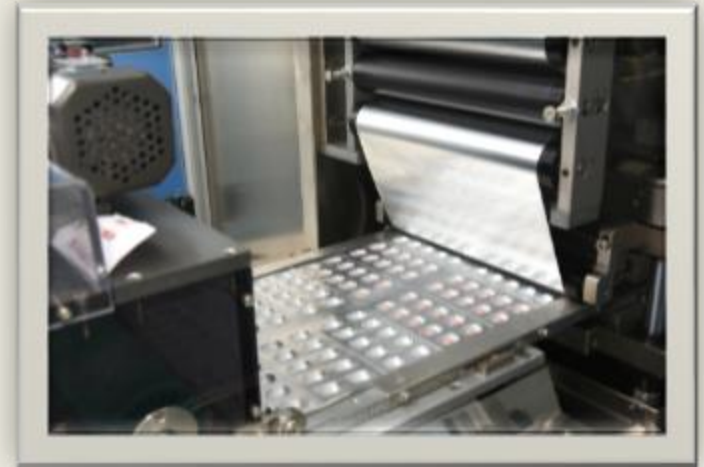
FnD Scale Up – In Images



FnD Scale Up – In Images



FnD Scale Up – In Images



FnD Scale Up – Equipment

Sr. No.	Main Equipment	Nos. Of Unit
1	RMG	02
2	FBP	02
3	Vibro Sifter	02
4	Multi Mill	02
5	V-Blender	02
6	Coating	02
7	Tabletting	02
8	Inspection	01
9	Blister Pack (ALU & PVC)	02

FnD Laboratory – Instruments

Sr. No.	Main instruments	Nos. Of Unit
1	HPLC	07
2	UPLC	01
3	Stability Chambers	08
4	Dissolution Test Apparatus	04
5	Gas Chromatograph with Head Space Sampler	01
6	Atomic absorption spectrophotometer	01
7	FTIR	01

Thank You!!