

WOW INC

'Intense containment Solutions'



21-C, MPIDC Maksi, MP, India

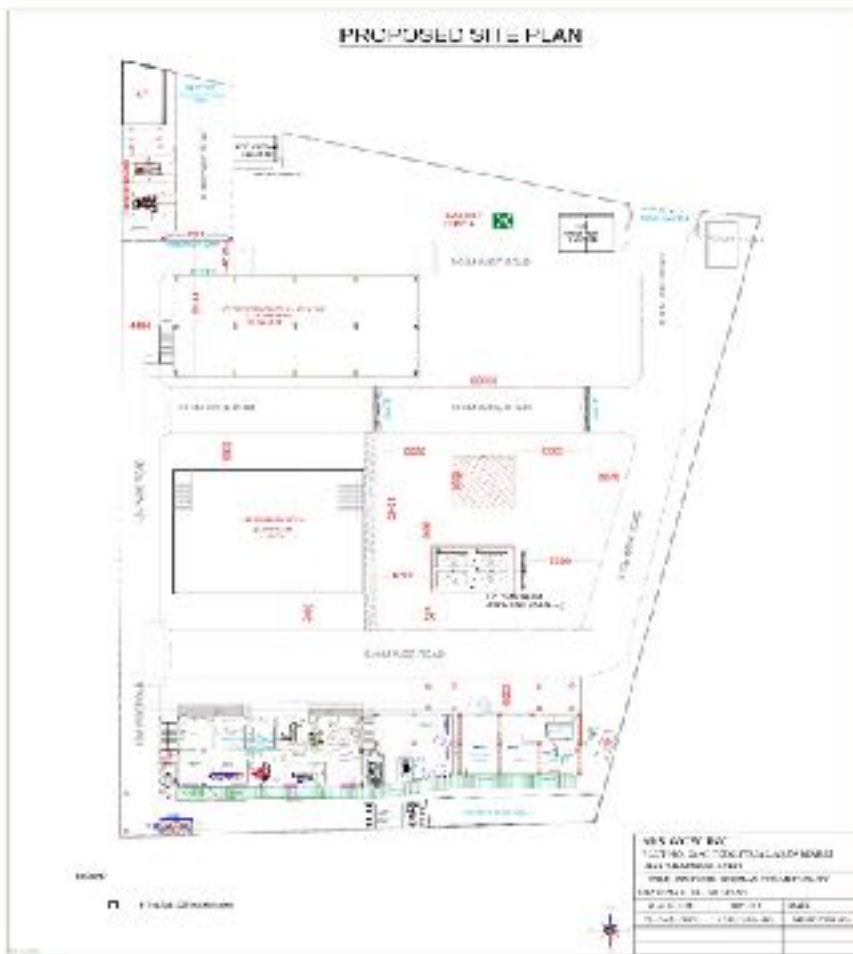


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WOW HAPI-Introduction

(1/3)

WOW is more than a Manufacturing facility



- ❑ **WOW is a high containment Development and commercial manufacturing Partner.**
- ❑ **Helping Global Pharmaceutical and Biotechnology companies accelerating their journey from process development and tech transfer to commercial Launch and supply of Complex Potent molecules.**
- ❑ **WOW specialises in ADCs Payload manufacturing.**
- ❑ **Enriched exposure in Precious Metal chemistry.**



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Leadership Team WOW (2/3)



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Anil Kumar Jain

40+ years of experience in APIs.

- Scale up (40 plus Molecules)
- Tech. Transfer (100 plus Molecules).
- Participated at 150 Plus Regulatory inspections
- Commercialised 250 Plus DMF,CEP filed Molecules.
- Handled operation across five continent with Diverse culture.
- Served as COO and CEO for multiple Indian MNCs



Shankar Sharma

- 30+ years in Process development
- Tech abs. Expert (20 plus Mol.)
- Sustainable processes
- Hazardous chemical handling expert



Gajanan Bapat

20+ years in containment

- Onco scale up (40+)
- Particle size Modification.
- Auditee 30 plus Reg Insp.



Achin Jain

10+ years Techno-Commercial

- Customer Eccentricity
- Process Automation ,QBD Design Space
- energy conservation



Harshitha Jain

- 10+ years in Digital IT with strong SAP background.
- Digitisation Expert
- Manages end-to-end Imp & Export
- MIT Grad



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WOW HAPI- **WOW Crew** (3/3)

Collectively bringing over 120 years of Global API business, Containment, regulatory and Digital Manufacturing experience



- ❑ **OEB-5 and OEB 6 (with additional material handling change parts) Containment operations.**
- ❑ **HAPI Oncology APIs including Precious Metal.**
- ❑ **ADC Payload manufacturing.**
- ❑ **End to End Tech. absorption / Tech. Transfer & scale up.**
- ❑ **Focussed on Global Regulatory compliance and Customer Confidentiality.**
- ❑ **Exposure of Regulatory Inspection of USFDA, EDQM, ANVISA, COFEPERIS & several other leading regulators.**
- ❑ **Excellent Communication & project management Skills.**
- ❑ **OE and Sustainability at CORE.**



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WOW HPAPI:

Brand New Facility



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6



- Isolator based raw material handling
- OEB 5 containment. (OEB 6 on Demand with Additional Material Handling items)

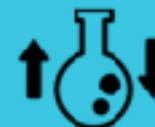


- Fully Digital Manufacturing Data Access.
- Part 11 complied system. Targeting Advance regulated markets of North America, EU, SEA, MEN A, Africa BRICS etc.



Exclusive potent manufacturing site

1. ADCs Payload manufacturing capability.
2. Small Volume commercial Manufacturing.
3. Flexible Batch size- from tox to commercial supply



State- of -the -art analytical capability (Nitrosamine, Genotoxic impurity cGMP compliant Validation lab.



ESG compliant utility and environmental systems. Experienced & capable Tech absorption team. Flow Chemistry on Demand.

WOW Inc remains lean and flexible to meet partner needs-

one-stop development & supply solution, quick decision making, backed by an experienced and credible promoter.



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Regulatory Strategy



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01

**Expedited
Process Validation,
Stability- Filing
Support**

02

**Tech transfer of
Existing DMF as
alternate site –
Risk Mitigation**

03

**Global
Compliance
Pathway-unique
process, Specs**

04

**NCE-1 Filing
Strategy**

05

**Early-stage
USFDA EMA &
PMDA Filing Support**

A well-defined regulatory strategy leveraging OEB-5 compliant infrastructure
Expedited Regulatory Submissions



WOW HAPI- Reliable Contract Manufacturer



WOW Don't Just Manufacture High-Potency Molecules-

- We help our partners **Derisk** Development,
- **Accelerate** Technology transfer,
- build **Reliability** and **Deliver** Products Global Markets **on time**.

Contract Manufacturing Services offered

- ❑ Tech transfer, Scale Ups
- ❑ Manufacturing services
- ❑ APIs life cycle management
- ❑ TOX quantities
- ❑ Stability, Analytical development

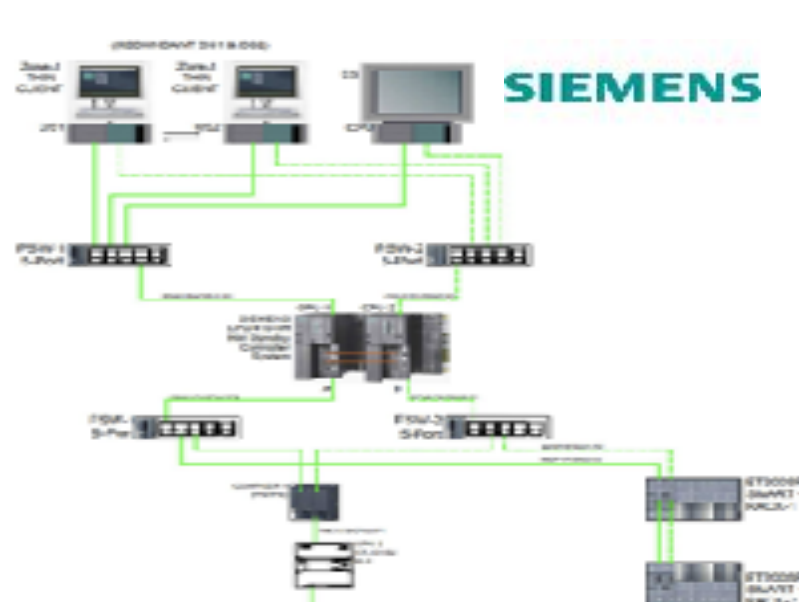


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Digitisation is at Core (1/3)

- IOT based plant automation with in built redundancy for data management.
- Siemens Centralised SCADA control adaptable to ERP systems.
- Automatic Controls for Utility focus on temperature mapping and precise control of CPP.
- Clean room Management centralised BMS
- Double layer of access security for Reactor Charging, Solvent dispensing, Raw material handling etc.
- Centralised Control room Multiple user with 21 CFR compliant access level.





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WOW HAPI-Digitisation-Plant Automation (3/3)



Utility Automation

- ❑ Monitoring of chiller, PSA nitrogen, Purified Water.
- ❑ Single fluid heat transfer methodology.

- ❑ BMS for Clean Area

Process Automation

- ❑ Integration of reactors, centrifuges, ANFD, and isolators with SCADA. Automated control of parameters (temperature, pressure, pH, RPM, vacuum).
- ❑ Alarm systems and interlocks for safety and compliance.



- ❑ Variety of SS316 & GL Reactors
 - ❑ Interchangeable agitators eg Turbine/ Anchor
 - ❑ Variable speed
- ❑ Solid separations
 - ❑ 10 kg and 30 kg ANFD combinations with Rigid wall Isolator
 - ❑ 24 Inch centrifuge with flexi containment
 - ❑ Zero Hold up Sparkler filter
- ❑ **Drying**
 - ❑ 6 Plate VTD, 250 ltr ANFD in SS and H Alloy C options
- ❑ Finishing - Multi mill , Sieving
- ❑ Flexible packing sizes
- ❑ Charging and Dispensing Isolators
- ❑ Decontamination Strategies



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Analytical Development Philosophy ^(2/3)

- ❑ Solution centric Onco specific analytical method development.
- ❑ Solution preparation within flexi barrier and glove port system.
- ❑ Microbiology Lab
- ❑ Global Stability Programme.
- ❑





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Purified Water System



- ❑ MPIDC Narmada River water is pretreated, Multiple Stage RO* and EDI system, followed by UV lamp, Distribution loop.
- ❑ Purified (& Potable Water) Systems: Qualified for phase 1 & phase 2 over, phase 3(running).
- ❑ Distribution loop is SS316L electropolished,
- ❑ Orbital welded,
- ❑ full borescope,
- ❑ 1:100 Slope,
- ❑ minimum velocity of 1 M/S.



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WOW HAPI- HVAC Systems



- ❑ The ambient air is passed through a series of pre filter , fine filter , Hepa filter.
- ❑ Conditioning is done with Dx coils.
- ❑ Hot water for design temperature and RH.
- ❑ BIBO HEPA/ filters in return ducts with containment facilitating replacement.
- ❑ 2 AHU at site of 3700 CFM and 3100 CFM dedicated for clean room.
- ❑ ACPH, PAO, Filter integrity, DP Particle count air flow.



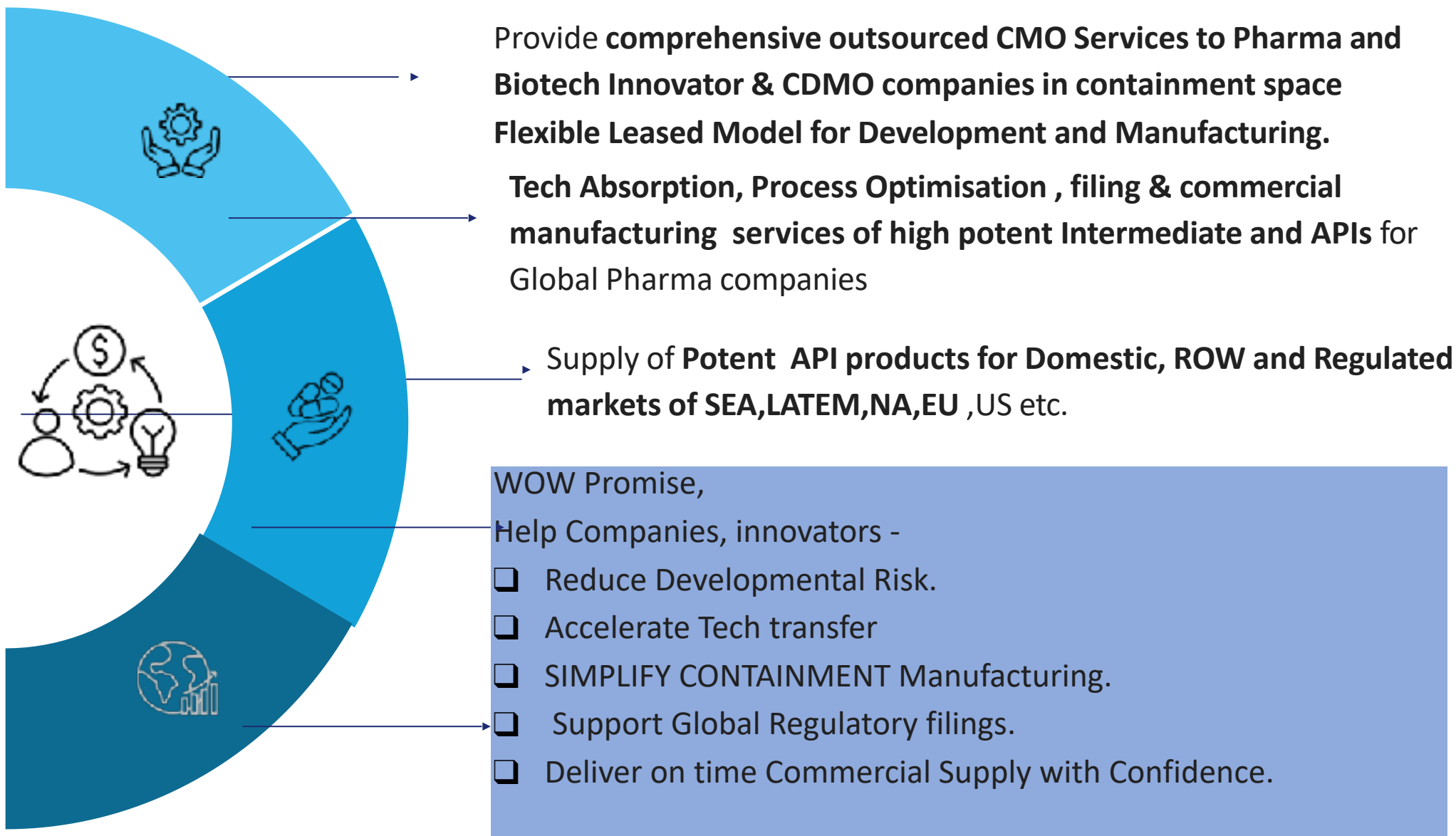
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Business Model





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WOW HAPI-Product Pipeline

Under commercialisation-oncology APIs

1. **Chemotherapy Medications-Platinum Derivatives**
2. **Antimetabolites-Pancreatic, Non Small Cell Lung Cancer, Brest and Overian Canser.**
3. **Oral Chemotherapy Medications.**

Under Development(Oncology & Immunology)

- ☐ **SN-38**
- ☐ **Topoisomerase I inhibitors.**
- ☐ **Immunomodulatory drugs (IMiDs)**
- ☐ **Osimertinib**
- ☐ **Alkylating Agents**
- ☐ **Tyrosine Kinase Inhibitors (TKIs)**
- ☐ **EGFR inhibitors**



Thank You &
Partner with WOW to accelerate your HPAPI
Journey – from Tox to Commercial supplies.

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