Callidus

We Care for You .....

Formulation Development Services.

Your trust is our reward…

Index

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Who we are?

Callidus
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We are a privately held research driven pharmaceutical company focussed on pharmaceutical drug product development and technology transfer to manufacturing site across the globe.

We aim to provide challenging solutions to generic as well as brand companies to develop and establish new technology platforms and seamless transfer of existing technologies

The research activities are conducted in a state of the art modern R&D facility set up with a vast scientific knowledge pool confirming to international standards

Mission & Vision

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Our Vision

Callidus research labs is committed to be a premier organization in drug product development.

Our vision is to be the first and best choice of our customers for services we provide. We will earn our customers trust by continuously improving ourselves through our values, integrity, transparency and teamwork of our people.

Our Mission

To gain and retain trust of our clients and to be their preferred partners in drug product development.

We believe in going an extra mile beyond customer satisfaction to customer delight

Where we can help you?

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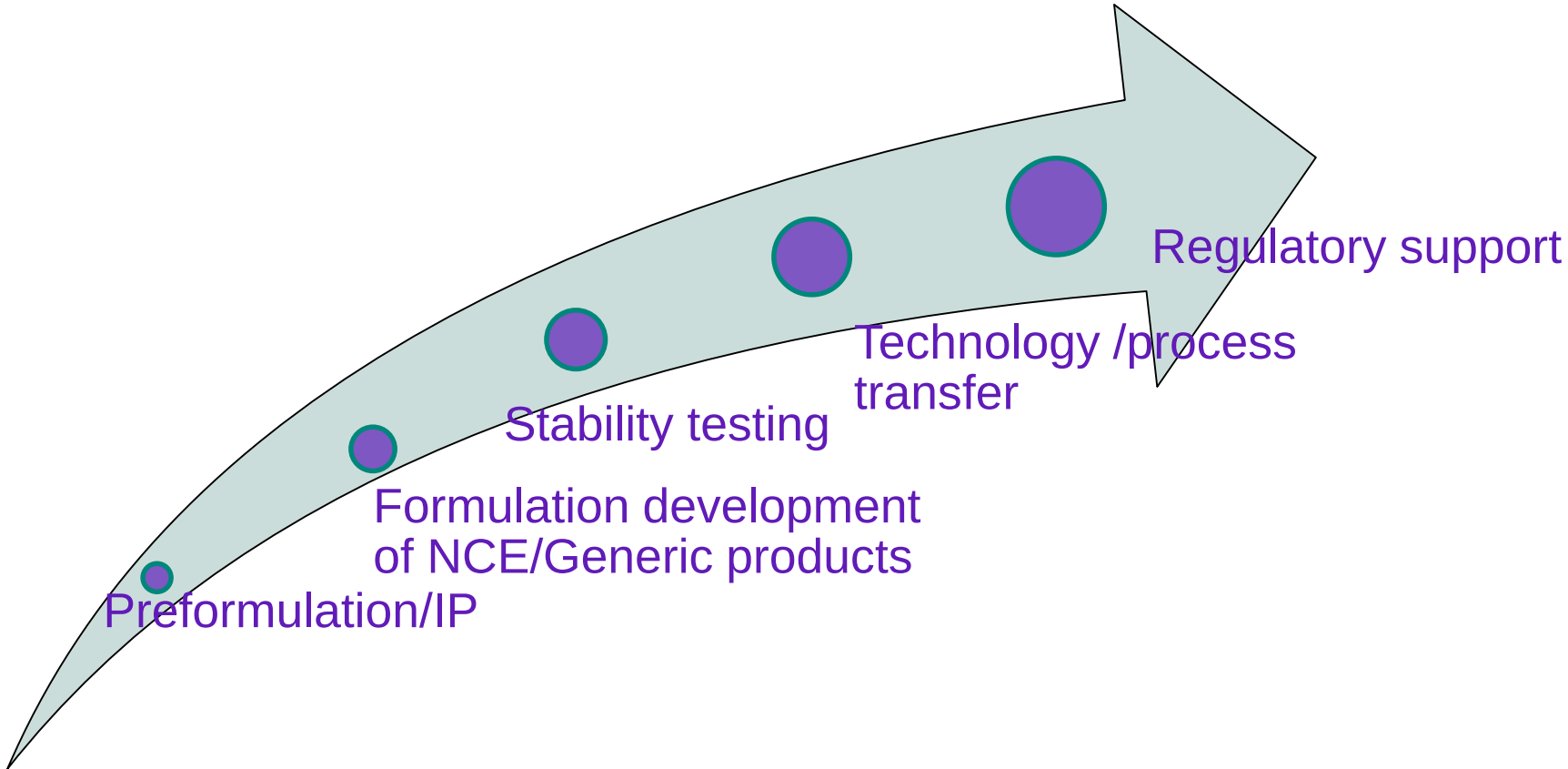

Infrastructure and Systems

We are a state of art pharmaceutical research and development facility spread over 8000 sq.ft (720 square meter) built as per international standards.

We have adequate eequipment and instruments to carryout research and development activities with highest quality standards.

Formulation

- High shear mixer granulator-SAMS
- Tablet compression with bilayer facility-Adept
- Autocoater-Gansons
- Fluid bed dryer
- Blister packaging machine-Mecktek
- Capsule filling machine
- Adequate equipment for liquid dosage forms

Analytical

- UHPLCs with PDA and UV detector
- UV spectrophotometer
- KF auto titrator
- Water purification system
- Stability chambers for entire ICH conditions

Site Plan-Floor 1

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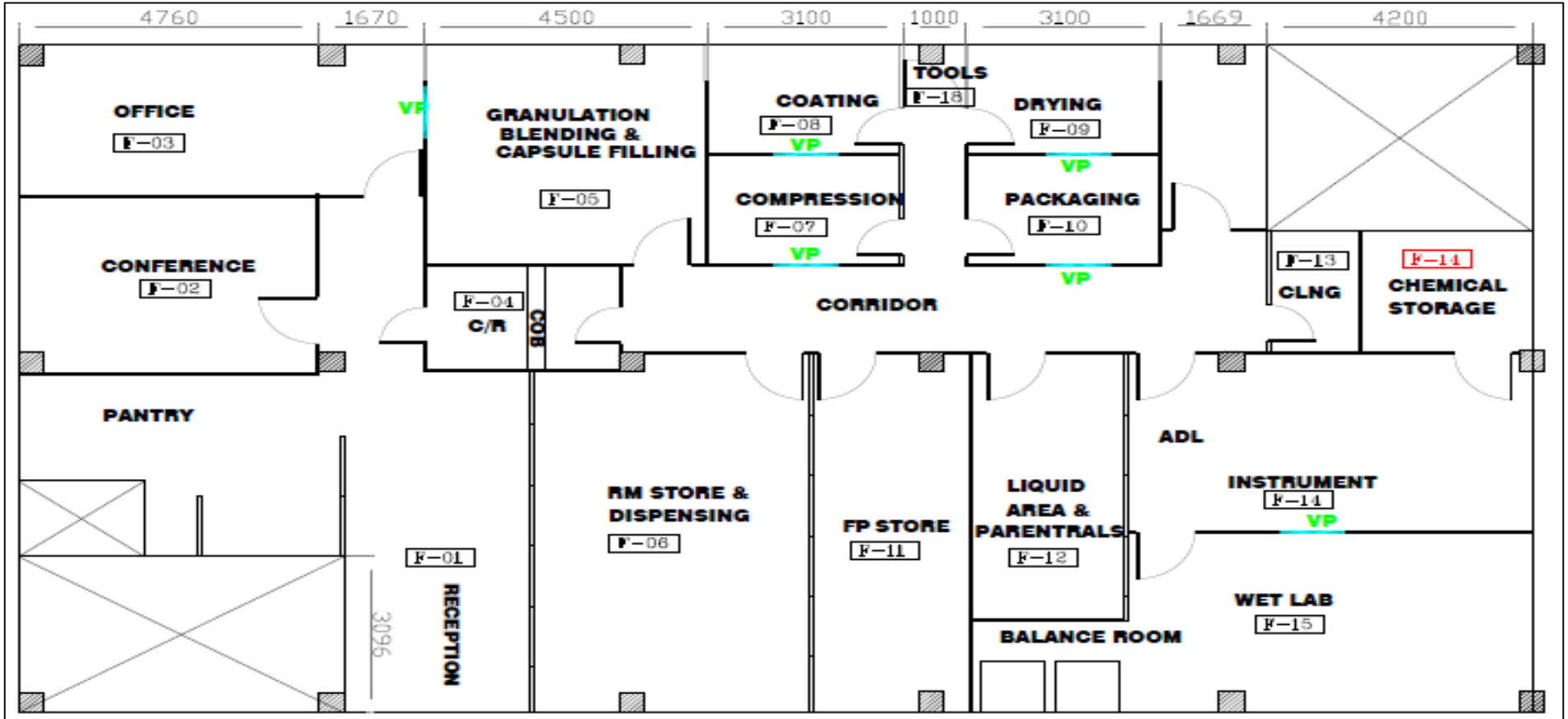
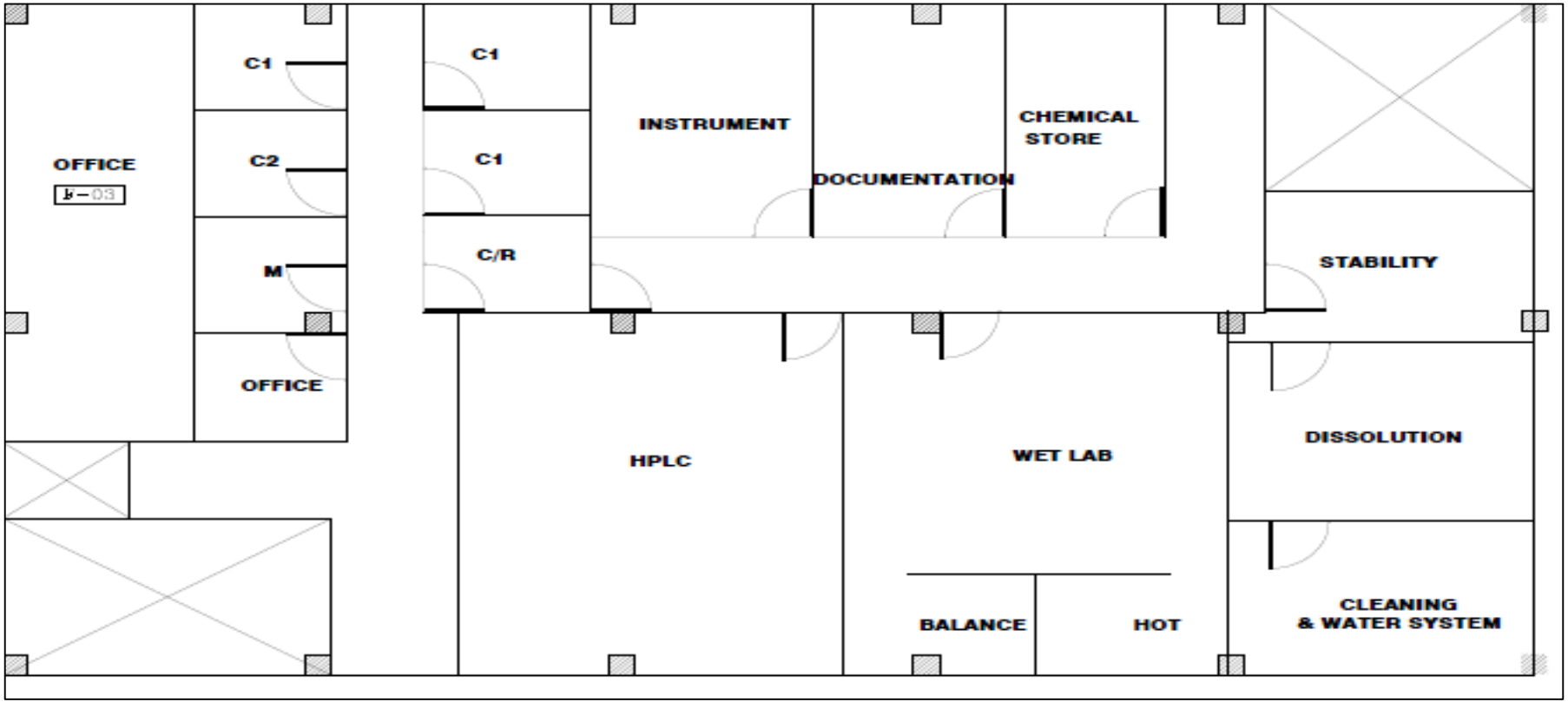


Site Plan-Floor 2



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Services We Offer

Pre-Formulation Services

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- API Characterization
- API forced degradation (including an evaluation of the effects of heat, light, and pH)
- Solubility profiling in buffers and non-aqueous solvents
- Compatibility testing of APIs and excipients
- Solid-state and solution-state stability and photo-stability
- Hygroscopicity
- Morphology assessment
- Intrinsic dissolution
- Micromeritic studies

Formulation Development Services

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Our extensive formulation development services and capabilities being offered to our clients for Generic formulations and NMEs are

- Formulation development for early safety studies
- Proof of concept establishment for clinical supplies(non GMP)
- Prototype formulation screening studies
- Formulation / process optimization
- Preliminary process identification
- Formulation development as per QBD for NME's, generics, OTC's and veterinary products
- Process development optimization
- Scale up / technology transfer
- Product improvement services

Analytical Development Services

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- Analytical method development for drug product as per QBD
- Method validation and transfer to manufacturing site in line with ICH
- API verification and transfer of API methods to manufacturing site
- Development and validation of cleaning methods to support manufacturing site
- Innovator characterization studies
- Reverse engineering studies of the innovator product
- Stability studies as per ICH guidelines
- Pharmaceutical equivalence studies/multimedia dissolution
- Cleaning method development and validation

Standalone Analytical Services

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- API method verification and transfer
- Finished product method verification and transfer
- API characterization studies
- Stability studies of API and formulations as per ICH
- Pharmacopoeial testing of API and finished product
- Innovator characterization studies
- Reverse engineering of Innovator product
- Finished product method development/validation
- Finished product stability studies as per ICH
- Pharmaceutical equivalence studies/multimedia dissolution
- Cleaning method development and validation

Technology Transfer

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The team at Callidus research Labs is conscious about the importance of technology transfer in project success.

We take pride in supporting our customers by offering end to end support.

Formulation and analytical scientists from Callidus will be present at manufacturing site for seamless execution of analytical method transfer, scale up and process validation batches mfg.

The team at Callidus is well placed to ensure seamless tech transfer of your products to the manufacturing site.

I. Preliminary Tech transfer dossier preparation and transfer to the mfg site

- Callidus prepares the pre-tech documentation(mfg guideline, spec, STP, transfer protocols, stability and sampling protocols etc) and hands it over to manufacturing site.

Technology Transfer

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II. Procurement phase

- Callidus ensures procurement and receipt of RMs/PMs, packaging change parts, columns, reagents for scale up and process validation batches at manufacturing site

III. Site transfer Phase

- Callidus reviews all the CMO documents and ensures that they are in line with product quality and regulatory requirements
- Finished product method transfer and report finalization
- Execution of scale up batches at Manufacturing sites
- Assistance in preparation and review of scale up summary report by Manufacturing site

Technology Transfer

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V. Process Validation phase

- Ensuring the preparation of Validation batch documentation by manufacturing site
- Review of validation batch documents.
- Execution of Validation batches as per protocols at the manufacturing site
- Assistance during preparation and review of validation reports.
- Evaluation of stability reports

If required the analytical scientists from Callidus shall be present during stability analysis of dossier submission batches at each time point in order to ensure seamless transfer of technology and prevent any issues

Product Improvement/Reformulation Services

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The need for cost reduction, changes in regulations may trigger the need for improvement/reformulation of any product already existing in the market.

Our formulation development expertise can definitely be useful to address the reformulation needs thereby adding value to the existing product portfolio of our customers.

After thoroughly studying the existing formulation, we would address the specific problem and offer a solution to our customers followed by systematic transfer of technology to the manufacturing site.

Few examples of reformulation are as follows.

- Alternate API source development
- Yield improvement
- Application of QBD principles
- To enhance product shelf life
- Cost reduction
- Replacement of any key excipient due to continuous supply constraints from vendor

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Technologies We Practice

Technologies We Practice

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					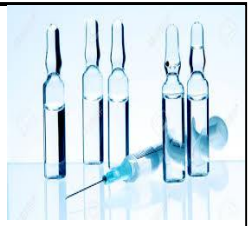
IR tablets Sustained release tablets Bilayerd tablets DR tablets Functional coated tablets Sugar coated tablets MUPS Gastro retentive tablets	Hard Gelatin capsules containing powders, Pellets	Thin films for oral, buccal and sublingual routes.	Solutions Suspensions Emulsions Syrups Taste masking technologies Paediatric formulations	Creams Ointments Gels Pastes	Liquid injectables

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Quality Systems

Quality Assurance

“Quality” is of paramount importance in everything we do at Callidus

We believe is quality by design not by chance. In order to achieve quality we meticulously follow good documentation practices

We maintain, monitor and make every effort to continuously improve on quality

Our quality systems includes but are not limited to the following

- Exhaustive standard operating procedures (SOP)
- Guidelines, Trainings
- Documentation control
- Change and CAPA management
- Site master plan
- Equipment / Instrument qualification and calibration programs

We believe in adding value to our customers by providing services of highest quality standards

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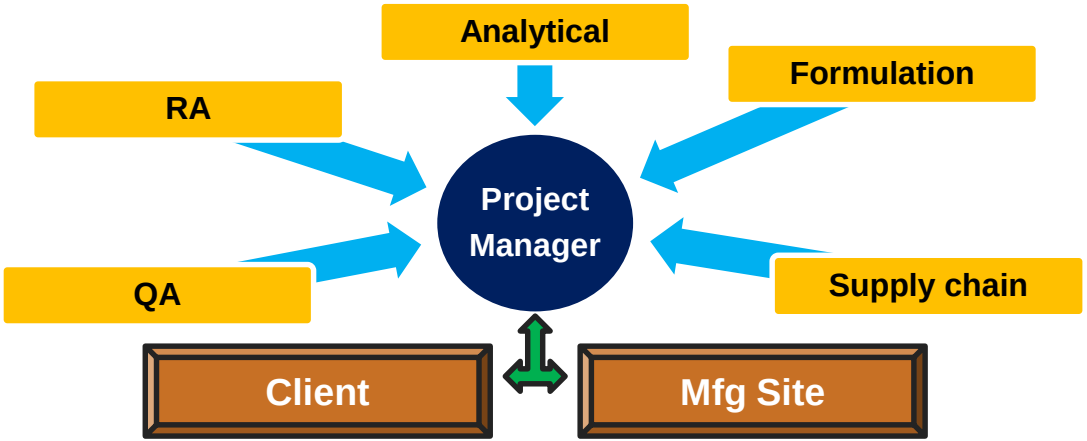
Project Management

Project Management

Callidus research labs is a dynamic, adaptive and projectized organization and is committed to deliver the projects on time as per plan and within budget.

The program manager has 360˚ view and is the “Single Point of Contact” for the project supported by a strong technical team.

The program managers possess both technical as well as commercial skill sets and have right skill to efficiently manage each project and its uncertainties.



Team

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Our team of techno-entrepreneurs are obsessive about details, deadlines and results and have an excellent track record of having successfully delivered drug products from concept to commercialization

Together as the management team we bring in exceptional technical expertise and business experience and hold more than 40 years of combined proven experience in the industry.

Our team has successfully delivered most complex projects in various renowned multinational pharmaceutical companies for regulated markets like U.S.A, Europe, South Africa, Canada, Brazil and Australia thereby adding value to the organizations we served.

Our team has a combined experience of delivering 100+ projects for regulated markets

Team

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Name	Department	No of products handled	Past Experience	Patents and Publications
Vardhaman Bafna M.Pharma, UDPS Nagpur **(Gold Medalist)**	Site Operations	70+	Ranbaxy, Dr.Reddys Labs Watson Pharma, Centaur Pharma, Sai Lifesciences	5 Patents, 3 international publications
Mahesh Bhadgale M.Pharma, Pune University	Formulation Development	70+	Dr. Reddys Labs,Mylan Perrigo,Centaur Pharma	6 Patents, 4 international publications
Dr.Santaji Nalwade M.Sc, PhD, JNTU Hyderabad	Analytical Development	40+	Dr. Reddys,Mcleaods Pharma,Aurobindo Pharma SAI Lifesciences	4 Int. Publications
Shailesh Shinde M.Tech Pharma, NIPER	Program Management	100+	Zydus Cadila,Torrent Pharmaceuticals Piramal Healthcare SAI Lifesciences	

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Case Studies

Case Studies

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Product name/market	Client	Criticality	Solution	Current status
Temazepam oral liquid, EU	EU based big Pharma	Product Quality	➢ Forced degradation was optimized ➢ Enrichment of impurity levels ➢ Analytical methods improved for better resolution of impurities	Impurity isolation completed, characterization in progress
Differentiated product for EU market	EU based big Pharma	Timeline	➢ Development completed in 4 months, product ready for tech transfer. ➢ Pilot bio study was bypassed	Tech transfer initiated
Metformin SR, EU/USA	IH	Cost	➢ Development was done by using significantly reduced quantity of release controlling polymer resulting in smallest generic tablet. ➢ Significant cost advantage	Development completed

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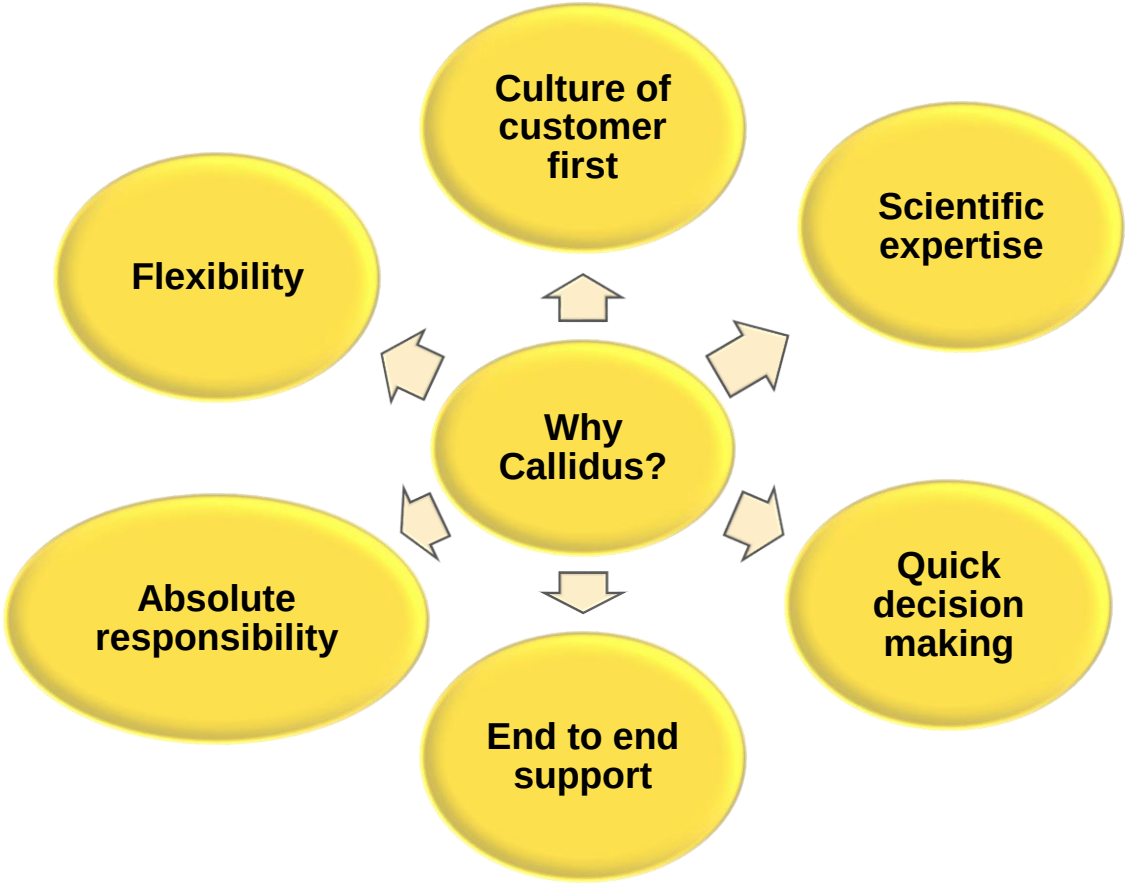


Thank
You