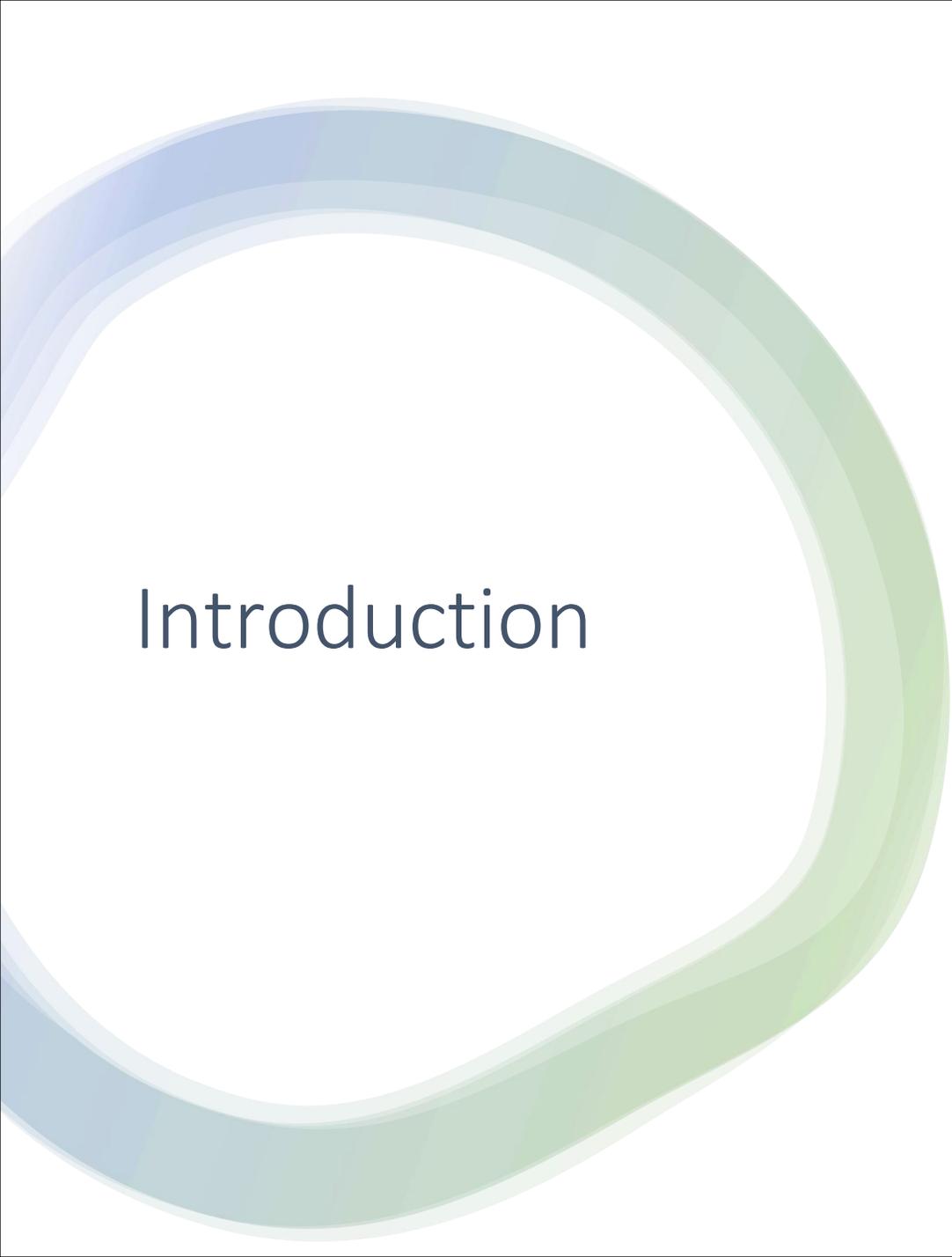




Partnered with



R&D Company
Overview



Introduction

- ❖ We are a Hyderabad based pharmaceutical contract research and development organization specialized in providing formulation R&D services of sterile dosage forms (Injectable & Ophthalmic) for various global regulated markets.
- ❖ Our R&D Facility is approved for both General and High potent molecules (Cyto-toxic , Peptides, Hormones and Steroids) .

We work on various models like :

Contract Development

Fee For Service model
for End-to-end development
(Formulation Strategy
to product approval)

Co-Development

Product development
with client collaboration

In House Development

Developing till proof
of concept/Tech
pack readiness

Consulting Services

Consulting services for all
other dosage forms R&D by
collaborating with other
companies

Our Strategy



Our mission is to deliver successful projects to the client with an E2 (Effective and Efficient) approach



We will support the Global Pharmaceutical Industry by reducing their cost of ownership of a product dossier



We will achieve our goal through a combination of science and operational excellence of product development



Our Technologies

OPHTHALMICS

- Ophthalmic solutions
- Complex Ophthalmic Suspensions / Emulsions

• INJECTABLES

- Simple/Complex Injections
- Lyophilized Injections
- High Potent Products (Cytotoxic, Hormones & Steroids)

OTHERS

- Nasal solutions / Sprays
- Peptides Formulations
- Novel formulations i.e 505 b(2) approaches

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Team strength

Our Team expertise to develop the sterile formulations i.e., Parenteral , Nasal and Ophthalmics.

Practical experience in developing the complex Ophthalmic products i.e., Size reduction ,Process optimization ,matching with Q3 parameters.

Team expertise to develop the Novel and 505(b)2 development approach.

Strong knowledge to develop the high potent compounds i.e. Hormones and Cyto-toxics.

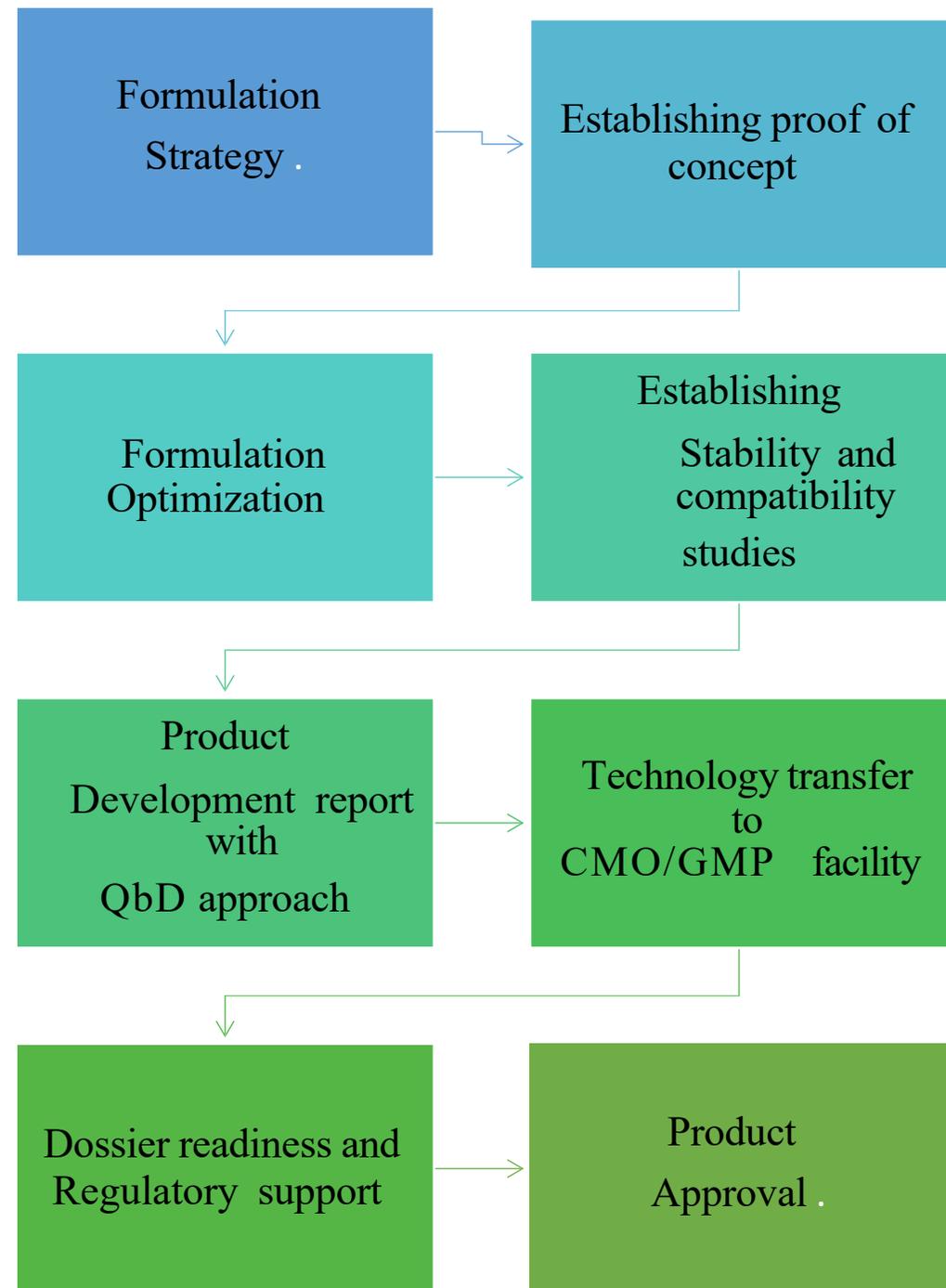
Good exposure to tech transfer the product from R&D to Scale up level in CMO's

Handling of trouble shooting Challenges during scaling up at CMO.

Analytical team expertise in development of sterile formulation and validations.

Product development exposure for various regulated markets i.e., US, Europe, Canada, Emerging and Rest of the world .

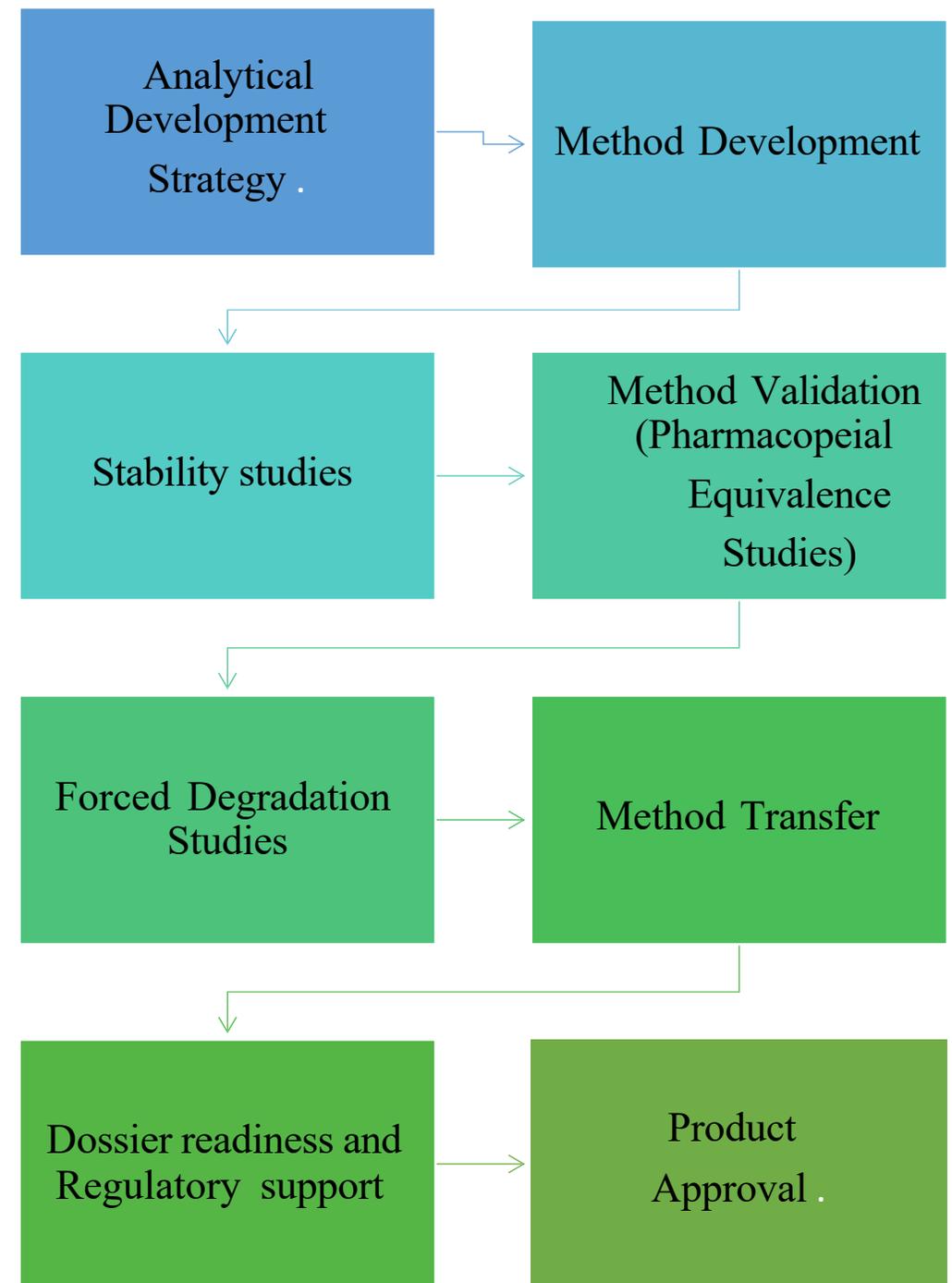
Formulation Development Stages



Note : FD services can be provided as end-to-end development or any stages of development

Analytical Development Services

Note : AD services can be provided as end-to-end Service or any Individual Service



Technology Transfer support

OPTIN PHARMA

- ❖ Master formula card
- ❖ Master packaging card
- ❖ Specification
- ❖ Standard test procedures
- ❖ Analytical method development
- ❖ Process evaluation protocol
- ❖ Stability summary protocol
- ❖ Risk assessment report
- ❖ Product development report
- ❖ Other documents related to product development



CMO/GMP facility

- ❖ Scale up for process feasibility
- ❖ Analytical method verification and Transfer
- ❖ Analytical method validation
- ❖ GMP Batches execution at CMO
- ❖ Monitoring of GMP batch stability
- ❖ Support for dossier readiness
- ❖ Regulatory deficiencies support

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Quality Management System

Quality Manual.

Site Master Plan

Qualification / Calibration and Preventive Maintenance program.

Data Integrity Conscious procedures in place

Internal and External audit process

Compliance enabled systems

Good Documentation Practices

Standard Operating Procedures

Major Instruments & Equipment's

HPLC (Alliance with Mpower software) .

Viscometer (Brookfield) .

Osmometer (Knauer).

Semi Micro Balance (Shimadzu).

Stability chambers (Nihaar)

PH Meter (Thermo Scientific).

Autoclave (Osworld).

Bio Safety Cabinet (Lennox) .

Others (Water System , Stirrers , Top Load Balance , Deep freezers , Refrigerators , Sonicator)

Facility

State of the art facility (6000 sft) in Hyderabad

Dedicated formulations laboratories.

Lab I - General

Lab II - High potent (Oncology , Hormones ,
Peptides and Steroids)

Analytical Lab is fully equipped with 21 CFR
compliance instruments.



Thank you

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