



PROVIDING SOLUTIONS TO
**PHARMACEUTICALS &
HEALTHCARE INDUSTRIES**

Pharmaxcell

Pharmaxcell Consultants

29, Devbhomi Bungalows, Gala Gymkhana Road, Near Garden Homes Bungalows, Ghuma, Tal: Daskroi,
District:: Ahmedabad, Gujarat (India), PIN-380 058

ABOUT COMPANY

Pharmaxcell

- ❑ Pharmaxcell consultants is a solution providing consultancy company for Pharmaceuticals and Healthcare industries , based at Ahmedabad, India
- ❑ Mr. Gaurang Purohit has founded the company who has expertise in providing solutions in pharmaceuticals and healthcare industries ranging from new facility design, facility up-gradation, cGMP enhancement, productivity improvement, regulatory audits and many more
- ❑ Gaurang purohit is a Graduate Mechanical Engineer and has very long 24 years of hands-on experience in handling of green and gray field pharmaceutical, Biological and Biotech projects for manufacturing of API and finished formulation products, successfully audited and approved by USFDA, MHRA, WHO and other various regulatory agencies
- ❑ He also has expertise in designing of facilities to manufacture new drug delivery systems (NDDS) and specialty drugs like Transdermal patches (TDS), Metered Dose Inhalers (MDIs), Dry Powder Inhalers (DPI), Human and Animal/Poultry Vaccines and Biological
- ❑ He also has rich hands-on experience in up-gradation of pharmaceutical facilities for bridging process flow gaps, enhancing productivity and improvement in Current Good Manufacturing
- ❑ Gaurang was directly involved in many regulatory inspections like USFDA, MHRA, Brazil ANVISA, Therapeutic Goods Administration (TGA) of Australia, Medicines Control Council, WHO and Indian FDA etc.

OUR VISION



To offer an affordable solutions to Pharmaceuticals and health care industries

To help Pharmaceuticals and Healthcare Industries by designing CAPEX and OPEX efficient manufacturing facilities

To help pharmaceutical Industries to keep people healthy

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- 01** | Up-gradation of domestic OSD and Injection manufacturing facilities for regulated markets like US and Europe which got approved by USFDA and MHRA repeatedly
- 02** | Concept to commissioning for USFDA and MHRA approved API facilities
- 03** | Designing of stand-alone Injection manufacturing facility for regulated markets like US and Europe with unique concepts. Some of the concepts incorporated are first of it's kind in Indian pharma industries
- 04** | Creation of multiple stand-alone Lyophilisation facilities for US and Europe markets
- 05** | Creation of three Transdermal patch manufacturing facilities, first time in India which are approved by USFDA
- 06** | Creation of state of the art viral vaccine manufacturing facility to manufacture MMRV vaccine
- 07** | Creation of state of the art viral vaccine manufacturing facility to manufacture Cell Culture based Rabies vaccine
- 08** | Creation of state of the art viral vaccine manufacturing facility to manufacture PDEV based Rabies vaccine
- 09** | Creation of state of the art Bacterial vaccine manufacturing facility to manufacture DPT-Hib vaccines
- 10** | Creation of state of the art Fill finish facility for Biosimilars and Biotech products
- 11** | Facing of successful regulated audits including USFDA, MHRA, Brazil Anvisa, TGA, MCC, Indian FDA and many more
- 12** | Multiple successful projects to improve cGMP and enhance productivity in existing facilities

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Providing solutions to Pharmaceuticals and Healthcare industries, ranging from concept to commissioning of new facilities as well as existing facilities, seeking for up-gradation to comply latest regulatory requirements.

GREEN FIELD PROJECTS



FACILITIES

Category: General, Oncology, Cephalosporin, Betalectum

Type: API and Finished Formulation

Dosage forms:

- ☐ Oral Solid Dosage (OSD)
- ☐ Liquid and Dry powder Injections
- ☐ Lyophilisation
- ☐ Ophthalmic
- ☐ Nasal
- ☐ Transdermal patches (TDS)
- ☐ Metered Dose Inhalers (MDIs)
- ☐ Dry Powder Inhalers (DPI)
- ☐ Vaccines including Human, Animal and Poultry Vaccines ranging from Viral vaccines, Bacterial Vaccines, Cell culture based vaccines, Purified Duck Embryo Vaccines
- ☐ Biotech and Biosimilars
- ☐ Ointment
- ☐ Nutraceuticals

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SCOPE OF WORK

Project conceptualization:

Preparation of Concept note on following

- ☐ Process
- ☐ Facility/Infrastructure
- ☐ Man movement
- ☐ Material Movement
- ☐ Handling of Products
- ☐ HVAC
- ☐ Utility services
- ☐ Electrical and other supporting systems like Solid and Liquid waste handling

User's Requirement Specifications (URS):

- ☐ Understanding of Client's Process
- ☐ Evaluation of Process requirement
- ☐ Preparation of URS for Facility, Equipment, HVAC, Utility, Electrical and associated services

Layout development:

- ☐ Designing of facility Layout considering process flow requirement to meet current regulatory requirements, Proper personal and Material flow and ease of operation

Type of Layouts include:

- ☐ Floor Layout
- ☐ Equipment Layout
- ☐ Man-Material Movement
- ☐ Area Classification Layout
- ☐ AHU Zoning Layout
- ☐ Differential Pressure Layout

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SCOPE OF WORK

Vendor and Equipment Finalization:

- ☐ Vendor audit
- ☐ Vendor evaluation
- ☐ Short listing of vendors
- ☐ Floating of inquiries to short listed vendors
- ☐ Receiving of offers
- ☐ Evaluation of Offers
- ☐ Comparison of offers
- ☐ Technical recommendation

Qualification and Validation Support:

- ☐ Protocol approval
- ☐ Gap analysis and bridging the gaps
- ☐ Technical Support during execution of validation activities

Project Execution Support:

- ☐ DQ approval
- ☐ Intermittent Inspections
- ☐ Technical Support during Factory Acceptance Test (FAT)
- ☐ Technical Support during Installation and Commissioning
- ☐ Technical Support during Site Acceptance Test (SAT)

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FACILITY UP-GRADATION PROJECTS



FACILITIES

Category:

General, Oncology, Cephalosporin, Betalectum, Vaccines, Biotech and Biosimilars

Type:

API and Finished Formulation including Tablet, Capsules, Injections, Transdermal, Nasal, Ophthalmic, Metered dose Inhaler, Dry Powder Inhaler, Various types of vaccine like Viral vaccines, Bacterial Vaccines, Cell culture based vaccines, Purified Duck Embryo Vaccines etc

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SCOPE OF WORK

- ❑ Facility audit
- ❑ Identification of gaps
- ❑ Gap analysis against current regulatory requirements
- ❑ Preparation of action plan
- ❑ Execution of action plan
- ❑ Technical support in preparation of URS, vendor and equipment finalization, DQ Approval, Factory acceptance test (FAT), Installation and Commissioning, Site acceptance test (SAT), execution of Qualification/Validation
- ❑ Providing technical support for regulatory inspections like USFDA, MHRA, Brazil ANVISA, Therapeutic Goods Administration (TGA) of Australia, Medicines Control Council, WHO and Indian FDA etc.
- ❑ Facility up-gradation to improve productivity

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