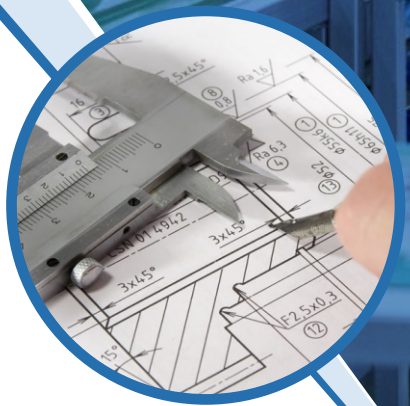
From Vision to Reality: Your Pharma Project Partner

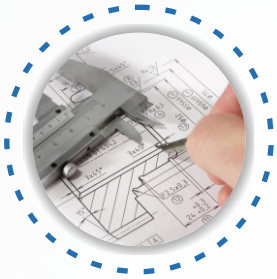
USAPack
MACHINES LLC.
"Ultimate Solutions Assistance"



UPML
Presents
Turnkey Project Services Support
for
PHARMACEUTICALS
Manufacturing Facility

www.usapack.net

SUPPORT & SERVICES



DRAWING & LAYOUT

INFRASTRUCTURE

MANUFACTURING LINE IDENTIFICATION

UTILITY DESIGN MEETING PROCESS REQUIREMENTS

MACHINERY & UTILITY DOCUMENTS

LABORATORY COMPLIANCE

PROCESS VALIDATION

PLANT VALIDATION DOCUMENTS

OFFERINGS

Meeting the requirement to protect Human life in the best possible way, industry regulators have initiated the most stringent norms to maintain the manufacturing standards. Keeping in mind cost & profit gaining markets can benefit, regulatory & world health organizations have started creating specified standards to comply for any pharmaceutical industry.

Over a period, time of market status, surveys & incidence reports has projected few principle polices to be followed by every pharmaceutical manufacturing plant. Following the same rules & make it more convenient to avoid human interface & errors, it's identified to part manufacturing process & categorize with product & molecule identification.

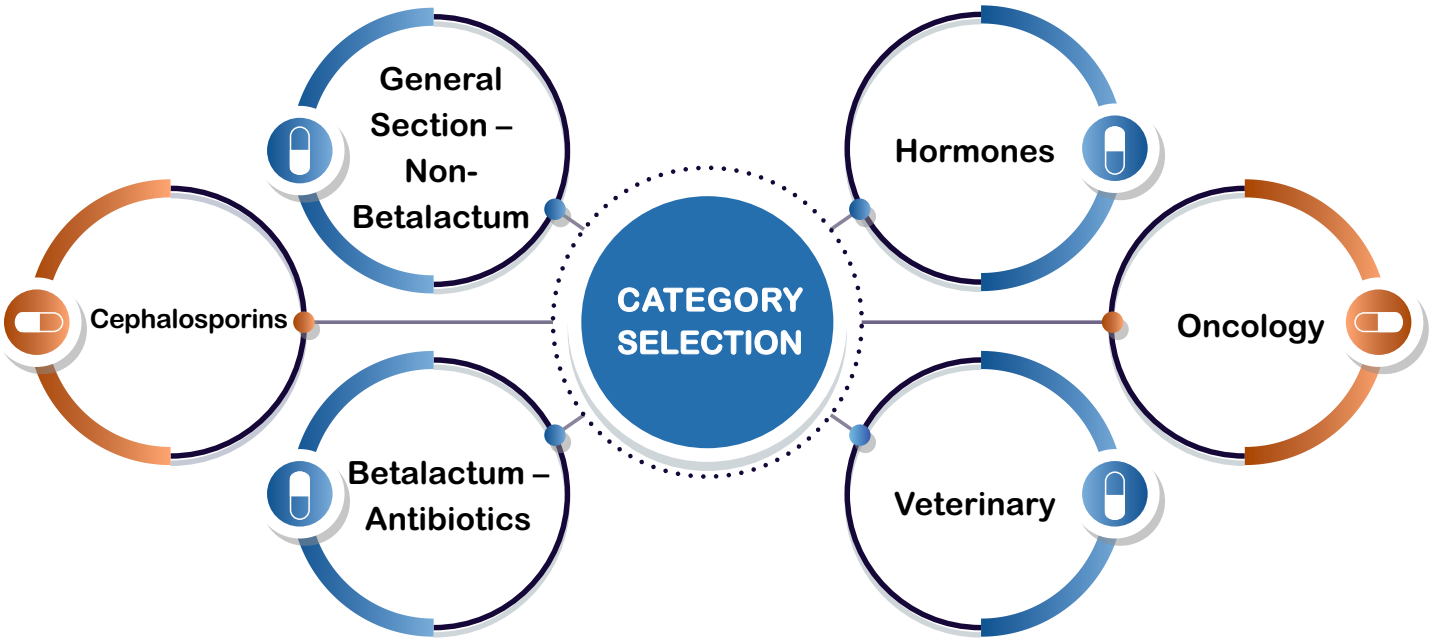
Referring the same, the manufacturing process is divided among Dosage forms & this dosage forms are applied into product categories. Which can be identified as below,

Oral Solid Dosages
Tablet
Capsule
Liquid Orals
Dry Powder – Syrups
Dry Powder Orals (ORS)
Sachet
Lozenges

Injections (Sterile)
SMALL VOLUME PARENTAL (SVP)Capsule
Liquid Injection – Vial / Ampoule
Dry Powder Injection
Lyophilized Operations
Pre-filled Syringes
LARGE VOLUME PARENTAL (LVP)
IV – Fluids – Form/Fill/Seal

External Preparation
Ointment
Toothpaste, Cream
Inhaler
Aerosols

Ophthalmic Preparation
Eye/Ear Drops



Upon identification of above dosage forms there are identification of product categories which can be supported in Dosage forms.

INTRODUCTION

As it has been made the survey that amongst the most encouraging business in the markets around the world today, is the industry which has been giving the new generation to the world of life science. Now days, human lives have become so precious that to save the life of a human being has been a motto of a human being. To expand the possibly the motto, the pharmaceutical industry has been able to give a very breakthrough to the industry in a way of introducing many more of the molecules and dredges to the world.

The - Turnkey Project team **USA Pack Machines LLC. (UPML)** consists of a diverse yet cohesive pool of experts with a feedback-rich dynamic environment that embraces change and learns from their collective experiences. We thrive on innovative design, validation, construction & in-operation Pharmaceutical plant is ready for operations. This adds value to our clients and their subsequent end-users and also adds great intrinsic value to our talent pool.

The core purpose for us to be in business is to add tangible value from a strategic business idea to Commercialization. We always thrive to serve our valued clients with the best & most comprehensive technical consulting and End to end (Turnkey solutions for Pharma Plant Establishment).

SERVICES

Giving an idea of operations, we like to highlight our key specialization to support any Pharmaceutical venture as below,

- Industry Guidance
- Investment suggestion & Guidance
- Manufacturing Guidance to follow GMP compliance (Product, Process, Plant & Execution)
- Regulatory Guidance accordance to the operation level set to meet accreditations
- Identifying the possibilities to explore business opportunities to meet investment plan
- Support system for manufacturing facility for start-up
- Plant Management - Supply Chain management, Input sources, Manufacturing methods & process, Laboratory management, New product development
- Supporting system Marketing set up to explore business model to achieve independent goal & identity creating within Domestic & International market
- International Regulatory support, Guidance, Compliance, Documentation, Training & support to meet the Audits
- Product sourcing, Sales & Marketing infrastructure, Contract manufacturing & sourcing
- International Sourcing contracts, Government Tender supplies & Market sourcing for SOS requirements

INVESTMENT SUGGESTION & GUIDANCE

As an experienced business investor, one can identify the goal to work on any business proposal. Upon this goals, business targets are to be set. On understanding the targets, our support comes to analyse the investment mentality.

By understanding the investment criteria, we can provide options for how business proposals can work. If the investment is imitated with a pharmaceutical background group, then it can help us to present our options better. In case of a non-pharma background, we need to understand the business and how it works & accordingly, we can provide our business projections. The topic remains,

- Project Conceptualization
- Project Requirements
- Product to Manufacturer
- Manufacturing Criteria
- Investment Requirement
- Optimization of Investment & Plant Requirements

GUIDANCE TO FOLLOW GMP COMPLIANCE

Manufacturing guidance will understand required compliance to any plant will require in case of setting up a pharmaceutical manufacturing unit. The criteria can be identified as below,

- Plant design – upon GMP compliance to the regulatory requirement
- Plant building - Follow GMP Compliance of regulatory requirement keeping in mind investment, manufacturing process suitability & esthetic requirement.
- Selection of equipment with synchronization of utility, allied equipment's to match the manufacturing process for utmost possible products in same area to follow validation to match GMP compliance.
- Justifying the GMP manufacturing method with the process equipment's identified to install with collective capacities & operations.
- Plant design to handle in manufacturing process with flow to maintain utmost care to comply GMP requirements.
- Human resource & recruitment to meet & handle most silent, sophisticated & smooth operations. This also follow right selection, eligibility, knowledge, capabilities, training & dedication to work.
- Correctly selected human interface with automation to the right side of the operations.
- Design to handle correctly the material movement – raw material, in process & finished with most justified identification to avoid most possible errors which can cause a great effect to end user.

REGULATORY GUIDANCE GMP COMPLIANCE

Being a human healthcare industry management, need to present & get approved all manufacturing facility with local regulatory department. For this need to follow the guidelines given by local & central authority of food & drug department. Following the required compliance for local authorities, the implementation follows International registration requirements for those requirements.

Steps followed as,

Regulatory Requirements

- Product Identification
- Product Manufacturing requirements to follow GMP.
- To Follow the manufacturing process identified by the domestic FDA and cGMP criteria.
- Compiling International accreditation targeted.
- Necessary in-house documentation format for all regulatory requirements.
- Relevant Document Preparation for Product Dosier Submission
- In-house Quality Management Services (QMS)
- Training of the in-house team to attend Regulatory Audits & Perform Documentation Submission as necessary & asked during audits.

IDENTIFYING POSSIBILITIES TO EXPLORE BUSINESS

OPPORTUNITIES TO MEET INVESTMENT

What are you going to sell?
What price you are going to sell?

Justify investment in right manner will require investment with right distribution & allocation. As elaborated earlier, the investment will require different segment of project. Each segment of project will justify its possibility to meet the return-on-investment plan.

The most important is to identify cost of manufacturing & cost of sale. Becomes priority for own marketing, sales & distribution or contract manufacturing.

This can be identified & executed with the project execution & according the operation investment can be divided. The general support to this division can be as below.

- Own Marketing (Domestic) – Ethical sales, Generic sales, Franchise allotment or OTC selection
- Own Marketing (International) – Depending on Countries identified, Guidance to Plant & product registration process, followed with distribution chain set-up with business guarantee.
- Contract Manufacturing (Domestic) – Contact manufacturing from local marketing companies, who will have their registration for our plant, usually they are identified as virtual manufacturers.
- Contract Manufacturing (International) - Connecting exporter and virtual manufacturer among different companies who look for manufacturing partners.
- Manufacturing collaborations

SUPPORT FOR FACILITY START-UP

The integration of a planning with product selection to plant design, equipment selection & operation synchronization will support the smooth start-up to any manufacturing facility. Supporting the same integration, need team for management & hierarchy to support facility start-up.

Support to identify, organize & recruit manpower to meet the targeted infrastructure results. This can be a backbone for any manufacturing facility to have right sourcing of recruitment to be placed during the right time of operations initiation.

This support will require the placement of human resource with below criteria implementation,

- Adequate knowledge to fit work profile
- Adequate status to perform complete eligibility & skill
- Adequate knowledge to support team - accompanying, Lower & Above
- Adequate nature to adopt
- Adequate training for specific work
- Adequate knowledge & training to meet international compliance standards

PLANT MANAGEMENT

SUPPLY INPUT, MANUFACTURING & PROCESS QUALITY CONTROL (Q.C)

ADMINISTRATION & PLANT MANAGEMENT:

- Analysing production requirement
- Suggest right Equipment, utility & infrastructure support - Given options & feature comparison
- Vendor selection & multiple options
- Set-up supply chain Equipment, utility, consumable, Raw Material with staff training.
- Analytical laboratory set up – suitability for manufacturing process & regulatory requirements
- Staff training & manufacturing process development
- Standard Operating Procedures (SOP) generation – from start operation to manufacturing process certification.
- Validation clearance for all SOP, equipments, utility & operations.

USA Pack
MACHINES LLC.

"Ultimate Solutions Assistance"

Get In Touch

+1 (984) 325-0352

boff@usapack.net

www.usapack.net

402 Apricot Circle Morrisville,
NC 27560 - United States