

MANAGING COMPLEXITIES IN COVID-19 VACCINE MANUFACTURING



GLOBAL CHALLENGES IN COVID-19 VACCINE DEVELOPMENT LIFECYCLE

Having a strong manufacturing system to avoid the manufacturing/dosing errors.

Meeting the massive vaccine demand and achieving the desired output.

Ensuring precisely the right concentration of vaccine in every vial.

Meeting all the required safety, quality, and regulatory measures.

Managing the extensive clinical trials, rigorous sample testing, and the approvals.

Maintaining the efficacy of the vaccines while moving them through the supply chain.

Pulling off a well-organized distribution program of a vaccine during the pandemic.



3 CRITICAL ISSUE AREAS FOR VACCINE MANUFACTURERS

1 Product Development

- Research & design a formula
- Perform intensive testing
- Quality monitoring and maintaining BOM revisions
- Synchronization of material flow
- Manage iterations of development
- Meet regulations while performing trials and analyzing data

2 Supply Chain Optimization

- Make supply chain resilient
- Knowledge of desired output, and required inventory to meet the schedule
- Capacity analysis to determine capacity
- Keep vaccines in the defined tolerance range while in transit

3 Commercialization, Distribution, and Post-Distribution Support

- Commercialization is crucial, since only about 10% of clinical trials are successful
- Taking the developed product from the lab to the last person
- Handling the massive data from the medical, commercial, regulatory, and R&D teams
- Role in planning and executing the comprehensive vaccine distribution plan

VACCINE DEVELOPMENT WORKFLOW



RESEARCH



**PRE-CLINICAL
TRIALS**



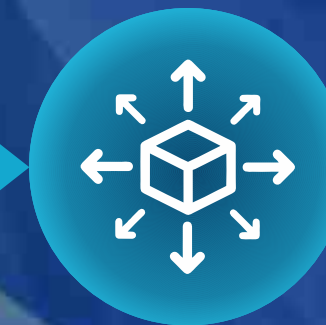
**CLINICAL
TRIALS/
HUMAN
TESTING**



**REGULATORY
REVIEW &
APPROVALS**



LICENSURE



**MANUFACTURING
& DISTRIBUTION**

BATCHMASTER VACCINES MANUFACTURING ERP SOFTWARE CAN HELP!

● **Formulation & Laboratory Management**

- Formula design based on physical properties analysis like potency and strength
- New product development, R&D, and its costing
- Material substitution in formula and revision tracking

● **Bills of Materials (BOM)**

- Complete visibility into the list of materials and intermediates
- Along with their quantity and unit of measure, packaging material, and dosage of finished drug
- Multiple BOMs for same formula to meet the need of different dosages

Supply Chain Management & Scheduling

- System built specifically for supply chain planning for vaccine manufacturers.
- Ensures availability of adequate raw material for production.
- Insights into upcoming preventative maintenance and repairs.
- Integration with tools for cold chain management



BATCHMASTER VACCINES MANUFACTURING ERP SOFTWARE CAN HELP!

● MRP & MPS

- Get knowledge of how much and when is to be produced
- And how much, and when the required material is to be procured to meet this schedule

● Quality Control

- Ensure quality is a part of every single process at every stage of supply chain
- Right from the point of material entering the facility, through to production, and the distribution

● Regulatory Compliance

- Operate in full adherence with all the safety, quality, and regulatory requirements
- Follow all the protocols required in vaccine manufacturing, distribution, and administration



BATCHMASTER VACCINES MANUFACTURING ERP SOFTWARE CAN HELP!

● **Traceability**

- Real-time, end-to-end traceability- right from receiving, weighing, formulation to packaging
- Fulfil all compliance and audit requirements, and reduce issue-tracking, and recall time
- Enhance accuracy through inventory and WIP visibility

● **Sample management, clinical trials, & commercialization support**

- Complete support with clinical trials, sample testing, distribution, and commercialization
- Maintain records of samples along with their trial histories in a single database

● **Distribution management with fleet handling**

- Manage the distribution of safe and efficient vaccine to the communities
- Solution for all- vaccine manufacturers, government bodies, healthcare organizations, distributors, and others





Integration with **BatchMaster's** in-house tools for fleet and personnel tracking and management

- Get granular visibility of the key stakeholders of the entire supply chain.
- Assign the duty of delivering vaccines, define the distribution area, and track the deliveries.
- Integrate this entire data with the data of ERP system, and manage centrally.

BENEFITS OF HAVING BATCHMASTER VACCINES MANUFACTURING ERP SOFTWARE

Faster
time-to-
market

'Right
first time'
quality

Right
concentration
in every vial

Absolute
compliance
to stringent
regulations

Quicker
preventive &
corrective
action

Platform for
continuous
development

Lower cost
of higher
quality

Learn more at: www.batchmaster.co.in