APPLIED MATERIALS®

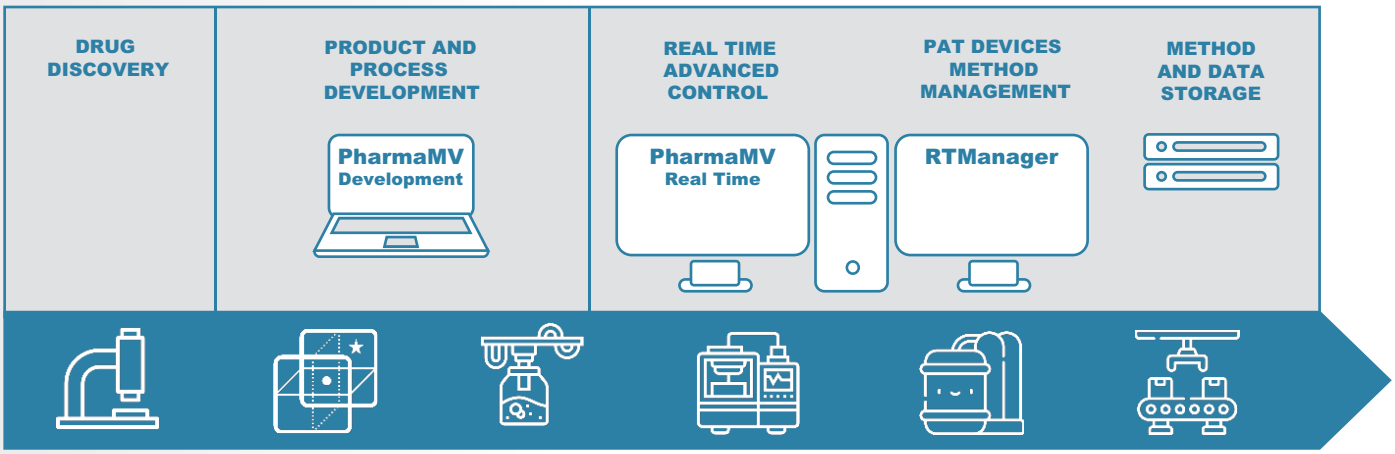
Vaccine Optimisation

Fast track new vaccines to market in-silico, in-vivo, in-situ, in safety

The discovery, development and manufacture of widely adopted vaccines is a highly prized goal for patients and pharma companies alike. Now more than ever there is a pressing need to bring effective vaccines and therapies to the market in as short and safe a timescale as possible.

The process is complex whether based on live or attenuated vaccines, acellular or toxoid components.

Vital steps are taking place in parallel, in shortened timescales, and although the need may be amplified, the challenges remain. To ensure that safety is not compromised there must be stringent control throughout the process, from optimised development and scale-up, into manufacturing resources that are ready to deliver mass volumes of vaccines, finished, filled and distributed on a global scale.



CHALLENGES

The challenges to formulating and manufacturing mass volumes of vaccine are significant.

With an average of 10-15 years in discovery and development – and costs often in excess of $1bn – the key to faster time to market is streamlining the process, employing quality by design (QbD) principals, conducting parallel activities, and building new, tightly-controlled manufacturing capacity around the world.

Once the vaccine candidate is identified, careful experimentation must determine the optimum formulation of API and excipient to ensure in-vivo efficacy. The active material must be purified to ensure patient safety. Where large volumes of vaccine are required around the globe, they must be stabilised for storage. Depending on the nature of the preparation – attenuated or live – this may mean managing the pH with buffer preparations, lyophilising, freeze-drying, for more unstable, live viral vaccines.

PharmaMV

To ensure optimised development, safety and efficacy, it is critical that there is continuity between the development, scale-up and production phases, as well as correlation of clinical data with manufacturing process data.

PharmaMV is a feature-rich and industrially proven Advanced Process Control (APC) software platform, designed to support this critical development and supply chain, enabling optimisation from development to scale-up into manufacturing.

BENEFITS

- **Comprehensive Optimised Experimental Design platform**
- **Data-driven Digital Design and Scale-up**
- **Continuous Process Verification (CPV) suite**
- **Powerful PAT analytics: monitor processes, trigger alerts, protect continuity of supply**
- **Advanced Process Control (APC) enabling precision operation with real time multivariate monitoring, to support teams throughout the vaccine development and production lifecycle.**
- **User-configurable dashboard reporting tools, to facilitate secure sharing of KPIs and learning with all team members.**

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PharmaMV

OPTIMISED EXPERIMENTAL DESIGN PLATFORM

With the race to develop an effective solution, PharmaMV incorporates a dedicated suite of tools for real-time Design of Experiments execution. Perceptive's OEDP includes Machine Learning techniques that allow "smart data" to be generated for process monitoring, control and optimisation.

DIGITAL DESIGN AND SCALE-UP

In preparation for sophisticated manufacturing processes, digital design techniques enable rapid development and testing of Advanced Process Control (APC) methodologies. In-silico monitoring schemes, using parameterised mechanistic models as Digital Twins, generate statistically rich datasets which save time, reduce API consumption and minimise cost before moving onto plant. This reduces the risk in producing high volumes of costly product at early stages.

ADVANCED PROCESS CONTROL

APC can be deployed to counter process disturbances which affect yield, throughput and final quality. The inherent biological variability in raw materials, complex purification processes, environmental controls and even the process itself can affect the integrity of the product. APC does not replace approved pharmaceutical control strategies, but combines dynamic process models with offline and online quality measurements to optimise the output, delivering improved product quality, higher yield, greater agility and tangible savings in time, cost and energy.

No matter which phase you operate in, PharmaMV provides you with a single, integrated, fully-featured and compliant platform, to support rapid product design, development and scale-up, moving confidently into efficient vaccine manufacturing.

SOLUTION

From manufacture to delivery

The development and production of vaccines requires precise Quality Control. Many have to be maintained within specific temperature ranges throughout manufacturing, finish and fill, transportation and storage, prior to administration, which requires a robust cold chain. Defined Critical Quality Attributes (CQAs) are measured using a variety of offline and online Process Analytical Techniques, enabling the 21 CFR Part 11 compliant PharmaMV platform to deliver model-based monitoring and control of multiple CQAs throughout the manufacturing process.

Changing demand

With variations in demand, whether responding to a global pandemic or seasonal vaccination programmes, PharmaMV enables manufacturers to produce high volumes of biopharmaceutical products safely, when and where needed.

Looking to the future

Driven by demand and data, PharmaMV enables and supports new technologies such as continuous manufacturing, real-time release, micro-factories and customized medicines.
Proven vaccines enjoy long product lifetimes, so manufacturing and packaging processes need to adapt to take advantage of new technologies. With the potential for the manufacturing process to be patented, rather than the product itself, dynamic process control strategies are finding an increasing place in the end-to-end development and longevity of new vaccines.

ADVANCED CONTROL FOR BIOPHARMA

Underpinned by Perceptive's PharmaMV, **BioAPC®** is the software solution for practical application of data analytics and advanced process control algorithms within biopharma manufacturing. The platform incorporates additional features to achieve continual monitoring and optimisation of biopharmaceutical processes:

- **Supports batch and continuous processes**
- **Flexible design and real-time execution of Design of Experiments**
- **Offline data analysis, pre-treatment and visualisation**
- **Model Development and Maintenance facilities in-built**
- **Real Time MVA Quality monitoring, Control and Predictive Maintenance**
- **User-configurable dashboards with secure web-based sharing**

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Email: SmartFactory_Rx@amat.com
www.appliedsmartfactory.com