



Innovative Approaches in Vaccine Development: Utilizing VAMFs and vPTMFs

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Goal presentation

To provide an overview of Vaccine Antigen Master Files (VAMFs) and Vaccine Platform Technology Master Files (vPTMFs), highlighting their roles in streamlining vaccine development, fostering innovation, and regulatory approval processes.

VAMF

Vaccine Antigen Master File



What is a VAMF?

❖ EU definition (EMA/CVMP/IWP/258755/2021):

A VAMF is a comprehensive dossier that contains all the detailed information about a specific antigen used in vaccine production. The VAMF includes details on the antigen's production process, its properties, methods of characterization, and quality control measures.

❖ Purpose:

Provide a centralized, standardized set of data that can be referenced by multiple vaccine applications that use the same antigen.

❖ Benefits:

Acceleration of regulatory approval and ensured quality by centralizing data on a specific antigen.

Examples of use of VAMFs

- ❖ A VAMF can be used for authorizing new "fall-out" or "build-up" vaccines containing the same antigen, without needing a full re-assessment of the antigen data.
- ❖ For a combined vaccine containing multiple antigens, a separate VAMF is required for each antigen.
- ❖ Inclusion of an already certified VAMF in a vaccine application is considered a variation not requiring assessment, if it does not affect the properties of the finished product.

EU data requirement for VAMF (1/2)

- ❖ The VAMF should contain information extracted from the relevant sections of Part 2 (Quality documentation) as set out in Section IIIb of Annex II to Regulation (EU) 2019/6. This includes details on:
 - Product description (qualitative/quantitative composition, product development)
 - Description of the manufacturing method
 - Production and control of starting materials (biological and non-biological)
 - Control tests during manufacturing process
 - Batch-to-batch consistency data
 - Stability data
 - Other relevant information

Balancing the Advantages and Challenges of VAMFs

Advantages:

- ❖ Faster Regulatory Approvals: Streamlines the review process by providing centralized, validated data.
- ❖ Enhanced Quality Control: Ensures consistency and high-quality standards across vaccine batches.
- ❖ Operational Efficiency and Risk Mitigation: Reduces duplication of efforts, allowing focus on innovation and production. Mitigates evolving extraneous agent testing and protects authorized seeds/antigens.

Challenge:

- ❖ Setup and Maintenance Complexity: Requires significant upfront effort, time, and resources to compile comprehensive and accurate data. Post-approval process can be complex and requires multiple variations.

vPTMF

Vaccine Platform Technology
Master File



What is a vPTMF?

❖ EU definition (EMA/CVMP/IWP/286631/2021):

A vPTMF is a file containing comprehensive data on a vaccine platform's manufacturing, quality control, stability, safety, and efficacy. Once a vPTMF is certified, the data already approved in the vPTMF does not need to be re-submitted for subsequent products. This allows for the omission and reduction of data requirements in future dossiers.

❖ Purpose:

Reduce data re-submission/re-evaluation and requirements for subsequent vaccines using the same platform.

❖ Benefits:

Saves time and costs, accelerates vaccine availability, and supports 3Rs (reduction in vivo studies).

Examples of vPTMF

A collection of technologies that have, in common, the use of a 'backbone' carrier or vector that is modified with a different active substance or set of active substances for each vaccine derived from the platform. This includes, but may not be limited to:

- Protein-based platforms (virus-like particles)
- DNA vaccine platforms
- mRNA-based platforms
- Replicons
- Self-amplifying RNA and viral and bacterial vector vaccines
(e.g porcine circovirus, myxoma vectored vaccine, fowlpox, turkey herpesvirus, *Erysipelothrix rhusiopathiae*, *Mycoplasma gallisepticum* and *Corynebacterium pseudotuberculosis*)

Examples of vPTMF

The data that may be included in a vPTMF can vary depending on the type of platform. However, common types of data that may be included are:

- ❖ Quality documentation: This includes information about the expression system, gene of interest, manufacturing process, starting materials, controls, specifications, batch-to-batch consistency and stability.
- ❖ Safety documentation: This includes safety data for the initial construct, such as maximum active substance content per dose.
- ❖ Efficacy documentation: This includes efficacy data for the initial construct, such as minimum active substance content per dose.

Balancing the Advantages and Challenges of vPTMFs

Advantages:

- ❖ Streamlined Regulatory Pathways: Facilitates faster regulatory approvals by providing a comprehensive and standardized dossier for platform technologies.
- ❖ Consistent Quality and Safety: Ensures uniformity in vaccine quality and safety across various vaccines developed using the same platform.
- ❖ Accelerated Development: Reduces the time and resources needed for developing new vaccines by leveraging pre-existing platform technology data, thereby fostering innovation in vaccine development.

Challenge:

- ❖ Initial Setup Complexity: Requires substantial upfront investment in terms of time, effort, and resources to compile detailed and accurate data for the master file.

Overall conclusions

VAMFs and vPTMF



Overall conclusions on VAMFs and vPTMFs (1/4)

Key points:

- ❖ VAMFs and vPTMFs as Critical Tools: VAMFs and vPTMFs are essential frameworks in the modern vaccine development landscape.
- ❖ Advantages: Both VAMFs and vPTMFs offer significant advantages, including streamlined regulatory pathways, enhanced quality control, and increased efficiency in resource utilization.
- ❖ Challenges: Acknowledging the initial setup complexity is crucial, as it requires substantial investment in time, effort, and resources to compile comprehensive and accurate data.

Overall conclusions on VAMFs and vPTMFs (2/4)

Importance of VAMFs and vPTMFs in Vaccine Development:

- ❖ Efficiency Gains: These master files can considerably reduce the time required to develop and approve new vaccines, which is critical during health emergencies like pandemics.
- ❖ Quality and Safety Assurance: They ensure consistent quality and safety across different vaccines and batches, thus maintaining high standards in public health.
- ❖ Facilitation of Innovation: By removing redundant efforts and centralizing data, VAMFs and vPTMFs allow researchers and manufacturers to focus more on innovation and less on repetitive documentation.

Overall conclusions on VAMFs and vPTMFs (3/4)

Future outlook:

- ❖ Integration with New Technologies: The potential to integrate VAMFs and vPTMFs with emerging vaccine technologies, such as mRNA and vector-based vaccines, can further accelerate vaccine development.
- ❖ Global Standardization: Improved standardization and harmonization at the global level can enable quicker, more consistent responses to health crises.
- ❖ Pandemic Preparedness and Response: With the foundational data already in place, rapid vaccine development and deployment can be achieved more effectively during pandemics.

Overall conclusions on VAMFs and vPTMFs (4/4)

Next Steps:

- ❖ Investment in Resources: Encourage stakeholders to invest in the initial setup and maintenance of VAMFs and vPTMFs to leverage their full benefits.
- ❖ Strategic Partnerships: While safeguarding proprietary information, there is an opportunity to engage in strategic partnerships with regulatory bodies and trusted industry partners.
- ❖ Continuous Update and Improvement: Commit to continuously updating and refining these master files to keep pace with technological advancements and evolving regulatory requirements.



Thank you.