TIME FOR GMP?

PROGRESSING BACTERIAL-DERIVED EXTRACELLULAR VESICLES TO CLINICAL STAGE

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INTRODUCTION

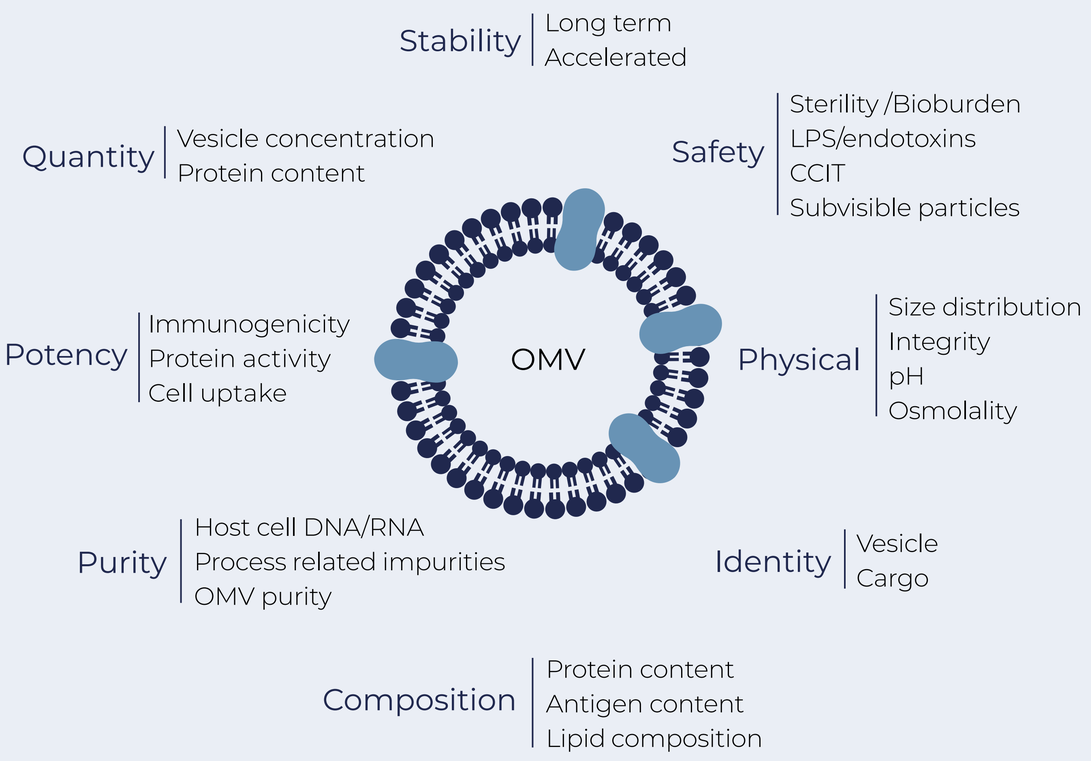
Bacterially derived extracellular vesicles (EVs) such as Outer Membrane Vesicles (OMVs) have emerged as an attractive new modality for both immunotherapy and as vectors for nucleotides and proteins.

Being a highly heterogenic biological, the translation from research to clinical use is not without challenges. Developing effective scalable manufacturing processes and qualified analytical methods meeting the CMC requirements of Good Manufacturing Practices (GMP) needs to follow a defined path.

DEFINE CRITICAL QUALITY ATTRIBUTES (CQA)

"A CQA is a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality" (ICHQ8).

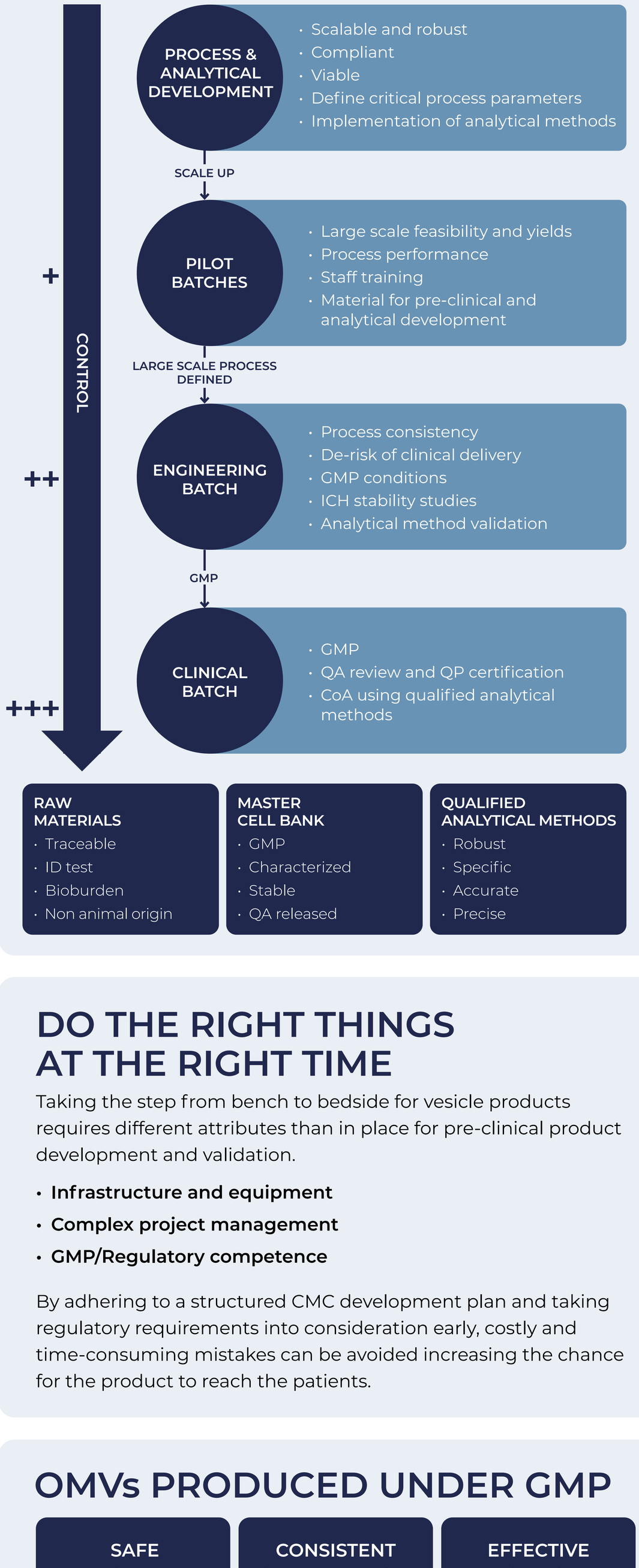
- **Establish preliminary CQAs as early as possible during the product development process.**
- **Link process parameters and material attributes to the CQAs.**



ENSURE A ROBUST CMC CONTROL STRATEGY

A robust, holistic control strategy is essential to ensure the safety and efficacy of OMV products.

PROGRESSING TO CLINICAL MANUFACTURING



DO THE RIGHT THINGS AT THE RIGHT TIME

Taking the step from bench to bedside for vesicle products requires different attributes than in place for pre-clinical product development and validation.

- **Infrastructure and equipment**
- **Complex project management**
- **GMP/Regulatory competence**

By adhering to a structured CMC development plan and taking regulatory requirements into consideration early, costly and time-consuming mistakes can be avoided increasing the chance for the product to reach the patients.

OMVs PRODUCED UNDER GMP

SAFE	CONSISTENT	EFFECTIVE
No harm to the patient	The same product every time	Gives the intended effect