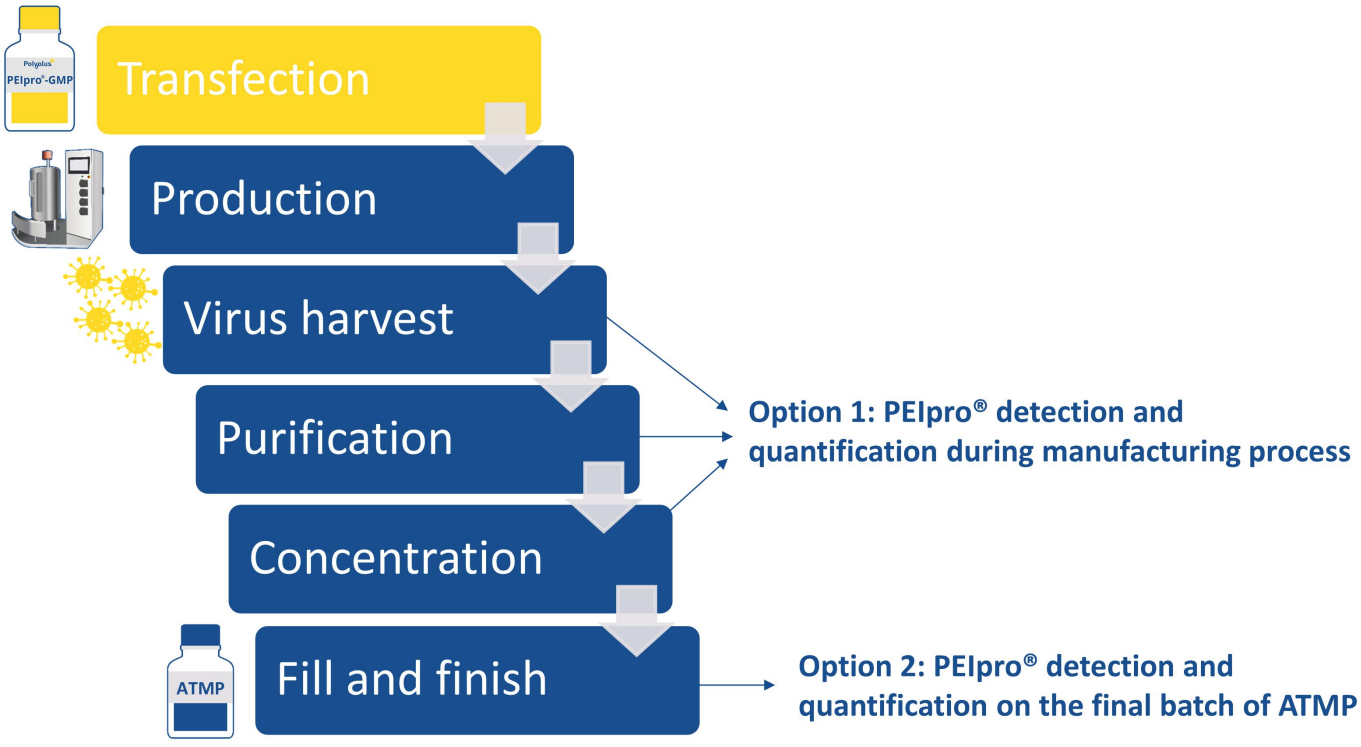
GMP-compliant residual PEIpro® test

Polyplus

GMP-compliant residual PEIpro® test

- Unique validated residual test for PEIpro®
- Risk management: comply with GMP guidelines by demonstrating traceability of residual PEIpro® throughout manufacturing process
- Accuracy: rely on the method developed by the inventors of PEI-based transfection reagents
- Custom-made: adapted to your process to ensure the lowest limit of detection

Regulatory guidelines for the production of ATMPs indicate that residual levels of raw materials used in the manufacturing process should be assessed as well as the significance of the residual level detected. This analysis ensures that the ATMP is reproducibly safe for patient administration. The unique GMP-compliant residual PEIpro® test is a highly accurate and sensitive HPLC/UV-based method validated in compliance with ICH Q2 (R1) guidelines to accurately detect and quantify residual PEIpro® at several stage of the manufacturing process:



Options for the detection and quantification of PEIpro® during the manufacturing process of ATMPs.

Service	Part N°
Residual PEIpro® test	702000006

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