Improvement of manufacturing process of MACS GMP Recombinant Human SCF

Product          REF
MACS® GMP Recombinant Human SCF, 10 µg  170-076-149
MACS® GMP Recombinant Human SCF, 100 µg  170-076-133

Category of change: Improvement of manufacturing process
Adaption of documentation

Current State: The manufacturing of MACS GMP Recombinant Human SCF is carried out according to implemented procedures.

Package Insert
The Data Sheet is specific for the products MACS GMP Recombinant Human SCF 10 µg (170-076-149) and 100 µg (170-076-133). The data sheet states different specifications (e.g. purity, host cell DNA etc.).

Planned change: The downstream processing of MACS GMP Recombinant Human SCF will be adapted to an optimized process. As part of optimizing the downstream processing of the afore mentioned products, package inserts will be harmonized with those of other MACS GMP cytokines.

Package insert
Replacement of individual specifications by “For detailed specifications of MACS GMP Recombinant Human SCF please refer to the respective Product Quality Certificate”.

Justification/Evaluation: By this change the manufacturing process of MACS GMP Recombinant Human SCF is updated and optimized.

The improved manufacturing process for MACS GMP Recombinant Human SCF has been adapted on the basis of existing processes and several development runs. The functionality of the improved manufacturing process was confirmed.

The required manufacturing instructions and product specifications will be implemented prior to manufacturing. No material of human or animal origin will be introduced into the process, therefore the Certificate of Origin is not affected by this change.

Therefore impact on the performance, quality and safety of the MACS GMP Recombinant Human SCF was assessed to be low.
Change Notification
CC-22-0166

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Estimated Implementation: Q4/2022

Please share, if applicable, this information with relevant staff in your organization. If there are any further questions, do not hesitate to contact us.

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Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG