Patent Claims

1. A method for producing C-terminally biotinylated FcRn comprising the steps of

   a) cultivating a mammalian cell comprising a deoxyribonucleic acid encoding FcRn and biotin-[acetyl-CoA-carboxylase] ligase (BirA) in a biotin containing medium, and

   b) recovering C-terminally biotinylated FcRn from the cell or the cultivation medium,

   wherein the deoxyribonucleic acid encoding FcRn and BirA is stably integrated into the genome of the mammalian cell and comprises in 5'- to 3'-direction
   - a first expression cassette encoding class I major histocompatibility complex-like protein (α-FcRn) comprising an Avi-tag at the C-terminus,
   - a second expression cassette encoding β2-microglobulin (β2m),
   - a third expression cassette encoding class I major histocompatibility complex-like protein (α-FcRn) comprising an Avi-tag at the C-terminus,
   - a fourth expression cassette encoding β2-microglobulin (β2m), and
   - a fifth expression cassette encoding biotin-[acetyl-CoA-carboxylase] ligase.

2. The method according to claim 1, wherein the deoxyribonucleic acid encoding FcRn and BirA further comprises
   - a first recombination recognition sequence located 5' to the first expression cassette,
   - a second recombination recognition sequence located 3' to the fifth expression cassette, and
   - a third recombination recognition sequence located between the second and the third expression cassette,

   and

   wherein all recombination recognition sequences are different.

3. The method according to claim 2, wherein the deoxyribonucleic acid encoding FcRn and BirA comprises a further expression cassette encoding for a selection marker and the expression cassette encoding for the selection marker is located

partly 5’ and partly 3’ to the third recombination recognition sequences, wherein the 5’-located part of said expression cassette comprises a promoter and a start-codon and the 3’-located part of said expression cassette comprises the coding sequence without a start-codon and a polyadenylation signal.

4. The method according to any one of claims 1 to 3, wherein each of the expression cassettes comprise in 5’-to-3’ direction a promoter, a coding sequence and a polyadenylation signal sequence optionally followed by a terminator sequence.

5. The method according to claim 4, wherein the promoter is a human CMV promoter with intron A, the polyadenylation signal sequence is a bGH polyA site and the terminator sequence is a hGT terminator except for the expression cassette of the selection marker, wherein the promoter is a SV40 promoter and the polyadenylation signal sequence site is a SV40 polyA site and a terminator sequence is absent.

6. The method according to any one of claims 1 to 5, wherein the mammalian cell is a CHO cell.

7. The method according to any one of claims 1 to 6, wherein the FcRn is human FcRn, the class I major histocompatibility complex-like protein (α-FcRn) is human class I major histocompatibility complex-like protein (α-FcRn), and the β2-microglobulin (β2m) is human β2-microglobulin (β2m).

8. The method according to any one of claims 1 to 6, wherein the FcRn is murine FcRn, the class I major histocompatibility complex-like protein (α-FcRn) is murine class I major histocompatibility complex-like protein (α-FcRn), and the β2-microglobulin (β2m) is murine β2-microglobulin (β2m).

9. The method according to any one of claims 1 to 6, wherein the FcRn is cynomolgus FcRn, the class I major histocompatibility complex-like protein (α-FcRn) is cynomolgus class I major histocompatibility complex-like protein (α-FcRn), and the β2-microglobulin (β2m) is cynomolgus β2-microglobulin (β2m).