with short stature is also problematic. There are reports of neutralizing antibody formation to some insulin products.

[0006] Other biologic drugs that have the potential to elicit neutralizing antibodies include whole blood, serum, plasma pools or other primary sources of biologic supply, for instance, human albumin, human Alpha1-Proteinase Inhibitor, human Antihemophilic Factor/von Willebrand Factor Complex, BabyBig Botulism Immune Globulin Intravenous, C1 Esterase Inhibitor, fibrin sealant, fibrinogen, Immune Globulin Intravenous, Immune Globulin Subcutaneous, Protein C Concentrate, Rho(D) Immune Globulin Intravenous, thrombin, von Willebrand Factor/Coagulation Factor VIII Complex.

[0007] Recombinant polypeptides and proteins elicit immune responses and neutralizing antibody generation based on multiple characteristics, including: the time frame of biologic treatment, the interval of repeat therapy, the amino acid composition of the biologic, and the modifications to the biologic such as glycosylation, methylation, nitrosylation, sialylation, phosphorylation, sulfation, prenylation, selenation, ubiquitinylation, vitamin-dependent modifications, protein binding associations, acylation, glycation, 3 dimensional configurations and supercoiling. Thus there is a need for methods of producing polypeptide protein products having reduced levels of antigenicity in an animal being treated with a biologic product.

[0008] The teachings of all of the references cited herein are incorporated in their entirety herein by reference.

SUMMARY

[0008a] In one aspect, there is provided a method for producing an isolated therapeutic recombinant biologic polypeptide or protein for treating a disease comprising transfecting a synthetically-produced Pluripotent Stem Cell (spPSC) with a nucleic acid that encodes for said therapeutic recombinant biologic polypeptide or protein, under conditions wherein the polypeptide or protein is expressed by said spPSC, and the polypeptide or protein is then isolated from the spPSC, and the spPSC is produced from a cell of an animal.

[0008b] In one aspect, there is provided the use of an isolated therapeutic recombinant biologic polypeptide or protein for the manufacture of a medicament for treating an animal suffering from a disease, wherein the isolated therapeutic recombinant biologic polypeptide or protein is produced by:

(a) identifying an animal suffering from the disease;

(b) providing a synthetically-produced Pluripotent Stem Cell (spPSC) derived from the species of animal suffering from the disease; and

(c) producing the isolated therapeutic recombinant biologic polypeptide or protein by transfecting the spPSC with a nucleic acid that encodes for the therapeutic recombinant biologic polypeptide or protein, under conditions wherein the polypeptide or protein is expressed by said spPSC, and the polypeptide or protein is then isolated from the spPSC.

DESCRIPTION OF THE INVENTION

[0009] The present invention fills this need by providing for methods to produce biologics such as polypeptides or proteins, nucleic acids, viruses and vaccines by transfecting or transforming synthetically produced pluripotent stem cells (spPSCs) or endogenous pluripotent stem cells (ePSC). These cells are derived from the species that is being treated and are transfected with vectors that express the desired biologic and induce expression of the biologic product by the transfected or transformed spPSC or ePSC.

[0010] The present invention further provides for a method for producing a recombinant polypeptide or protein comprising producing spPSCs from adult cells or isolating ePSCs of an animal and transfecting or transforming said spPSCs or ePSCs with a nucleic acid that encodes for said polypeptide or protein under conditions wherein the polypeptide or protein is expressed by said stem cell.

6. The method of claim 5 further comprising immortalizing the transfected, differentiated cells.

7. The method of claim 1 wherein the spPSC is selected from the group consisting of transfected non-Pluripotent ~~Stem~~ Cells, pluripotent stem cells produced by Somatic cell nuclear transfer (SCNT pluripotent stem cells), pluripotent stem cells produced by Altered nuclear transfer, oocyte assisted reprogramming (ANT-OAR pluripotent stem cells) and pluripotent stem cells produced by parthenogenesis (PGA pluripotent).

8. The method of claim 1, wherein the therapeutic recombinant biologic polypeptide or protein is selected from the group consisting of: growth hormones, cytotoxic biologics, and monoclonal antibodies.

9. Use of an isolated therapeutic recombinant biologic polypeptide or protein for the manufacture of a medicament for treating an animal suffering from a disease, wherein the isolated therapeutic recombinant biologic polypeptide or protein is produced by:

(a) identifying an animal suffering from the disease;

(b) providing a synthetically-produced Pluripotent Stem Cell (spPSC) derived from the species of animal suffering from the disease; and

(c) producing the isolated therapeutic recombinant biologic polypeptide or protein by transfecting the spPSC with a nucleic acid that encodes for the therapeutic recombinant biologic polypeptide or protein, under conditions wherein the polypeptide or protein is expressed by said spPSC, and the polypeptide or protein is then isolated from the spPSC.

10. The use of claim 9 wherein the therapeutic biologic polypeptide or protein is selected from the group consisting of erythropoietin, factor VIII, factor IX, thrombin, an antibody or antibody fragment, alpha interferon, interferon alpha 2A and 2B, beta interferon, growth hormone, antihemophilic factor, G-CSF, GM-CSF, a soluble receptor, TGF-ß, bone morphogenic proteins (BMP), TGFα, interleukin 2, ß-glucocerebrosidase or an analogue thereof, alpha1-proteinase inhibitor, fibrin, fibrinogen, von Willebrand factor, imiglucerase, agalsidase beta, laronidase, glucosidase alpha, thyrotropin alpha, and thymosin alpha.

11. The use of claim 9 further comprising immortalizing the transfected spPSC.

12. The use of claim 11 further comprising inducing differentiation of the transfected, immortalized spPSCs.

13. The use of claim 9 further comprising inducing differentiation of the transfected spPSC.

14. The use of claim 13 further comprising immortalizing the transfected, differentiated cells.

15. The use of claim 9 wherein the spPSC is selected from the group consisting of: transfected non-Pluripotent ~~Stem~~ Cells, pluripotent stem cells produced by Somatic cell nuclear transfer (SCNT pluripotent stem cells), pluripotent stem cells produced by Altered nuclear