CLAIMS

What is claimed is:

1. A process for separating target proteins from non-target proteins, comprising:

a) obtaining a liquid sample containing target proteins and non-target proteins;

b) increasing the concentration of the target proteins and substantially all of the non-target proteins in the sample to produce a concentrated feed for delivery to an affinity chromatography device;

c) delivering the concentrated feed to the affinity chromatography device;

d) separating the target proteins from the non-target proteins in the affinity chromatography device; and

e) recovering the target proteins from the affinity chromatography device.

2. The process of Claim 1, wherein the concentration of the target proteins and non-target proteins in the sample is increased using a tangential flow filtration (TFF) process.

3. The process of Claim 2, wherein the TFF process is a single-pass TFF (SPTFF) process; a TFF process operating in a mode where at least a portion of the retentate is recirculated after a first pass through the TFF system; or a recirculating TFF process.

4. The process of Claim 1 or Claim 2, wherein the sample is diluted to produce a diluted feed, prior to increasing the concentration of the target proteins and non-target proteins in the sample in step b).

5. The process of Claim 1 or Claim 2, wherein the target proteins are monoclonal antibodies.

6. The process of Claim 1 or Claim 2, wherein the non-target proteins are host cell proteins from hybridoma cells expressing the target protein.

7. The process of Claim 1 or Claim 2, wherein the affinity chromatography device includes an affinity chromatography medium.

8. The process of Claim 1 or Claim 2, wherein the affinity chromatography device is disposable.

9. A process for increasing the capacity of a chromatography device for a target protein, comprising:

a) obtaining a liquid sample containing target proteins and non-target proteins;

b) increasing the concentration of the target proteins and substantially all of the non-target proteins in the sample to produce a concentrated feed for delivery to an affinity chromatography device; and

c) delivering the concentrated feed to the affinity chromatography device,

wherein the capacity of the affinity chromatography device for the target protein is increased.

10. The process of Claim 9, wherein the concentration of the target proteins and non-target proteins in the sample is increased using a tangential flow filtration (TFF) process.

11. The process of Claim 10, wherein the TFF process is a single-pass TFF (SPTFF) process, a TFF process operating in a mode where at least a portion of the retentate is recirculated after a first pass through the TFF system or; is a recirculating TFF process.

12. The process of Claim 9 or Claim 10, wherein the sample is diluted to produce a diluted feed, prior to increasing the concentration of the target proteins and non-target proteins in the sample in step b).

13. The process of Claim 9 or Claim 10, wherein the target proteins are monoclonal antibodies.

14. The process of Claim 9 or Claim 10, wherein the non-target proteins are host cell proteins from hybridoma cells expressing the target protein.

15. The process of Claim 9 or Claim 10, wherein the affinity chromatography device includes an affinity chromatography medium.

16. The process of Claim 7 or 15, wherein the affinity chromatography medium is a protein A medium, a protein G medium or an immobilized metal ion medium.

17. The process of any one of Claims 2, 3, 10 or 11, wherein the TFF process comprises performing continuous diafiltration or discontinuous diafiltration.

18. A process for purifying target proteins from non-target proteins in a liquid sample, comprising:

a) increasing a concentration of target proteins and substantially all of the non-target proteins in the sample by a single-pass tangential flow filtration (SPTFF) process to produce a concentrated feed;

b) delivering the concentrated feed to a protein A chromatography device;

c) separating the target proteins from the non-target proteins in the protein A chromatography device; and

e) recovering the target proteins from the protein A chromatography device.

19. The process of Claim 18, wherein the SPTFF process provides direct flow-through concentration of the liquid sample to the protein A chromatography device.

20. The process of Claim 18 or Claim 19, wherein the protein A chromatography device includes a protein A affinity resin.

21. The process of Claim 18 or Claim 19, wherein the protein A chromatography device includes a protein A affinity membrane.