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 non-target proteins in the sample to produce a concentrated feed for delivery to a chromatography device;

c) delivering the concentrated feed to the chromatography device;

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

e) recovering the target proteins from the 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 single-pass TFF mode where at least a portion of the retentate is recirculated after the 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 chromatography device includes 1) an anion-exchange chromatography medium or a hydrophobic interaction

chromatography medium; 2) a size-exclusion chromatography medium; 3) a salt-tolerant membrane adsorber; or 4) an affinity chromatography medium.

8. The process of Claim 1 or Claim 2, wherein the 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 non-target proteins in the sample to produce a concentrated feed for delivery to a chromatography device; and

c) delivering the concentrated feed to the chromatography device,

wherein the capacity of the 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 single-pass TFF mode where at least a portion of the retentate is recirculated after the 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 chromatography device includes 1) an anion-exchange chromatography medium; 2) a hydrophobic interaction

chromatography medium; 3) a size-exclusion chromatography medium; or 4) a salt-tolerant membrane adsorber.

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

17. A process for filtering viruses from a liquid sample, comprising:

a) obtaining a liquid sample containing target proteins and viruses;

b) increasing the concentration of the target proteins and viruses in the sample to produce a concentrated feed for delivery to a viral filtration device;

c) delivering the concentrated feed to the viral filtration device; and

d) removing viruses from the feed in the viral filtration device.

18. The process of Claim 17, wherein the protein concentration of the sample is increased using a tangential flow filtration (TFF) process.

19. The process of Claim 18, wherein the TFF process is a single-pass TFF (SPTFF) process; a TFF process operating in single-pass TFF mode where at least a portion of the retentate is recirculated after the first pass through the TFF system; or a recirculating TFF process.

20. The process of Claim 17 or Claim 18, wherein the viral filtration device includes a flux-limited filter.

21. The process of any one of Claims 1 to 3, 9 to 11 and 17 to 19 , further comprising performing continuous diafiltration or discontinuous diafiltration.

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

a) increasing a concentration of target proteins and 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 an anion exchange (AEX) chromatography device;

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

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

23. The process of Claim 22, wherein the sample further includes viruses, and further comprising:

increasing a concentration of viruses in the sample by the SPTFF process; and

separating the target proteins from the viruses in the AEX chromatography device.

24. The process of Claim 22 or Claim 23, further comprising diafiltering the liquid sample prior to increasing the concentration of target proteins and non-target proteins in the sample by the SPTFF process.

25. The process of Claim 24, wherein diafiltering the liquid sample includes adding a diafiltration solution to the unfiltered sample at a same rate of removing permeate from the sample during the SPTFF process.

26. The process of Claim 22, wherein the SPTFF process provides direct flow-through concentration of the liquid sample to the AEX device.

27. The process of Claim 22 or Claim 23, wherein the AEX chromatography device includes an Eshmuno® Q resin.

28. The process of Claim 22 or Claim 23, wherein the SPTFF process is an ultrafiltration SPTFF process.

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

a) increasing a concentration of target proteins and 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 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.

30. The process of Claim 29, wherein the SPTFF process provides direct flow-through concentration of the liquid sample to the protein A chromatography device.

31. The process of Claim 29 or Claim30, wherein the protein A chromatography device includes a protein A affinity resin.

32. The process of Claim 29 or Claim 30, wherein the protein A chromatography device includes a protein A affinity membrane.