CLAIMS

1. A system for producing a small-scale mixer for mixing biopharmaceutical proteins into an aqueous formulation, the system comprising:

a first plurality of dimensions based on a respective plurality of dimensions of an at-scale mixer;

a second plurality of dimensions independent of the respective plurality of the at-scale mixer, wherein the second plurality of dimensions is calculated to prevent degradation of the biopharmaceutical proteins in the aqueous formulation;

a three-dimensional printer configured to receive the first plurality of dimensions and the second plurality of dimensions and produce the small-scale mixer; and

a smoothing apparatus configured to smooth a surface of the small-scale mixer.

2. The system of claim 1, wherein a scaling factor relates the first plurality of dimensions of the small-scale mixer to the respective plurality of dimensions of the at-scale mixer.

3. The system of claim 1, wherein the first plurality of dimensions of the small-scale mixer and the respective plurality of dimensions of the at-scale mixer comprise impeller clearance off bottom of mixer (C), impeller diameter (D), liquid level (H), rotational speed (N), tank diameter (T), blade width (W), blade height (BH), and baffle width (WB).

4. The system of claim 1, wherein the second plurality of dimensions is generated by a computational fluid dynamic technique simulating physical forces imparted on an impeller of the small-scale mixer during mixing of the biopharmaceutical proteins in the aqueous formulation.

5. The system of claim 1, wherein the three-dimensional printer is configured to produce the small-scale mixer using one of the following: polycarbonate (PC), acrylonitrile butadiene styrene (ABS), polylactic acid (PLA), polyethylene terephthalate (PET), nylon, metal, and glass/PET.

6. The system of claim 1, wherein the smoothing apparatus is configured to mechanically smooth the surface of the small-scale mixer.

7. The system of claim 1, wherein the smoothing apparatus is configured to chemically smooth the surface of the small-scale mixer using a volatile solvent bath.

8. The system of claim 7, wherein the volatile solvent is acetone or dichloromethane.

9. A method for producing a small-scale mixer for mixing biopharmaceutical proteins into an aqueous formulation, the method comprising:

obtaining a respective plurality of dimensions of an at-scale mixer;

determining a first plurality of dimensions of the small-scale mixer based on the respective plurality of dimensions of the at-scale mixer;

determining a second plurality of dimensions of the small-scale mixer independent of the respective plurality of dimensions of the at-scale mixer, wherein the second plurality of dimensions are calculated to prevent degradation of the biopharmaceutical proteins in the aqueous formulation; and

generating, using a three-dimensional printer, the small-scale mixer based on a combination of the first plurality of dimensions and the second plurality of dimensions.

10. The method of claim 9, further comprising:

smoothing a surface of the small-scale mixer.

11. The method of claim 10, wherein smoothing comprises mechanically abrading the surface of the small-scale mixer.

12. The method of claim 10, wherein smoothing comprises chemically polishing the surface of the small-scale mixer using a volatile solvent.

13. The method of claim 9, wherein the first plurality of dimensions of the small-scale mixer and the respective plurality of dimensions of the at-scale mixer comprise impeller clearance off bottom of mixer (C), impeller diameter (D), liquid level (H), rotational speed (N), tank diameter (T), blade width (W), blade height (BH), and baffle width (WB).

14. The method of claim 9, wherein determining the second plurality of dimensions of the small-scale mixer comprises determining physical forces on an impeller of the small-scale mixer during mixing of the biopharmaceutical proteins in the aqueous formulation.

15. The method of claim 9, wherein generating the small-scale mixer comprises comprises fused filament fabrication of the small-scale mixer.

16. The method of claim 15, wherein generating the small-scale mixer comprises producing the small-scale mixer using one of the following: polycarbonate (PC), acrylonitrile butadiene styrene (ABS), polylactic acid (PLA), polyethylene terephthalate (PET), nylon, metal, and glass/PET.

17. The method of claim 9, further comprising

generating a first volume of a first product using the at-scale mixer;

generating a second volume of the first product using the small-scale mixer; and

comparing one or more physical parameters of the first volume and the second volume.

18. The method of claim 17, further comprising:

comparing shear stress of generating the first volume with shear stress of generating the second volume.

19. The method of claim 18, wherein the shear stress comprises shear stress imparted on an impeller of the small-scale mixer.

20. The method of claim 17, wherein the one or more physical parameters include visual inspection, pH, protein concentration, turbidity, purity, particulate density, or a combination thereof.