

Assessment of your knowledge

(a) Answer the following questions to assess your command on terminology, facts, concepts, and theories learned in this chapter:

1. Describe in layman's terms what a digital twin is and what it can be used for.
2. Why is soft sensing essential for personalized TEP manufacturing?
3. What is process robustness and why is it important?
4. What is the connection between ATMPs and TEPs?
5. Why is process scalability important?
6. Mention two advantages and two disadvantages of both mechanistic and data-driven models.
7. How can digital twins aid in reducing the cost and time needed to develop a TEP manufacturing process?
8. What is the difference between an autologous and an allogeneic process or therapy?
9. What is a Unit Operation? Give an example of a common Unit Operation in a TE manufacturing process.
10. What is DoE? What is its role in Quality-by-Design?
11. What is the role of Critical Quality Attributes in TE manufacturing?
12. What is the role of Critical Quality Attributes from a regulatory standpoint?
13. Why is process automation important?
14. What is the relationship between Process Parameters, Material Attributes, and Critical Quality Attributes?
15. What is the importance of a QC strategy?

(b) Answer the following questions to assess your ability to apply the concepts and theories learned in this chapter in real life, clinical, and scientific situations.

1. What is the added value of Quality-by-Design in the context of TE process development?
2. For a selected TE publication, describe the manufacturing process of the TEP in terms of Critical Quality Attributes, Unit Operations, Process Parameters, and Material Attributes.
3. What are the main challenges in TE manufacturing?
4. What is the importance of product quality?
5. What are the unit operations and the process parameters of the Cocoon bioreactor?
6. What is the added value of digital twins for process development?
7. Research and describe an analytical method for one of the most common TEP CQAs that is nondestructive and automatable.
8. What is the potential of personalized medicine? What extra challenges does it bring?