SiO2 Medical Products™
SCIENCE INSIDE™

Target Drug Product Profile Questionnaire

In order to become your preferred vendor, SiO_2 needs to know more about you and your project to ensure that our products are compatible with yours. The purpose of this questionnaire is to confirm that we are able to provide you with a package that meets the needs of your product. We want to be aware of the chemical, physical and biological parameters of your product so that we can meet your packaging needs. We respect your confidentiality, so if there is information that cannot be provided, please note "CONFIDENTIAL" in the text boxes below. If necessary, we can execute a confidentiality agreement in order to move forward. If you would rather speak to someone one-on-one, please reach out to Eugene Polini to discuss your project, 334-332-4076, or contact our team at sio2-info@sio2med.com.

SiO_2 Medical Products
Auburn, Alabama

Target Drug Product Profile Questionnaire

Client Contact Information

1. Company Name:
2. Client Contact Name and Title:
3. Address:
4. Telephone:
5. Email:

Drug Product Requirements

6. Chemical/Generic Name of Drug Product:
7. pH:
8. Excipients:
9. Inert Gas Headspace: ◯ Yes ◯ No If yes, please detail:
10. Viscosity:
11. Particle Requirements:
12. Target Shelf Life:
13. Sensitivities (e.g. latex, oxygen, heavy metals, etc.):
14. Biological/Sterilization Requirements:
15. Lyophilized: ◯ Yes ◯ No Cake Weight: Moisture Specification:

Primary Container Requirements

16. Vial Size and Finish:
17. Fill Volume:
18. Syringe - Prefilled: ◯ Yes ◯ No Volume:
    ◯ Luer Lock ◯ Staked Needle
    Needle Gauge: Length:
    Flange: ◯ Cut ◯ Round ◯ Small Round
19. Unique Unit Identification/Serialization Requirements (Laser Engraving, 2D Bar Code, etc.)

Secondary Container Requirements

20. Secondary Packaging (bulk/brick, tub, nest):
21. Ancillary device which will interact with primary packaging like auto-injector, pen, safety devices, reconstitution system, etc.:
22. Printing requirements on syringe (print line/print graduations/etc.) and dimensions, etc.:

Secondary Container Requirements

23. Drug Development Process Phase:
24. Regional Regulatory Requirements: ◯ US ◯ Europe ◯ Japan ◯ Other (Please detail):

Logistics

25. Sample Requirements:
    Feasibility:
    Stability:
    Process Validation:
    Packaging Line Verification/Validation:
26. Labeling Requirements:

27. Shipping Requirements:

28. Anticipated Future Volume Requirements: Year 1 _____ Year 2 _____ Year 3 _____
29. Will you fill in-house or CMO?:
    What type of equipment will you use?
30. Comments: