

Material Development Questionnaire

Initiation date:

Customer name:

Location:

Product name and type:

Brief description of the application / functional requirement:

What is the base polymer?

Volume of business (quantity/year):

\$ Amount/year: \$

Any material specifications like hardness, tensile strength, elongation, modulus, tear property?

Yes No

If yes, please provide all the information.

Customer has their own material:

Yes No

If yes, provide detail of that material.

Any customer input about material requirements?

Yes No

If yes, provide detail.

Is the customer open to different materials (for trial and evaluation):

Yes No

Does this material exist in our library or does it need to be developed?

Do we need to develop this material internally or externally?

What is color of the finished parts? Do they have any samples to match color? Yes No

Other requirements:

Does it require self-sealing? Yes No If yes, what's the target requirement? Needle type/size etc.

Is there a cytotoxicity requirement? Yes No If yes, need more detail.

Is cytotoxicity test absolutely required? Yes No If yes, who is going to perform the test?

Is there a USP, EP, JP or ISO 10993 requirement? Yes No Which one?

Is there a turbidity requirement? Yes No If yes, what's the target? Which method-USP,EP etc.?

Is there a reducing agent requirement? Yes No If yes, please define requirement.

Is there a penetrability test? Yes No **If yes, provide a brief description about needle/Spike etc.**

Are any other functional tests required? Yes No **If yes, please provide a brief description.**

Will the material come in contact with drug media? Yes No **If yes, how long and what temperature?**

What's the type of drug solution? Is it Highly Acidic Neutral

Will the functional part in actual application remain in: Compressed mode Non-compressed mode
If it is in compressed mode - then how long?

Is there any extractable and leachable concern or requirement? Yes No

Will the parts need to be siliconized? Yes No **If yes, who will do it?** Customer Qure Med

Will the part be used in: Static application Dynamic application

Method of sterilization: Gamma EtO Steam Other

If it is gamma sterilization, what's the maximum dosage exposure?

Estimated time to develop the material(s):

Project Priority #: High Medium Low **Rank:**

Please include additional comments the box below: