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Elastomer Stoppers with FluroTec® Film: The Right Choice for SARS-CoV-2 Vaccines

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Lack of certainty regarding whether a package system is available, and can accommodate the format needed, creates a risk

Development and distribution of a vaccine for SARS-CoV-2 presents challenges that are, without hint of exaggeration, unprecedented. One of these challenges concerns storage, namely selection of vial/stopper primary package systems that guarantee quality and safety of the vaccine from manufacture through delivery. This selection is complicated greatly by the accelerated timelines for vaccine approval.

Two aspects comprise the challenge in package system selection:

1. The first concerns the vaccine platform. Six platforms are now considered; they are listed with their proposed vehicles in Table 1. (1) Noteworthy is that two of them (RNA, DNA) are new. Ordinarily, there would be no difficulty in selecting a package system for any of the platforms, since ample time would be available for evaluation of compatibility with both the vaccine and the vehicle. But, for a SARS- CoV-2 vaccine, this is not the case, since approval timelines are accelerated. So, whether the vaccine platform is extant or new, selection of the package system must be made quickly. This creates a risk.
2. The second concerns stability during storage and distribution. A vaccine platform and package system may be identified, but other factors must be considered, such as:

? Form: serum or lyophilized

? Delivery: multi- or single-dose

? Temperature: room (25oC), refrigerated (2-8oC), or low (-80oC)

? Availability of package system components

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Table 1. Potential Vaccines for SARS-CoV-2 (1)

Vaccine Platform	Chemical Composition	Vehicle	Existing, Licensed Human Vaccine
RNA	nucleotides (ribose groups, amino/amide groups, charged phosphate groups)	encapsulated in lipid in non-polar liquid	No
DNA	nucleotides (ribose groups, amino/amide groups, charged phosphate groups)	aqueous (saline) solution, encapsulated in lipid in non-polar liquid	No
Recombinant Protein	polypeptides (amino acid groups)	aqueous	Yes (baculovirus and yeast expression)
Viral Vector Based	virus shell comprises proteins (i.e., polypeptide: amino acid groups)	aqueous	Yes (vesicular stomatitis virus)
Live Attenuated	virus shell comprises proteins (i.e., polypeptide: amino acid groups)	aqueous	Yes
Inactivated	virus shell comprises proteins (i.e., polypeptide: amino acid groups)	aqueous	Yes

This is discussed in a new report by West scientists: Elastomer Stoppers with FluroTec Film:The Right Choice for SARS-CoV-2 Vaccines. To download the report or learn more about the FluroTec Film,please contact **Shraddha.Sharma@Westpharma.com**

1. Amanat, F. and Krammer, F. SARS-CoV-2 Vaccines: Status Report. Immunity, 52, 583-589 (April 14, 2020)

(This article is abstracted from Ranjana Singh, Ph.D., William Garzon-Rodriguez, Ph.D., Peggy Frandolig, Cathy Zhao, Ph.D. and T.Page McAndrew, Ph.D. Elastomer Stoppers with FluroTec Film: The Right Choice for SARS-CoV-2 Vaccines)