

Supplier Scouting Opportunity Synopsis 2023-039

Item Information

Item to be scouted: Sterile nasal saline solution in BOV packaging

Days: 30

Item description: Client is seeking a third party to manufacture sterile nasal saline solution, 0.9% sodium chloride. This item will be ordered via the client's website as an accessory to the existing pediatric nasal device already manufactured and distributed by client. Manufacturer is expected to have full QMS and FDA certifications, potentially ISO 13485 as an additional certification. Finished product would need to be shipped to Atlanta, GA for consolidation with client's existing product.

Technical Information

Supplier Information

Type of supplier being sought: Contract manufacturer

Reason for scouting submission: New product startup

Summary of technical specifications and performance requirements

Describe the manufacturing processes (elaborate to provide as much detail as possible): Standard saline solution manufacturing. packaged in bag-on-valve (BOV) format.

Provide dimensions / size / tolerances / performance specifications for the

item: The item must be packaged in a Bag-on-valve (BOV) format, with no preservatives. The item packaging (outer can) must support the client's custom branding/artwork. The can diameter is expected to be 45mm; the can volume is expected to be 3.1 oz. The client is open to alternative can diameters and fill volume based on costs or general recommendations. Client has not established on-going volumes, but would expect to purchase an initial quantity of 30K over 6 - 12 months. Client is targeting to have an initial supply by August 2023 (earliest) or by 4Q, 2023.

List required materials needed to make the product, including materials of product components: This is a sterile sodium chloride (0.9%) solution.

Are there applicable certification requirements?: FDA, ISO 13485 **Are there applicable regulations?:** All applicable FDA certification requirements

Are there any other standards, requirements, etc.?: N/A

Business Information

Volume and pricing

Estimated potential business volume:

Annual volume not yet known, as this is a new product. Client is expecting to procure around 30K in the initial purchase, and determine on-going requirements after that point.

Estimated target price / unit cost information (if unavailable explain):

\$2.00 - \$2.50 EA

Delivery requirements

When is it needed by?: Target is August, 2023 (earliest), or 4Q 2023

Describe packaging requirements: Bag-on-valve (BOV) for individual unit; client is open to discussion on packaging of individual units in overpack case (qty per case, etc.)

Where will this item be shipped?: Atlanta, GA

Additional comments

Is there other information you would like to include?: N/A