

Competitive Contract Notice

Title :	GB-SALISBURY: SUSTAINED RELEASE THERAPY FOR TREATING PERCUTANEOUS POISONING
Awarding Authority :	Defence Science & Technology Laboratory (DSTL) DSTL G02-D, Bldg 5 Porton Down SALISBURY SP4 0JQ United Kingdom Tel: 01980 613121 , Fax: 01980 658400 Email: centralenquiries@dstl.gov.uk
Contract Type :	SERVICES
Description :	<p>Pharmaceutical products.</p> <p>Dstl has a requirement to develop medical countermeasures to prevent or mitigate the physiological effects of exposure to nerve agents by the percutaneous route. A new drug combination therapy has been developed for intramuscular administration against nerve agent poisoning consisting of HI-6 dimethanesulphonate (DMS), atropine sulphate and Avizafone (known as “Triple Therapy”). There is now a requirement to deliver this combination of drugs by a form of slow delivery following a single administration in order to combat the effects of the slow absorption of these agents by the percutaneous route.</p> <p>MINIMUM STATEMENT OF REQUIREMENT.</p> <ol style="list-style-type: none"> 1. A formulation that delivers the following therapy drugs at the following rates <ol style="list-style-type: none"> a. Atropine sulphate release rate= $0.07 \text{ mg.kg}^{-1}.\text{min}^{-1}$ b. HI-6 (DMS) release rate = $0.24 \text{ mg.kg}^{-1}.\text{min}^{-1}$ c. Avizafone/ diazepam release rate = $0.01 \text{ mg.kg}^{-1}.\text{min}^{-1}$ 2. A formulation that will release all the therapy drugs over a period of at least 6 hours with a maximum reduction in delivery rate of each component of 10%. 3. A formulation that can be delivered via a route that is neither oral nor rectal, nor one that utilises mucosal membranes (e.g. sub-lingual, buccal, nasal). These restrictions are in place due to the toxicological effects of nerve agents which include salivation, lacrimation, rhinorrhea, general hyper-secretion, vomiting, diarrhoea and gastric hyper-mobility. 4. A formulation volume suitable for pre-clinical use that can be scaled up for use in humans for future studies. 5. A formulation that can be transitioned to production via Good Manufacturing Practice (GMP) techniques. Whilst manufacture to GMP is not required for the current pre-clinical studies, the formulation should be able to be adapted to allow manufacture to GMP standards for future studies. 6. Delivery of Qty 16 doses in addition to Qty 4 placebo doses required by October 2012 for use in proof of principle studies. 7. Delivery of the in vitro release rate characteristics of the therapy drugs from the proposed formulation by July 2012 8. Production of Progress Reports and participation in regular Progress Meetings with representatives of Dstl. <p>DESIRABLE CHARACTERISTICS.</p> <p>Ultimately we are seeking a solution that can be used in a wide variety of environments by individuals wearing full body personal protective equipment (respirator with CBRN suit and gloves). As a result, the following properties in the proposed formulation are highly desirable:</p> <ol style="list-style-type: none"> 1. Robust, e.g. Insensitive to mechanical shock

	<ol style="list-style-type: none"> 2. Insensitive to environmental conditions, e.g. cold, heat, damp 3. No need for special storage conditions, e.g. refrigeration 4. A delivery route that minimises any breach in the personal protective equipment and can be delivered easily. (A comparable product currently In Service (Combopen ®) is delivered via intra-muscular injection through the protective suit) 5. Well tolerated by individuals 6. Stable 7. Does not need surgical removal post delivery of therapy drugs
CPV Codes :	33600000 - Pharmaceutical products.
NUTS codes :	UKK1 - Gloucestershire, Wiltshire and Bristol/Bath area
Main Site or Location of Works, Main Place of Delivery or Main Place of Performance :	Gloucestershire, Wiltshire and Bristol/Bath area,
Reference Attributed by the Awarding Authority :	DSRLX-1000063118
Category II:	40K - 93K GBP
Deadline for Expression of Interest :	Fri Nov 25 17:00:00 GMT 2011
Address to which they must be sent :	<p>Dstl G02-D Bldg5 Porton Down SALISBURY SP4 0JQ United Kingdom</p> <p>Tel: 01980 658259, Fax: 01980 658400 Email: bsmorris@dstl.gov.uk,</p>
Other Information :	<p>INFORMATION REQUIRED: - TECHNICAL.</p> <ol style="list-style-type: none"> 1. An overview of the formulation type and mechanism of sustained release from the proposed formulation. 2. How well established are the technologies you are proposing to use? 3. What is the proposed route of delivery? 4. Does the proposed formulation allow the release rates of the therapy drugs to be altered, if so to what extent? 5. Does the proposed formulation need refrigeration? 6. Do you have any background information from formulations utilising similar preparations to the proposed formulation on the:- <ol style="list-style-type: none"> a. Stability b. Robustness c. Effects of the environment d. Tolerability by humans. 7. Can you provide estimates on the delivery profile of the therapy drugs from the formulation? 8. Can the proposed formulation be used for the release of other drugs in the same families of those stated above? <p>INFORMATION REQUIRED: - COMMERCIAL. Please provide evidence of: -</p> <ol style="list-style-type: none"> 1. Your track record in the field of sustained release with special reference to systems that have used the formulation approach you are proposing, e.g. marketed products,

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| | <p>publications, companies/ institutions you have collaborated with.</p> <ol style="list-style-type: none">2. Maturity of the technologies you are proposing to use.3. Ability to handle the APIs – (currently held or ability to obtain). Customer to supply APIs.4. Working to GMP standards or products you have produced that have progressed to manufacture at GMP standard. |
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