NOTICE OF SOLE SOURCE INTENT

Requisition No. 1244689

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The U.S. Food and Drug Administration (FDA), Office of Acquisitions & Grants Services (OAGS), intends to award a sole source purchase order to Malcolm Sparrow, Ph.D. Dr. Sparrow is able to supply the required training course: Malcolm Sparrow, Ph.D., Harvard Kennedy School for the Risk-Informed Regulation Workshop. This one (1) day course will occur between August 1, 2021 – September 30, 2021. The Statement of Work is attached.

A determination that the proposed price is fair and reasonable will be made in accordance with FAR 13.106-3. Interested parties may identify in writing their interest and capability to respond. Responses must be received by no later than 12:00 PM, Eastern Time, Thursday, July 8, 2021. If the FDA identifies no other capable sources by that day and time, a Firm-Fixed-Price Purchase Order will be issued to Malcolm Sparrow, Ph.D.

Any inquiries should be directed to Bonnie M. Amond at bonnie.amond@fda.hhs.gov; with a cc: to James G. Whitt at james.whitt@fda.hhs.gov.

Posted July 1, 2021

This notice of intent is not a Request for Quotations (RFQ).

Statement of Work (SOW)

Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), Talent Development Learning Center (TDLC), Risk-Informed Regulation Workshop

Background:

The U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) has a need to offer a risk-informed regulation workshop to its staff. Although it is understood what risk-informed regulation means for the regulations themselves, CVM has a need for a course that focuses on what it means to be a risk-informed regulator at the operational level. Although the risk literature tends to focus on the ways in which risks are perceived by individuals, and how social, emotional and psychological factors distort risk-assessments and affect behavior, CVM is interested in research-based approaches to addressing the challenges regulatory professionals face in a government regulatory program.

Objective:

The purpose of this requirement is to provide a course to our Center that defines "risk-informed regulation" and its relationship to the fundamental design dilemmas relevant to regulatory settings, such as the Center of Veterinary Medicine.

Scope of Work:

The Contractor shall provide a virtual course to CVM staff that is up to one (1) full day in length. It is expected that this virtual course would be held in the August 2021 to September 2021 timeframe.

CVM is interested in a course that defines "risk-informed regulation" and its relationship to the fundamental design dilemmas relevant to regulatory settings, such as CVM. Specifically, the Contractor shall address the following learning objectives:

- Explore the relationship between compliance and risk-management
- Discuss the balance between promoting "goods" and identification and control of "bads"
- Discuss the concept of Regulatory Craftsmanship
- Address the challenges of organizing around risks rather than functions and processes
- Explore the implications of adopting a "risk-informed" or "problem-centric" focus
- Examine the classes of risk that prove the need for problem-centric capability.
- Discuss the relationship between risk-management and the choice of regulatory structures
- Explore different types of relationships with regulated industry
    - Discuss setting the tone, and appropriate expectations, for the nature of relationships between regulators and regulated industry
- Explore classes of risk that present special challenges for regulators

The Contractor shall discuss how "success" should be defined within a regulatory organization. The Contractor, based on their professional expertise and experience, shall design an engaging course that addresses these learning objectives in a way that best meets the needs of a regulatory agency, such as CVM. The course shall be 100% virtual (CVM has the capability to host the course using Zoom or Adobe Connect) and no longer than one day in length, including several breaks throughout the day and a lunch break.

Tasks, Deliverables and Milestones:

Virtual Course Title	Quantity	Unit of Issue	To occur one day within this Time Frame
Risk-Informed Regulation Workshop (including all course materials)	1	DY	August 1, 2021 – September 30, 2021

Period of Performance:

One day course to occur between August 1, 2021 – September 30, 2021.

Place of Performance:

Virtual communications via Zoom or Adobe Connect platform.

Contract Type:

Firm Fixed Price

Government Furnished Property (GFP)/Information (GFI):

No equipment or information will be supplied to the contractor.

Contracting Officer Representative:

To be named at time of award

Contract Specialist:

Bonnie M. Amond
Phone: 240-402-7561
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Contracting Officer:

James G. Whitt
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Security and Privacy Language:

Security and Privacy is not applicable to this requirement as per the Privacy and Security offices.