From:	Shelly Smith </O=PARTNER FUND/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=SHELLY SMITHD4F>
Sent:	1/23/2014 7:45:33 AM
To:	Vivek Khanna <vivek@pfmlp.com>
Subject:	AR/VK: Dr. Anand Akerkar, PhD [Laboratory Developed Tests]
Show Time As:	Free
Recurrence:	(none)
Required Attendees:	Vivek Khanna

Alex,

A consultation is confirmed with Anand Akerkar on Laboratory Developed Tests (# 249588).
Please call this Advisor at the number below at the time of the scheduled consultation.

Date: Thursday, January 23, 2014
Time: 11:30 AM EST
Request: Laboratory Developed Tests
Client: Alex Rabodzey
Advisor: Anand Akerkar
Company: Mdi Consultants Inc
Phone Number: [redacted]
Email: [redacted]

Advisor Bio:

Anand Akerkar, Ph.D, is the President and CEO of MDI Consultants Inc., a firm that provides quality assurance, regulatory, and clinical services to the Medical Device, Pharmaceutical and Food industries. MDI's services include: FDA regulatory strategy development, clinical trial development/management, cGMP compliance, on-site audits, validation (process, software and sterilization) and 510(k), PMA, ANDA, and NDA submission services. Dr. Akerkar has 40 years of experience in the healthcare industry. Previously, Dr. Akerkar held several senior management positions at Ciba Geigy, Becton Dickinson, and Technicon Corporation. Dr. Akerkar has successfully managed the development, launch and management of in-vitro diagnostic products. While at Becton Dickinson, he was a member of the industry review board for the FDA that helped to define the 510(K) submission requirements and other clinical chemistry standards. Dr. Akerkar holds 11 patents and has been published over 60 times in recognized scientific journals. Dr. Akerkar has been a consultant to the healthcare industry since 1986. Dr. Akerkar was the Scientific Advisor to ex-U.S. Congressman Benjamin Gilman (1976-2002). He has been President and CEO of MDI Consultants, Inc. since 1994 and President and CEO of CST Technologies, Inc since its inception.

Screening Questions:

2. Are you familiar with and and able to discuss the requirements that are needed for Laboratory-Developed Tests (LDTs) to be CLIA certified? Please briefly elaborate.
Response - I wrote the CLIA manual for users of IVD tests and quite familiar with its regulations.

2. Please describe any experience you have submitting these tests for approval OR evaluating these tests for FDA and/or CLIA approval and certification.
Response - WE have guded several of our clients to get CLIA waiver.

Please contact me if you have any questions or if you need to re-schedule for any reason.

Best regards,

Ashley Chilton
Guidepoint Global
New York
[redacted]
E: [redacted]