



CDRH ELP Site Visit Do's and Don'ts

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The following items are provided to ensure that the site visit is conducted in a professional manner, as well as adherence to the learning objectives during this training site visit and compliance with applicable FDA laws, regulations, and policies. Please review each item carefully and refer to this document whenever necessary.

- All communication for any site visit must be handled through [ELP Program Management](#). Any division contact with the firm, without going through ELP Program Management, may jeopardize our opportunity to coordinate a visit within the guidelines of the program. Please refer all questions or concerns to the ELP Advisory Committee.
- The site visit agenda is the guide for the day and must be adhered to at all times.
- Do not put yourself in a one-on-one situation with a member of the firm during the site visit (i.e., during the escort to and from the site, at lunch, etc.).
- Do not discuss specific applications or documents (including those that are in-house, pending, or imminent), or give an opinion, or advice on specific applications or documents. The firm should contact the [ELP Program Manager](#) to arrange for a meeting to discuss any such issues.
- Each site visit is intended for **training purposes only**, and is established as such to address the training content within the agenda. During this training site visit, inquiries on inspections and compliance related issues **will not** be discussed, and cannot be answered by our reviewers or employees during each training/ site visit. Do not discuss documents or ask questions associated with an inspection or questions that may be interpreted as such.
 - Should you have any separate inquiries on Compliance/ Inspection related issues, you may contact the [ELP Program Manager](#) at 240-402-2246 for further information. Any and all Compliance related questions addressed to [ELP Program Management](#) WILL NOT be followed up by our training site visit participants during a site visit.

- During your visit, do not give a presentation or schedule an "after meeting" regarding any CDRH guidance, policies, initiatives, etc., that are current or under development. If the firm has any questions regarding these items, they may contact the [ELP Program Manager](#) for the proper information or to arrange for a meeting to discuss any such issues.
- Do not discuss any nonpublic information, such as confidential commercial information or trade secrets.
- Photos, information, and details regarding the site visit, and any obtained during the site visit/training may not be posted publicly.
- Attire will depend on the specifics of the site visit and will be communicated to you prior to the visit.
- Shuttle services may be offered by the site but must be considered "reasonable."
- Participants must pay for their own meals. The firm cannot pay for or supplement any portion of the meal. Participants may accept modest items of food and refreshments, but must fall under the details listed below:
 - Modest items of food and refreshments, such as soft drinks, coffee and donuts, offered other than as part of a meal, does not constitute a gift and may be accepted by participants; and
 - According to the gift exception in the **Standards of Ethical Conduct**, Subpart B – unsolicited gifts of **\$20 or less** per occasion may be accepted by an employee from a single source. However, you may not accept more than \$50 from any one source in any one calendar year. For purposes of applying the yearly \$50 limitation on gifts of \$20 or less from any one source, multiple representatives of the same outside entity, including the corporate entity and its officers and employees, constitute the same source.
 - For additional details on meals and gifts guidance please contact [CDRH Ethics](#) or visit the following link; [Gifts Guidance](#)

