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In this fast-paced, global contracting environment, traditional due diligence is a thing of the past. Therefore, we have found that ascertaining certain information upfront serves as a form of due diligence that cannot possibly be done in isolation. This allows us to know that the request relating to Regulated Products (as defined below) has been properly vetted (i.e. gone through a robust legal, regulatory, and compliance review as deemed appropriate) and all necessary approvals were obtained confirming the concept the contract relates to is not deemed to violate any applicable law, including the anti-kickback statute and false claims act. In the alternative, if such robust legal, regulatory or compliance review was deemed unnecessary, an attestation to this effect can state so with a simple explanation why such reviews were deemed unnecessary.

Faulk & Associates' Protocol for any IT and/or IT-related Contracts in which FDA-approved drugs or devices ("Regulated Products") are involved (or a third party in the case where the Client's and such third party's Regulated Product is associated with the request) and which serve as the premise for a contract review relating to IT initiatives. For our legal review we require (some or all of) the following to ensure the protection of a Client's interest and to conduct a proper legal review (depending on what the IT initiative the contract request relates to):

- Contract Review Form, which includes those pre-reviewers and/or pre-approvers who handled the conceptual basis underlying the proposed contract.
- The Contract Review Form should indicate any attachments and the persons responsible for such attachments, including who determined the relevancy of the attachment for the particular contract and why.
- If the contract is off-the-shelf commercial software – please obtain the software provider's license agreement template unless the Client has its own. Typically, we draft templates for start-up clients, but that is a different engagement from our regular contract review process.

- Term Sheet – indicating the particulars, including Client's business owner(s), business terms (purpose/objective, pricing, term, etc.). We obtain copies of a Client's relevant Guidance Documents, Standard Operating Procedures and/or Policies ("Client Protocols") at the start of our engagement. Therefore, it is not necessary to provide information to us that is governed by such Client Protocols, but you can do so if you prefer. We believe our Contract Template Tool, when completed is more than sufficient for our review needs.
- We do want to have a clear indication that protected health information, personally identifiable information or personal data (collectively, "Personal Information") is (or is not) or will likely be associated with the intended use or purpose of any software (off-the-shelf or otherwise), but this is not the only information that may be needed. Also, we provide you with a comprehensive list of the overlapping data points for Personal Information.
- Client's and Vendor's legal entity that will enter the contract with the appropriate address.
    - Please do not send contract requests that leave the Client's and Vendor's legal entity blank or incomplete.
    - If for whatever reason a tax determination is required before ascertaining the correct legal entity, please advise and try to obtain that information prior to requesting legal review.
    - Please ensure the vendor's complete legal name, legal entity type and jurisdiction with full address is included.
- How will the technology be used, by whom (do not limit to IT, as IT is also procuring IT or IT related goods and services for the benefit of Clients as an enterprise, but also different business units/divisions/departments within the Client's enterprise), as well as what is the purpose for procuring the particular good or service?
- Will Field Sales reps use the technology?
- Indicate the category for the cost center if it is unclear whether the request is for promotional, marketing, sales and other related matters for such Regulated Products that are generally referred to as the commercial department or division versus research and development departments or divisions.
    - If yes, is it Corporate or Marketing/Sales (as those terms are defined by the Client)?
    - If Promotion/Marketing/Sales, please see below for further criteria.
- Is the technology or technology-enabled good(s) or service(s) intended use for or related to marketing/promotional/sales/distribution activities for Regulated Products? If yes,
    - Which Client's Regulated Product is the technology associated with (name the product)?
    - Is the Regulated Product a drug or medical device?
    - If it falls under medical device, is it deemed cosmetic or device?
    - Who is the intended audience?
    - Is it limited to a US audience? If no,
    - Is it a global audience or restricted to certain countries?
    - If restricted to certain countries, what are those countries?
    - Is content associated with the technology or technology-enabled good or service? If yes,
    - What type of content is involved and who owns the content (i.e. is the content Client's or a third party's IP)?
    - Is the technology for the benefit of an HCP?
    - Is the technology for the benefit of consumers/patients?
- Will the content the technology will be associated with intended to or required to be submitted to any regulatory authority (e.g. FDA or FTC)?
- Will HCPs and/or HCPs' practices receive or have access to the technology from websites, platforms or otherwise and are these financially sponsored by Client?
    - If so, for what purpose?
    - How will the HCP receive the technology from Client?
    - Is the HCP receiving the technology for free? What is the justification for same?

  - What is the benefit of the technology to the HCP and/or its practice?
  - What is the benefit to Client of providing the technology to the HCP (free or otherwise)?
- Is Client acting as a marketing company in connection with the HCP and/or technology?
- Is Client acting as a billing company in connection with the HCP and/or technology?
- What is the type of IT involved, including the functionality and purpose (internally, externally and/or both).
  - For applications, describe the intended interfaces?
- Indicate if the IT is related to the sale, marketing and/or distribution of the Client's Regulated Product.
- If yes, is the sale and/or marketing in the US only or globally?
- Indicate the Client's brand or product attorney handling (or handled) the Regulated Product, including any concepts involving the technology.
- Whether such review and/or contract were required to and then went through a compliance review process?
- Whether the contract was required and went through tax review?
- Whether the contract was required and went through a security risk assessment process?
- Whether the contract was required and went through a privacy assessment?
  - How does the Client treat Personal Information (inside and outside the USA) as we treat all such data as high risk and require the Client to instruct us on whether there are iterations for its Personal Information in terms of qualifying it as low, moderate, high risk (or other) and how it weighs such data types and why.
  - Different countries in which such data may be touched or housed (e.g. Germany, India, Russia, etc.).
- Is the IT initiative related to an unbranded Client-owned, operated or controlled website or platform?
- If anything involved with a branded/marketed/commercial Regulated Product is being classified as research for whatsoever reason, including post-marketing – please indicate so.
- When we are not involved in the legal and compliance review of the underlying concepts for such contracts, we do obtain copies of legal, compliance, regulatory, if applicable, attestations from relevant approvers (legal, regulatory, compliance) and such attestations are accepted in any manner other than verbal.
- Is the vendor a cloud service provider ("CSP")? If yes, please contact us for our separate checklist when the vendor is a CSP and we will provide you with same.