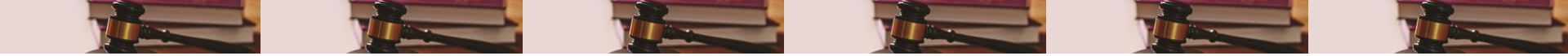

Enforcement Throughout the Supply Chain: Compliance and Due Diligence

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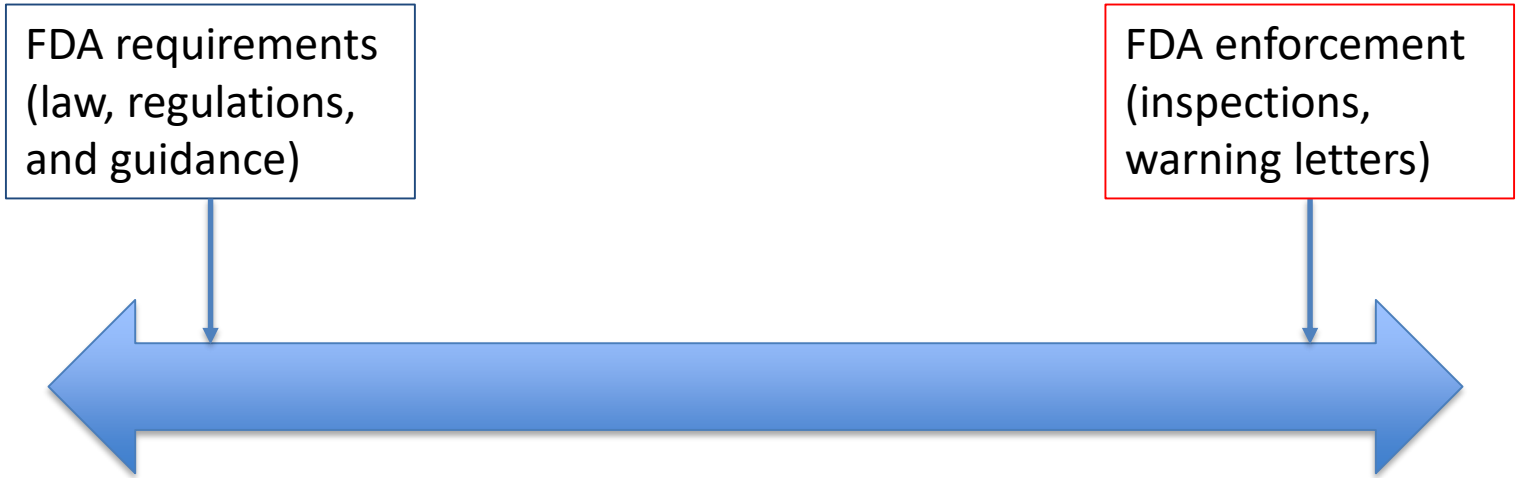
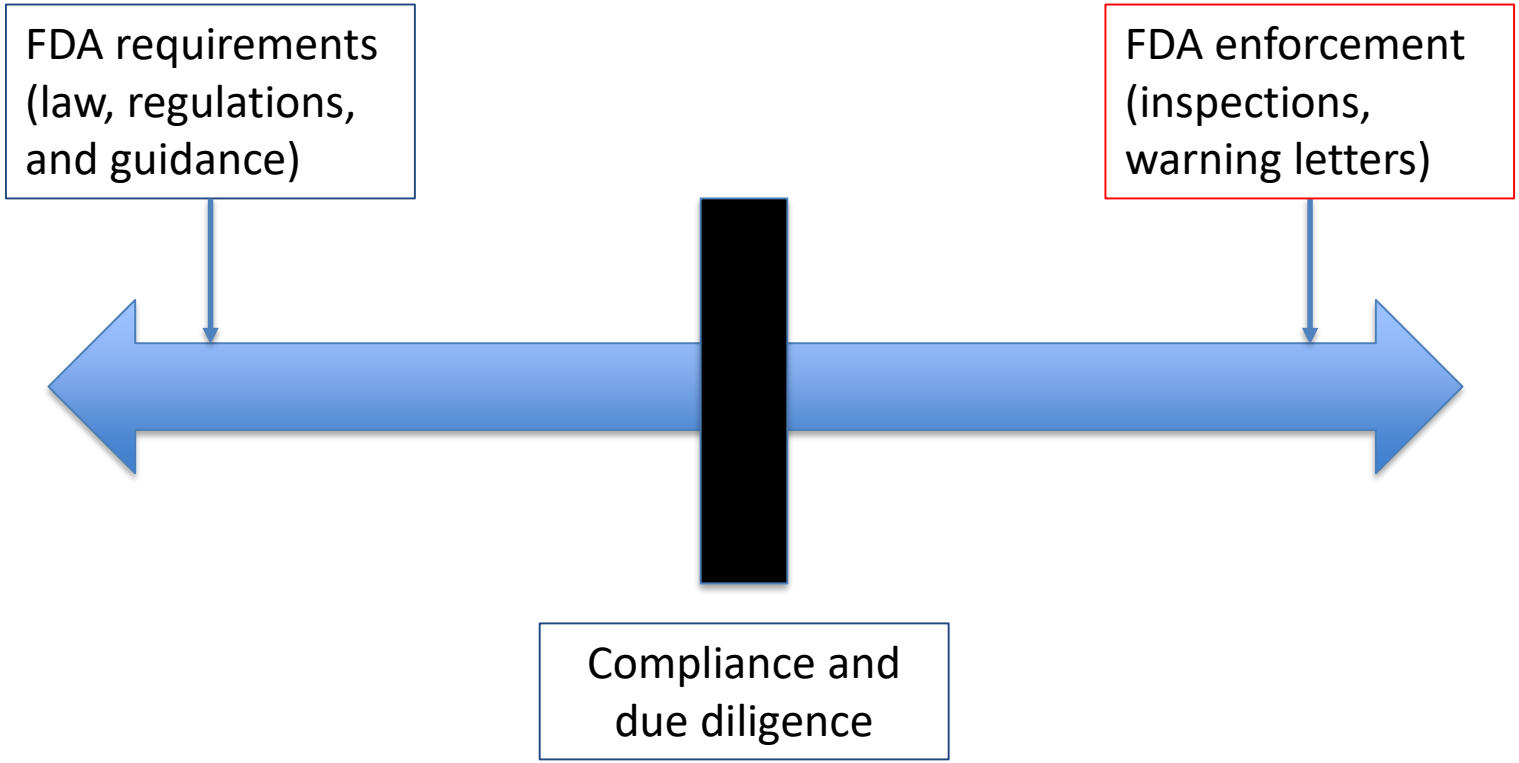
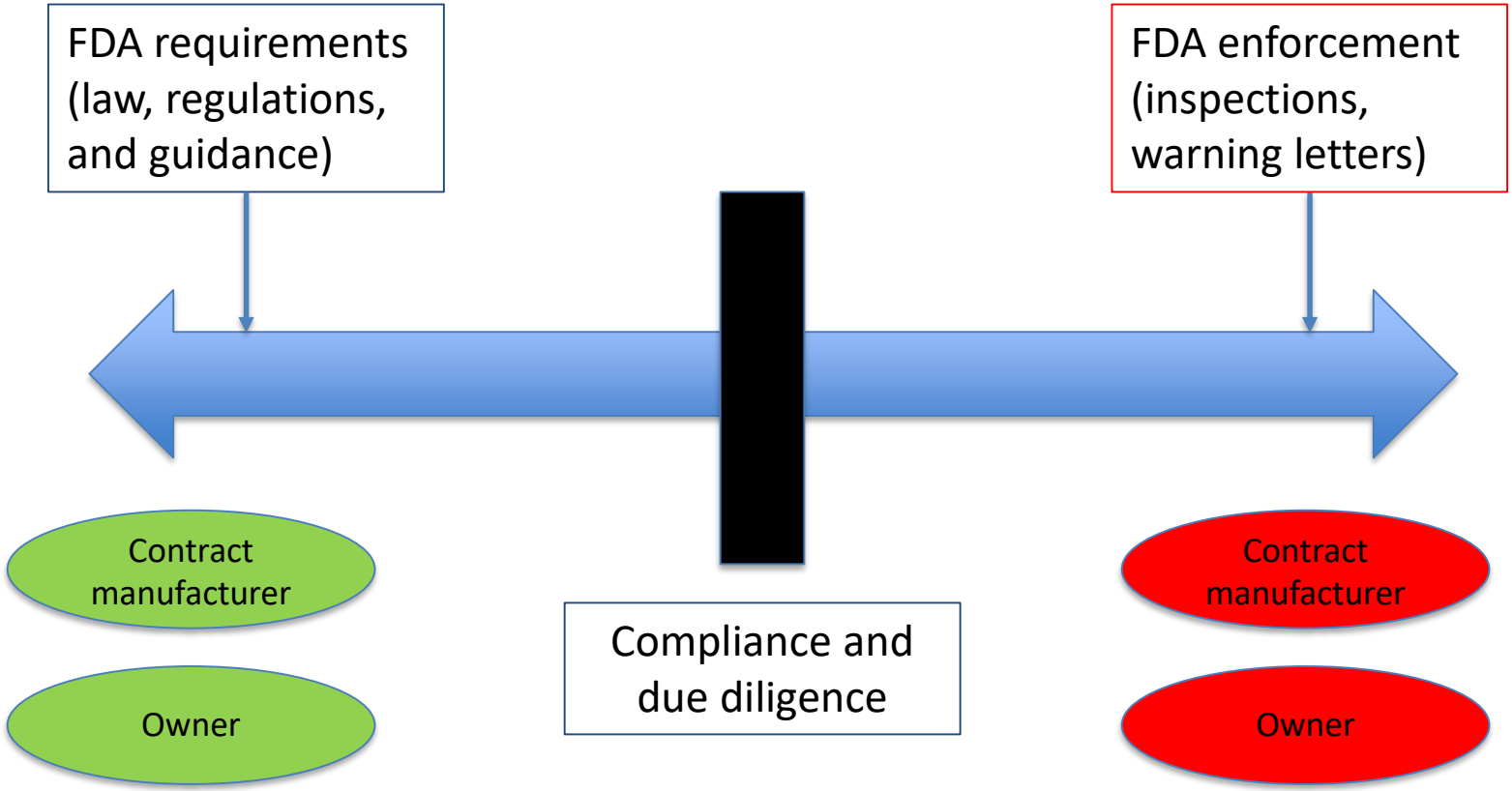
FDLI


FDA requirements (law, regulations, and guidance)
FDA enforcement (inspections, warning letters)


FDA requirements (law, regulations, and guidance)
FDA enforcement (inspections, warning letters)
Compliance and due diligence


FDA requirements (law, regulations, and guidance)
FDA enforcement (inspections, warning letters)
Contract manufacturer
Owner
Compliance and due diligence
Contract manufacturer
Owner

Evaluate Potential Partners Carefully

- In determining whether to partner with a potential customer, you should consider whether their quality culture aligns with yours.
- Considerations:
  - This relationship is not short-term.
  - FDA will view you a contract manufacturer as an extension of the owner
  - Manage demands for a broader/deeper engagement

Evaluate Potential Partners Carefully

- Questions to ask:
  - Are you a good fit for your customer? Are they a good fit for you?
  - What will it look like when your QMS becomes an extension of theirs?
  - How will your other customers be affected?
- Ground rules to establish at the outset:
  - Set boundaries
  - Expect oversight
  - The Quality Agreement is a living document, and should be used to establish boundaries at the outset, but evolve as the relationship evolves

Review Quality Agreements

- FDA intends to review quality agreements during facility inspections.
  - Consider keeping quality agreements separate from other contracts between owners and contract facilities.
- There is no statutory or regulatory requirement for a quality agreement between owners and contract facilities.
  - The use of quality agreements is both becoming standard industry practice and is useful in clarifying specific roles and responsibilities between parties.
  - We have seen a significant increase in writing and negotiating quality agreements between many different types of parties.
  - Quality Agreements can be helpful even if they are not required (e.g., distributors, brokers, private label distributors, own label distributors). These concepts could be helpful to those entities.

Review Quality Agreements

- Assess the relationship between the parties
  - Are the roles/responsibilities of the parties clear? And are they appropriate?
  - Are there communication channels between the two organizations, and are they being used?
  - What additional controls, if any, are needed for continued manufacture and use of product?
  - Is it clear what approach to take when responding to an FDA inspection? Who will be involved in preparing the response? Is there a response for 3rd party consultants?
- Do not hesitate to revise Quality Agreements during the course of the relationship.

Ensure Quality

- Prevent cGMP issues
  - Establish and maintain a robust quality system
  - Conduct internal audits
  - Management involvement is critical
- Should a violation be found, conduct the following activities:
  - A comprehensive evaluation of the issue
  - A risk assessment
  - A remediation and management strategy (including a corrective action plan)

Questions?