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- FDA's inspection and enforcement practices
- Developing processes and procedures for compliance
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- Science and risk-based system inspections – What does this mean?
- Going through an FDA inspection
- Effective response to 483s and Warning Letters

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- Risk assessment
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- Generation and maintenance of SOPs
- Qualification of equipment

3. Real Enforcement Examples

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- FDA EIRs of initial and follow-up inspections
- Product recalls
- Consent decrees

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- Non-Compliance consequences – 483s, Warning Letters, product recalls, seizures, consent decrees, import alerts, debarment
- FDA's inspection and enforcement practices – examples of Warning Letters and 483s
- Processes and procedures for compliance
- Surviving an FDA Inspection
- Effective Response to 483s and Warning Letters
- Impact of FDA's 21st cGMP – initiative on inspections

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