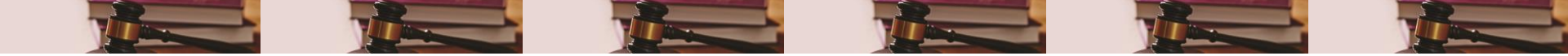

The Benefits and Risks of Internal Audits and Investigations

Thomas J. Cosgrove, Partner, Covington & Burling LLP

John Geissler, Global Head, Compliance, Incident Management and Audit, Novartis

Frances M. Zipp, President & CEO, Lachman Consultant Services, Inc.

Moderated by **Howard R. Sklamberg**, Partner, Akin Gump Strauss Hauer & Feld LLP

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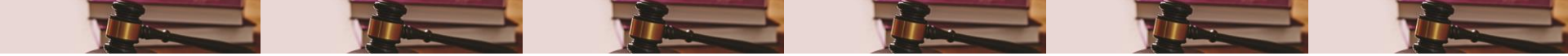

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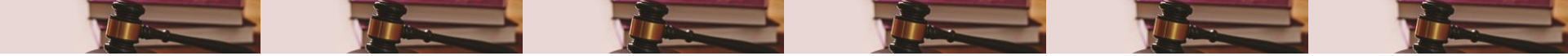

The Lawyer's Perspective

GMP Audits and Investigations

Tom Cosgrove
Partner, Food, Drug & Device Practice Group

COVINGTON

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What is a GMP Audit?

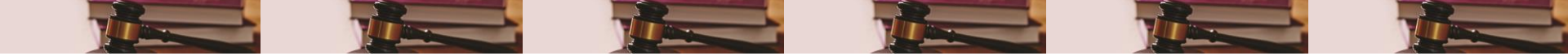
- Can be internal or external
- Designed to assess state of system being audited (production, lab, facilities & equip, entire facility, etc.)
- Is system in “control” and consistently performing within specification?
- Distinguished from an “investigation”
- Further distinguished from a formal, CGMP investigation
  - See 21 CFR § 211.192

Potential Disclosure of Audits and Investigations

- Audit Reports
  - FDA, CPG 130.300 (“During routine inspections and investigations . . . FDA will not review or copy reports and records that result from audits and inspections of the written quality assurance program”)
  - EU and Rest of World
- GMP Investigations (211.192)
  - Report of investigation to be in the records of the quality system
  - Typically tracked as a deviation or a CAPA
  - Available to FDA
- Privileged Investigations
  - Privilege may be challenged
  - Privilege can backfire

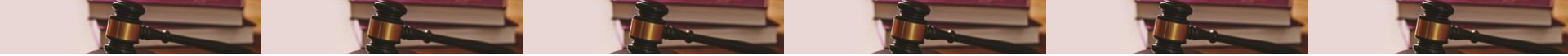
Why conduct a privileged investigation in a CGMP context?

- Issues may go beyond scope of quality system
  - H.R.
  - EHS
- Need for management to understand legal risk
- Desire to manage potential follow-on liability (e.g., products liability, false claims act)
- Ability of in-house and outside counsel to investigate certain issues more effectively
  - Ability enhanced by collaboration with outside consultants



“Parallel” CGMP Investigations

- FDA regulations require “any unexplained discrepancy” to be “thoroughly investigated” by the Quality Unit
  - This does not mean an investigation by legal
- If a privileged investigation on a CGMP issue is initiated, the Quality Unit will often still need to do its own investigation
- If privileged investigation uncovers information pertinent to CGMP and Quality Unit investigation, facts should be conveyed to Quality Unit



Balance use of the Privilege in the CGMP Context

- Avoid knee-jerk instinct to privilege everything
  - May conflict with other obligations
  - May impede ability to correct quality issues
  - May deflate effectiveness and profile of quality and compliance programs
- Act quickly on findings that may affect product quality
  - Obligation to patients
  - Single best strategy to minimize risk on all fronts
  - “Information wants to be free”
- Ensure non-privileged audits are properly scoped
  - Lawyers can help frame the purpose and method of the audit
  - Audit reports will often be used in follow-on litigation

Questions?

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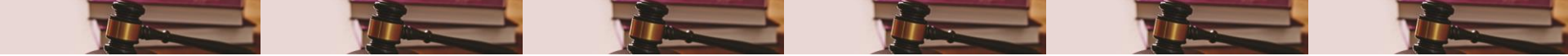

The Role of the Consultant

Frances Zipp
President and CEO
Lachman Consultant Services, Inc.

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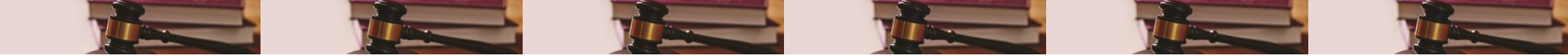

Legal Notice

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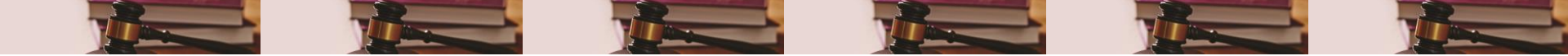

When is it advantageous to use a Consultant?

- Consultants can bring a fresh view to a situation
- The independence of consultants over internal resources can be a source of trust by regulators in certain situations
- Resources can be made available in expedited timeframes
- Consultants can deploy vetted experts in specific areas
- Consultants can bring perspective of many different companies and approaches, for robust conclusions

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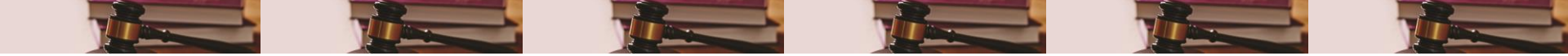

The role of the consultant

- To provide independent review, oversight, and assessment of a company, area, system
- To provide expert quality and compliance advice on various matters
  - Responses, protocols, reports, other compliance issues
- To fulfill regulator requests

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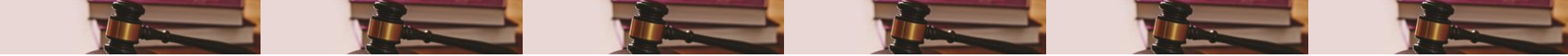
When can FDA ask for consultants reports

- The consultant can serve as an extension of the firm. If the firm communicates that a consultant is providing a role, the description and outcome of that role can be requested.
- If the firm provides any part of any consultant protocol or report to the FDA or references such, it is a fair assumption that the entire protocol/report will be requested.



Can a firm minimize the risk of FDA getting access to consultant work?

- Why??
- Have well-defined protocols in place that describe the who what, why, when and the deliverables.
- Avail the protections of Attorney-Client Privilege
- Partner with consultants as part of internal audits (within limits)

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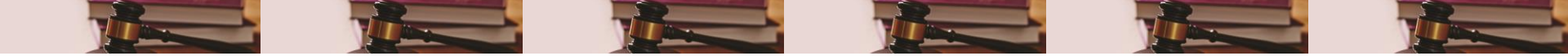

What if there is a Warning Letter – how does consultant proceed ?

- Very often, in Warning Letter situations, FDA is "recommending" that a 3rd party be used, so firm discloses to FDA if and when consultants are used.
- Consultant does not disclose; assure agreements are in place.
- Is the recommendation a suggestion or an expectation?
- The consultant can be an advisor or provide oversight? Can they do both? Carefully!!!!

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Lachman CONSULTANTS

The Pharmaceutical Experience and Reputation **You Can Trust**

Thank you for attending!

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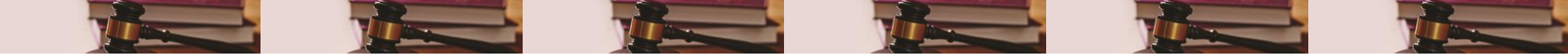

The Client's Perspective

Hiring and Managing a GxP Consultant

John Geissler

Global Head, Compliance, Incident Management and Audit

NOVARTIS

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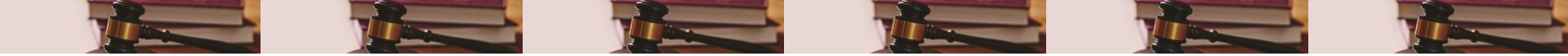

Before Engaging a Consultant:

- Define scope well!
  - Augment operation of existing quality system
  - Investigate, assess or advise on operations ex-QS
- Select appropriately, assuring documentation of qualifications for the firm and its assigned resources
- Pre-define deliverables and set appropriate expectations
- Many considerations - technical, managerial, geographic, communication, confidentiality, collaborations...

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Consultant Reports:

- Did you commit actions by a consultant to a HA?
  - Confirming the client's assertions and corrective actions can help expedite re-inspections. HAs may want to understand the evaluation criteria / protocol and review the report.
- "Hot-Line" investigation and other internal audit reports may end up being disclosed to HAs
- Be sure advice / recommendations are separate and distinct from compliance concerns; one-time, or periodic?

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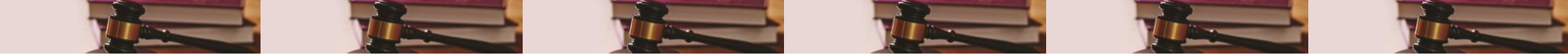

Considerations for Large Remediation Projects:

- Difficulties in managing numbers of consultants
- Avoiding information overload
- Prioritization and focus
- Pre-verifications for consent decree reviews
- When and how to end remediation activities

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Thanks very much!

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