

Compliance by Contract: Drafting and Negotiating Terms for Peer-to-Peer Compliance

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As appropriate, a large organization should **encourage small organizations** (especially those that have, or seek to have, a business relationship with the large organization) **to implement effective compliance and ethics programs.**

- U.S. Sentencing Commission

FDA recommends that Owners and Contracted Facilities **implement written Quality Agreements** as a tool to delineate responsibilities and assure the quality, safety, and effectiveness of drug products.

- U.S. Food and Drug Administration

We can hope that as [private contractual compliance] assurances become more routine, a consensus will emerge around generally accepted practices for demanding and enforcing assurances from one's counterparty and its value chain. **Today, however, [private contractual] compliance is in its awkward, adolescent phase.**

- Scott Killingsworth, "The Privatization of Compliance"



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Introductions



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Jason B. Meyer, JD, CCEP

President, LeadGood, LLC

Principal Lawyer, Meyer Business Law

- Former SMB general counsel, chief compliance officer, executive
- Decades at the intersection of education, ethical leadership & compliance
 - => LeadGood
 - => LRN
 - => EduNeering
- Consulting on engagement, content organization & maximization, learning & EdTech vendor selection and management, education program assessments, "how to talk" compliance and ethics...
- **8x Entrepreneur and "outside general counsel" for SMBs**

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Amy McDougal, JD, CCEP

President, CLEAResources, LLC

- US Air Force veteran - 12 years as JAG officer
- Former federal prosecutor (SAUSA)
- Former Associate General Counsel of SMB firm specializing in defense-sector security issues
- Advises organizations on culture, policies, training, investigations, monitoring and auditing, reporting, remediation, discipline and incentives
- Founding Director of International Association of Independent Corporate Monitors

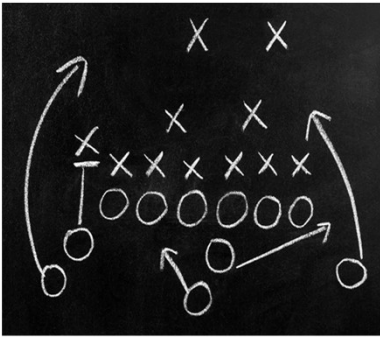
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Agenda

- Playing Offense and Defense: A Mock Negotiation
- Lessons Learned: Putting Contracts to Work for Your Program
- Crowd Sourcing: Your Questions / Peeves / Lessons

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"Playing Offense and Defense"



OFFENSE: Using contract clauses to strengthen and expand my compliance program, internally and externally

DEFENSE: Avoiding contract clauses that weaken, dilute or jeopardize my compliance program or impose onerous or burdensome requirements

It all depends on your perspective...

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In This Corner...

Amy

Represents a large public company and government contractor

"Client" or "Contractor"

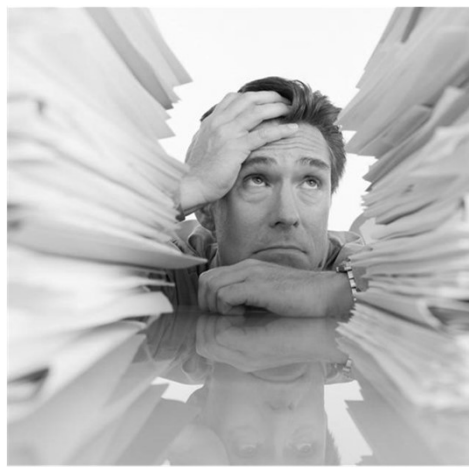
Jason

Represents a potential subcontractor/vendor, with designs on becoming a strategic partner

"Vendor" or "Subcontractor"

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Let the negotiations begin!



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<p>Code of Conduct Clause</p>	<p>Code of Conduct. Vendor hereby represents and agrees to adopt and act in a manner consistent with the ethical and professional standards set forth in the Client's <i>Code of Business Ethics</i>, as well as obligations identified therein, including prompt reporting of fraudulent or unlawful conduct.</p>

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<div data-bbox="246 396 579 451" data-label="Section-Header"> <h2>Training Clause</h2> </div>	<div data-bbox="656 378 1386 947" data-label="Text"> <p>Training. Vendor will be required to certify that its employees, sub-distributors, representatives, and agents have completed all anti-corruption and anti-bribery training requirements, consistent with Client's standards, whether by taking advantage of access to trainings provided by Client or by separately arranging for comprehensive training by area experts. Trainings should be provided in the appropriate language(s) for the recipient.</p> </div>
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<div data-bbox="254 1203 576 1304" data-label="Section-Header"> <h2>Sales Incentive Clause</h2> </div>	<div data-bbox="656 1211 1393 1740" data-label="Text"> <p>Sales Incentives. Vendor agrees not to implement any sales incentives programs, bonus programs or structures, or performance incentives for employees which reward financial returns under this Agreement without a quantifiable measurement of compliant and ethical conduct in the achievement of the financial return. Vendor agrees to provide information to Client on any formula or criteria used to calculate bonus payments.</p> </div>
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<div data-bbox="251 373 574 476" data-label="Section-Header"> <h2>Auditing Rights Clause</h2> </div>	<div data-bbox="657 378 1401 844" data-label="Text"> <p>Auditing Rights. Client may audit the records of Vendor to ensure compliance with this Agreement. Vendor agrees that it will retain such records for a minimum of three (3) years after Termination. Except for audits based on alleged violation of ethics or laws where no notice is required, Client will notify Vendor in writing at least ten (10) business days prior to any such audit. Any such audit will be conducted during Vendor's regular business hours at Vendor's offices and will not interfere unreasonably with Vendor's business activities. Client may audit Vendor no more than once in any six (6) month period...</p> </div>
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<div data-bbox="263 1197 561 1297" data-label="Section-Header"> <h2>Investigations Clause</h2> </div>	<div data-bbox="665 1201 1393 1728" data-label="Text"> <p>Investigations. Vendor agrees to cooperate and participate fully in investigations initiated by Client. Upon Client request, Vendor agrees to promptly provide any and all documents, including any information stored digitally, and to make available for interviews any Vendor employees Client deems necessary for internal Client investigations. Vendor further agrees to immediately notify Client if any employee, director, officer or agent of the Vendor comes under investigation for conduct arising out of or related to performance under this Agreement and shall promptly share all internal investigative findings, conclusions, recommendations and corrective action plans with Client.</p> </div>
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<div data-bbox="298 386 527 491" data-label="Section-Header"> <h2>Quality Agreement</h2> </div>	<div data-bbox="657 386 1403 869" data-label="Text"> <p>Quality. Notwithstanding anything in this Agreement, Client is ultimately responsible for approving or rejecting the Products, and is further responsible for the release of Products or other finished goods for distribution to the public and consumers and any and all liability arising therefrom.</p> </div>
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<div data-bbox="303 1211 537 1369" data-label="Section-Header"> <h2>Mandatory Flow-down Clauses</h2> </div> <div data-bbox="217 1442 605 1478" data-label="Section-Header"> <h3>§ 200.326 Contract provisions.</h3> </div> <div data-bbox="217 1503 609 1732" data-label="Text"> <p><i>The non-Federal entity's contracts must contain the applicable provisions described in Appendix II to Part 200 - Contract Provisions for non-Federal Entity Contracts Under Federal Awards.</i></p> </div>	<div data-bbox="651 1218 938 1247" data-label="Section-Header"> <h3>Davis-Bacon Act.</h3> </div> <div data-bbox="651 1249 1385 1407" data-label="Text"> <p>WHEREAS, because the relevant prime construction contract is in excess of \$2,000, Contractor is required to include provisions for compliance with the Davis-Bacon Act and DOL regulations...</p> </div> <div data-bbox="651 1407 1403 1749" data-label="Text"> <p>THEREFORE, Subcontractor is required to pay wages to laborers and mechanics, not less than once a week, at a rate not less than the Prevailing Wages. Subcontractor shall report all suspected or reported violations. Subcontractor is prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which they are otherwise entitled.</p> </div>
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<p>Indemnification</p> <p><i>(The “because we say so” clause)</i></p>	<p>Indemnification. Vendor shall defend, indemnify and hold Client and Client’s franchisees, affiliates and licensees harmless from and against all claims... arising in connection with (i) the failure of the Products to meet label claims or Client’s quality control standards, or (ii) the promotion, sale or use of the Products or any litigation or threatened litigation based thereon. Such right of indemnity shall exist in favor of Client, even though the negligence, gross negligence, strict liability, common law or statutory fault of Client was the sole cause, a producing clause or the concurring cause of the claim...</p>
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Putting Contracts to Work for Your Compliance Program





CLEAR RESOURCES, LLC
COMPLIANCE | LEGAL | ETHICS | RISK

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Primary Lessons

More than bargaining power?

- See "The Intel Gambit"

Take credit

But balance...

- The risks and burden on each party
- Compliance vs. Business Objective

Know the deal

"Working," not "Winning"

- Dispute resolution clause
- A "User Guide" for the Parties
- **The lawyer as "closer"**
- **Pick your battles**



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Exhibit Q-1 Quality Responsibilities Table

Pursuant to the Quality Agreement to which this Exhibit Q-1 ("Quality Responsibilities Table") is attached, the Parties agree to assign responsibilities for quality and compliance with Applicable Law, as follows:

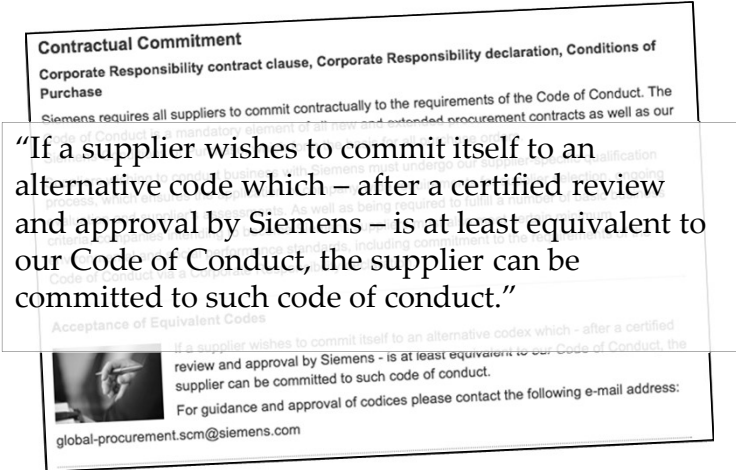
Item	Responsibility	NovaCare	Client	Both Parties	Not Applicable
1.	Compliance Requirements	Check here if this set of activities does not apply to this Agreement:			
1.01	Implement procedures and/or documented training to meet obligations under this Agreement.	[]	[]	[✓]	[]
1.02	Follow applicable current Good Manufacturing Practices (cGMPs), including International Conference on Harmonization (ICH) Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (API) and locally imposed requirements.	[✓]	[]	[]	[]



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<h2>Oversight</h2>	<p>Ensure contracts include a point of contact for the C&E program</p> <p>Ensure that the provision educates the other party about the existence of the program</p> <p>Make clear the difference between who is in charge of contract compliance and who is in charge of corporate compliance</p> <p>Detail informal dispute resolution options prior to adversarial steps</p>
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<h2>Codes & Values</h2> <p>Use a vendor Code, not your employee Code – or accept the vendor's code</p> <p>Be realistic</p>	 <p>Contractual Commitment Corporate Responsibility contract clause, Corporate Responsibility declaration, Conditions of Purchase</p> <p>Siemens requires all suppliers to commit contractually to the requirements of the Code of Conduct. The Code of Conduct is mandatory for all new and extended procurement contracts as well as our suppliers.</p> <p>Acceptance of Equivalent Codes</p> <p>“If a supplier wishes to commit itself to an alternative code which – after a certified review and approval by Siemens – is at least equivalent to our Code of Conduct, the supplier can be committed to such code of conduct.”</p> <p>For guidance and approval of codes please contact the following e-mail address: global-procurement.scm@siemens.com</p>
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<h2>Codes & Values</h2>	<p>Ensure that a comparable code binds each company's performance and behavior</p> <p>Watch out for ...</p> <ul style="list-style-type: none"> ▪ blank checks (agreeing without seeing) ▪ empty promises (agreeing without educating) ▪ Ensure your contracts mention your corporate values somewhere
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<h2>Training & Education</h2>	<p>Be aware of flow-down requirements from the Government or major contracts</p> <p>Clearly describe in contract language any training that the other party will provide to your employees</p> <p>Rewards and risks of offering specific training to the other party – better to just require/report/monitor/obtain certification of completion?</p> <p>Protect your company with indemnification if the training is deficient</p>
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<p>Monitoring & Auditing</p>	<p>Overlooked?</p> <p>Be sure your contract language permits your CE program to monitor and audit in the areas needed, and as often as may be necessary to protect your company</p> <p>Ensure that non-cooperation with the exercise of auditing rights is a basis for termination</p> <p>Ensure sufficient document retention clauses to meet mandatory flow-downs and to enable auditing within reasonable timeframe after performance</p>
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<p>Reporting</p>	<p>Hotline?</p> <ul style="list-style-type: none"> • Require that violations be reported to your hotline ? • Info in contract language? • (Does your agreement with vendor include increased number of callers?) <p>Require any complaints or concerns related to your company that come through the other party's hotline to be immediately reported to you</p> <p>Make failure to report violations (and retaliation) a basis for termination of the contract – and for fed funded programs, include indemnification (when mandatory disclosure is required to avoid suspension and debarment)</p>
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<p>Investigations</p>	<p>Require cooperation and participation by:</p> <ul style="list-style-type: none"> • Making witnesses available • Producing and providing documents and evidence <p>If the other party requests reciprocal cooperation:</p> <ul style="list-style-type: none"> • Ensure that you retain some control over the exercise of attorney-client privilege • Consider how participation may compromise your assertion of privilege <p>Ensure that the other party is required to investigate misconduct or fraud related to the performance of the contract and share the findings with your company</p>
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<p>Discipline & Incentives</p>	<p>Not many options for contract language, but...</p> <ul style="list-style-type: none"> • Consider R&W of adequate disciplinary processes in place to address misconduct involving contract performance • Consider R&W that they do not have any incentive structure in place (ex: performance bonus) that may encourage non-compliance or misconduct; particularly on time & materials type contracts billable to the government
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<p>The Culture of Compliance and The Culture of Negotiation</p> <p><i>(or, be careful what you ask for...)</i></p>	<p>"Adhesion tactics" may result in covenants without commitment</p> <p>Insistence may ensure concealment or breach</p> <p>Asking for powers you will not exercise sends a counterproductive message</p> <p>So apply the approach that works internally:</p> <ul style="list-style-type: none"> • Shared Values, over Rules • Shared Interests, over Mandates <p><i>Play "The Intel Gambit"... but for your values</i></p>

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Crowd-Sourcing

?????

Any questions?

Did you bring any clauses you would like us all to consider?

What clauses have been giving you fits?

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In closing...

What's the worst
contract clause for
an authentic
compliance and
ethics program?

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Final Questions /Discussion?



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Thanks!

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Please, keep in touch!

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Appendix



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