



Compliance Insight Code of Conduct

There is one thing that will determine the success of the company and each colleague. It is “reputation”. A good one will equate to positive engagements and success. A bad or poor one leads to the inevitable position of failure.

Our goal is to not just be a good compliance service provider but one that is considered **great!** Each colleague is different but there must be fundamental behavioral conduct for everyone. This document is designed to provide a set of rules outlining the professional / social norms and rules / responsibilities for each colleague.

- Consider client needs in conjunction with compliance needs
- Be a polite source of knowledge which will encourage people to come to you for advice. Have the patience of a saint!
- Be a team player. Adapt to the clients ever changing needs.
- Don't just say “you can't do that” – offer guidance, options.
- Be a friend, an ally, an asset to your client.
- Have a positive attitude. Don't get involved in office politics.
- When you are assigned a task – own it! Drive it to completion.
- Everyone at the site is important from the janitor to the President/CEO.
- Be down to earth, straight forward with your approach.
- Be frugal – remember, it is the client's money. Treat it like it is your own.
- Be persuasive, not demanding, condescending or combative.
- Be empathetic – understand what the client (as a person and as a company at large) is going through.
- Be happy. Don't complain about the work or how things are so messed up.
- Be calm – even in the face of criticism, be professional.
- Whatever you do, no matter what the task, be the best at it!!

Detailed Discussion Points

There is one thing that will determine the success of the company and each colleague. It is “reputation”. A good one will equate to positive engagements and success. A bad or poor one leads to the inevitable position of failure.

Our goal is to not just be a good compliance service provider but one that is considered **great**! Each colleague is different but there must be fundamental behavioral conduct for everyone. This document is designed to provide a set of rules outlining the professional / social norms and rules / responsibilities for each colleague

Client needs: Many times the client will give you a set of goals or targets. Sometimes they are specific, sometimes very general. Oftentimes, the client does not articulate nor understand what they want from you. In a general sense, the client wants the “pain to go away”. To be a great consultant, consider the following approaches:

- Observe the operations to understand the process. This could involve manufacturing, packaging, lab testing, validation, management oversight, clinical issues, etc. Speak to the client with the knowledge and understanding of their process.
- Feel their pain. Understand the issues that they are undergoing. The chaos, the insecurity. Understand how you can mitigate this pain, run interception for the resolution of the problems.

To be a great consultant, you will routinely need about 50% skilled knowledge (process, equipment, lab testing, GMP knowledge, etc.) and 50% human relationship skills (how to speak to people, how to push just enough to get something done without overstepping your bounds, how to lead, how to be lead). Of these, human relations are the more important of the items.

Your main tasks upon engaging with a client typically involves the following:

1. Learn the specific process at the site
2. Find the key players
 - a. Who gets things done
 - b. Who knows everything or those who know key processes that you want to understand
 - c. Who are the roadblocks
3. Determine what the client needs (in addition to what they convey to you that they want)
4. Determine how you can accomplish these goals as quickly, efficiently and effectively as possible
 - a. Per client! Each client is different and some want more than others. Determine what your client wants and needs.
5. Make your direct report at the client site look good. Give them the credit.
6. Put in the extra effort. Do a few things without charging them for the activity. Let them know that you’ve provided this service without charging them for it. Pro bono...
 - a. Send a text or email to follow-up on a task
 - b. Do some research on a specific issue and provide them with the details

Be a polite source of knowledge which will encourage people to come to you for advice. Have the patience of a saint!

Watch for opportunities on which you could provide insight/advice. Be careful here. If you offer advice too early, you can be seen as butting in where you are not wanted or a “know it all” consultant. In other cases the client may make it clear that they do not want insight or advice; they want you to do what only is asked of you. Be sure to know which type of client you are working with. You are there to work yourself out of a job. The projects are not forever. Work hard, diligently to get the task completed. If you do a great job and the client views you as an asset, then you have a higher opportunity to get other tasks/projects.

Adapt to the clients ever changing needs.

Don't say “when I worked at xxx company, we did it this way”. That's great but the client is not your previous company. It also makes you sound like you are viewing all your clients in light of the actions taken by your single previous experience. You can say “I've seen various ways to accomplish or resolve this issue. Let me bullet point out a few items to you and see if any would work here.”

Don't just say “you can't do that” – offer guidance, options. We are not a company that says “my way or the highway”. Theory sounds good in an office setting but does not always work when implemented. We are a “hands-on approach” company. Be there, see the activity, and know how to make the activity work while also meeting the GxP requirements.

If the client decides to take a different path than you suggested, live with it. DO NOT get angry, upset or combative. You accept the approach and work diligently to get it accomplished. If the decision is in violation of a regulation, tell them – write it down, show them, discuss it. Be open minded that you may be incorrect.

When you get feedback on your work, don't get upset. Accept it. Learn and adapt to what is requested of you. Sometimes you will get contradicting feedback – work with your main contact to resolve the issue and adapt to the situation.

You will always learn and grow. If you believe that you have all the knowledge and answers, you will fail. There is always a different approach that works when you thought it would not. There is always a different idea. Adapt, grow, learn, excel at what you do and provide. Don't overlook cooperating with other consultants on site. They can be great sounding boards and may know things you don't.

If you don't know – say it. But you can say that you will ask the others at Compliance Insight for input; perhaps even getting a knowledgeable person on a conference call to provide input. Be a friend, an ally, an asset to your client.

Dress the part. Nice clothes – not necessarily a suit. No jeans – even on “jeans day”. Nice shoes. Always display a clean, professional look.

You are not there to belittle people or make them look bad. If they are incompetent, let them hang themselves. Don't get involved in office politics. People can use you as a “tool” to get their own political agenda completed. Be careful. Understand what you are doing. You aren't there to get thrown under the bus so don't get into that position.

Have a positive attitude. Many times, the client is beaten down and depressed. You offer the path to get out of the current situation. People will gravitate to those who offer hope. On several occasions, people have brought in candy or baked bread for the client's staff. I purchase these things myself and offer them to the client in order to build bonds. Also note that people will gravitate to a leader if one is not present. Don't rush in and take over – just “lead” (guide) people along a path.

When you are assigned a task – own it! Drive it to completion. If you are part of a team, do your specific task to the best of your ability. Don't push someone else out of owning their job – help them, be a guide, an asset, let them take the credit.

Everyone at the site is important from the janitor to the President/CEO. Be friendly to all of them. Know how to speak to the janitor as well as to the President. Each has a different vocabulary and you must use the right one for each group or your message will be lost.

Be down to earth, straight forward with your approach. No long, complex pathways to success unless warranted or necessary. You need to be approachable by all personnel.

Be frugal – remember, it is the client's money. If you drive up in an expensive rental, people will view you as wasteful and self-absorbed. I've actually used a small car as a benefit when the client asked if I could “find a smaller car”. I told them that it was inexpensive and I am a good steward of their money. They always appreciate the fact that you are looking out for them.

Be persuasive, not demanding, condescending or combative. If in trouble, the client not only has to learn how to do their job correctly, they have to “un-learn” how they've been doing it previously (probably for years). You offer guidance and help. Know that the goal of compliance is the destination and there are many pathways to get there whether you see them or not. If possible, take steps to get there – not just jump to the final goal. Remember, to climb a mountain, it takes that first step to get it going. Sometimes, that is all it takes – one small step in the right direction.

Give credit to the folks that do the work (your client). They take the action, they do the work, and they ultimately own the process. It is not compliance nor strategy nor technology that is the key to success, it is teamwork. Become part of their team to get the job done.

Be empathetic – understand what the client (as a person and as a company at large) is going through.

Be a team player. Know the overall goals of the company and work to achieve those goals. You are as much of the client's company as anyone else. We are partners with our clients and need show we are part of their “team”. Avoid exclusive phrases such as “You should...”, “You need to...” Instead use inclusive phrases such as “How can we...” “What options are available to us?” Demonstrate your loyalty not only to Compliance Insight but also to the client. Once they trust that you “have their back”, your job will be so much easier.

Don't milk the company. If you have nothing to do, check with the client. If nothing to do, leave for the day. Offer to pick up the slack from others, if needed.

Do not bill for time not worked. If you are caught billing for time that you did not work for the client, then our reputation is lost, we lose clients and serious personal consequences on your part will include termination.

Be happy. Don't complain about the work or how things are so messed up. There are not 'problems', only "opportunities for improvement".

Be calm – even in the face of criticism, be professional. Also – a "please" and "thank you" go a long way! Finally: Whatever you do, no matter what the task, be the best at it!! If you are asked to "sweep the floors" then you should be the best floor sweeper around. Never, ever say that "this task is beneath me" or act offended.

Don't settle for good, not even great – always ask if there is a way that you could do it better. Always strive for excellence in everything you do.