



## Episode Title: Tips for Working with Foreign Regulators in China -- A Conversation with David Cragin, Ph.D.

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**Lynn L. Bergeson (LLB):** Hello, and welcome to All Things Chemical, a podcast produced by Bergeson & Campbell, [P.C. (B&C<sup>®</sup>)], a Washington, D.C., law firm focusing on chemical law, business, and litigation matters. I'm Lynn Bergeson.

This week, I had the distinct pleasure of sitting down with David Cragin, Director of Global Quality Assurance for a very large multinational pharmaceutical company, to discuss his experience living and working in China. For many listeners, working with foreign regulators can be particularly challenging for a variety of reasons, including language barriers, cultural differences, and differing regulatory standards. Dave shares his experience working in China and explains his approach to managing these issues successfully. Now here is my conversation with Dave Cragin.

Dave, welcome. I am so looking forward to chatting with you. You have just an astonishing career, a wonderful résumé, and your ability to communicate is unparalleled. So, welcome.

**David Cragin (DC):** That's quite an introduction.

**LLB:** Well, let's get into it. I've known you for a little while now. You're a Board-certified toxicologist. You have managed global chemical programs in the United States, in Europe, in China. You've worked for a long time with a very large international pharmaceutical company. And this just intrigues the heck out of me -- you are a Distinguished Toastmaster, something that I just really admire about you. Tell us a little bit more about yourself.

**DC:** Well, I love the field of toxicology, both at a professional level and a personal level. I talk to kids, kindergarten through grad school, about toxicology. I'm a fellow of the Education Foundation, and I'm the kind of person if you ask, "If you could pick another major, what would you pick?" I would still pick toxicology. And then I also -- I like language and culture. I speak reasonably fluent Chinese and small amounts of many other languages. And I find it really helpful in building rapport with people from around the globe.

**LLB:** Well, true that, and I guess all of those skills contribute to your ability to be considered a Distinguished Toastmaster.

**DC:** The Toastmasters training helped me much with my communication skills and abilities.

**LLB:** Interesting. Mm-hmm. Well, I'd like to hear that toast skill at some point, Dave.

**DC:** Sure, I'd be glad to.

**LLB:** Well, given your extensive experience working in China and your engagement in a wide range of Chinese regulatory issues, I'd like to focus, if I may, in that area. I know you've worked certainly elsewhere in Europe and managing programs all over planet Earth, but China is the one that fascinates, I think, many of our listeners, because it's probably one of the more challenging jurisdictions. Due to the size of the Chinese economy and its population, decisions made by China impact the world supply chain and environmental systems generally. Can you just summarize generally what you have learned over the years, given your vast experience in China?

**DC:** Sure. China is a land of contrasts. It's a leader in both green energy and coal-fired power plants. Even though it's a one-party system, you have people who have different opinions, different goals. Part of -- many people want to see a move towards greener energy, cleaner air. But then there's others who are just as concerned about the economy and worried about economic growth. So you have those two things going on at the same time.

Another thing about China, it's highly regulated, but not always effectively regulated. And some of that comes from the dramatic changes that have happened. Just numbers illustrate things. There's a city in southern China called Shenzhen. It's a high-tech center. In 1979, it had about 30,000 people. By 2011, by one estimate, there were 14 million people there.

**LLB:** Oh, good grief. Wow.

**DC:** That rate of change is just something we can't even imagine.

**LLB:** Mm-hmm.

**DC:** And another thing I've found is there's great respect for U.S. regulatory processes, whether I talk to friends in the Ministry of Environmental Ecology, which is their version of our [U.S. Environmental Protection Agency] (EPA), or in the National Medical Products Administration, which is equivalent to our [Food and Drug Administration] (FDA), or friends in industry. They often will say the [United States] U.S. has good regulatory processes. And what they mean is -- they're referring to the quality of our food and drugs, clean water, clean air that the FDA and EPA have done a very good job in the U.S. in managing those. And they have admiration for that.

**LLB:** Is that to say, Dave, that the admiration is for the outcome and the fruits of our collective regulatory processes generally, or the actual way we have achieved these results is to be emulated? Because you can get to the same result with a very different process.

**DC:** I think it's more the end result. The individuals who are talking to me may not always know the intermediate steps to that, but they see the end result, and they know that -- they know what the environment is like in the U.S., and it's something they would like to have, too.

**LLB:** Interesting. Our consulting affiliate, The Acta Group (Acta<sup>®</sup>), has worked for years and is working now on a whole range of Chinese regulatory issues involving both industrial chemicals and agricultural chemicals, with regard to notification, regulation, and the ability to use those chemicals in China. Working with Chinese regulators can be, in my view, from my perch, just very challenging, particularly if you've not done that before or have little track record on which to rely. Maybe you could identify for our listeners some key points for being effective in China.

**DC:** Sure. And some of these points will really work anywhere in the world. I mean, you start off with respect. When you go to another country, if you show respect for that country, there's an immediate connection there. Another thing about working with staff is recognize the challenge in translation, that it's difficult to be fully fluent in two languages. Great example of this is I have a good Belgian friend, and he came to the U.S. for three years working on vaccines in the U.S. And he's a Flemish-speaking Belgian, a Dutch-speaking Belgian. He went back to the Netherlands after those three years, and he said, "It was so embarrassing!" He goes, "I couldn't talk about vaccines, and it's my own language!" And that was just after three years.

So when you're working with staff, recognize that it can be a challenge to work across languages. And really focus on clear and concise language. Avoid idioms and acronyms. In my current job, I've hosted Chinese regulatory agencies many times in the U.S., and over the years, my Chinese has gotten better and better. So I could understand the translations. And an American might, to answer a question, might use lots of idioms and other things to emphasize the point. And when it gets translated, it's translated into three or four Chinese words, in other words, just the essence. So really think about that when you're talking, what's going to be clear to the people, when you're speaking to them, what your key points are.

**LLB:** It's very good advice.

**DC:** Another thing in working with agencies, I am a big fan of the risk communicator, Peter Sandman, and he talks about strike when the iron is cold. In other words, develop relationships before you need them. So should you need to talk with them about a technical issue later, you have that entrée; the level of trust is already there.

**LLB:** You had indicated that in some instances you have a younger generation of Chinese regulatory folks handling issues, some of whom are empowered with significant authority. Have you found that the consistency in leadership at both the working level and the leadership level are conducive to establishing those types of relationships, because the same holds true here, right? We establish relationships with the regulatory institutions and the people tasked with discharging the roles they have been empowered to implement, because those relationships are huge. But if there's significant turnover, or people are bounced around in different departments with some degree of regularity, that continuity is more illusory than it is real. So what has your experience there in China been like?

**DC:** In my experience, there has been that consistency. And part of that is a difference in culture, in that government jobs there tend to be highly prized. So if a person gets into a government role, they may stay in it for a number of years, and you can have ongoing interactions with them. But it always depends. I mean, individuals can change jobs, too.

**LLB:** I know when I was in China most recently, language is huge. Unlike you -- I'm presuming you speak Mandarin, correct?

**DC:** That's correct.

**LLB:** Yes, I absolutely wish I *did* speak Mandarin, but I don't. So I relied upon the people with whom I was staying to handle the communication side of the equation. I'm presuming the flip side of that is there are a lot of our Chinese regulators and counterparts there don't speak English. Unlike going to Europe. You don't really need to speak French or Italian or Spanish because a lot of Europeans are bilingual, or trilingual, unlike most Americans. What is your response to that?

**DC:** Well, English is the language of science and business. So there are -- and in regulatory agencies, you're going to have individuals with all different levels of language. They still may want a translator, even if they understand some of what you say. But it is important to recognize that the level of English skills can be quite a bit different. But I've found generally it's rare to find someone who speaks no English.

**LLB:** Interesting, okay. And one further point on the translation front. You just mentioned that English is the language of science and technical things like that. But when we work on matters here in the United States or through our offices in China or Europe, we insist upon very high quality, not inexpensive translations of Chinese regulatory initiatives for fear that if it's not done well, you can end up with a document that really does not capture the essence and the literal word of the Chinese missive, whatever it may be, a letter, or regulation, or law. What is your sense on translations for U.S. businesses? Is it okay to just go with a standard commercial translating service or rely upon in-house personnel? Or what is your recommendation?

**DC:** As you discussed, how things are translated is key and worth the investment to get a professional translation. Because of that, there's a great book called *Is That A Fish in Your Ear?* about translations. And it talks about -- even between two closely related languages, you can still have quite a bit of variation in translations. And when it comes to legal, it's even more of a challenge because the words can matter so much. I remember a number of years ago there was a change in the Chinese chemical notification regulations, and there was a change in term. We thought there was a change about products being sold for export. It turned out the regulation hadn't changed at all. It was just the individual translating it had added a little bit of extra text to it, and we discussed it. And they said, "Well, it's just assumed that in Chinese when you export it, it's exported for profit." I don't remember the specifics on that, but it was just a simple change in how the word was translated. So I think it's important to invest in good translations.

**LLB:** Dave, you've been engaged in matters involving China for, I think, a good number of years now. I don't know when your first experience began, but I'm guessing, given that period of time, you have seen probably a lot of change over those years. Are there any in particular that warrant mention here to assist our listeners with -- if they haven't been to China for a while or if they're planning on going soon, or just to appreciate all of the changes that *have* taken place over the last 15, 20 years. Maybe you could tick them off, in no particular order.

**DC:** I'd say there's a great desire to improve quality. That's both drug quality, food quality, but also laboratories, like toxicology and ecotoxicology labs. There's a great desire to bring up the standard of them, and there are some very good ones there. Previously, I've been involved in [Good Laboratory Practice] GLP audits of multiple laboratories. And one lab in particular was so good, our consultant we work with had no findings, and she is very dogmatic. She looks for everything!

**LLB:** That's pretty amazing. No findings at all?

**DC:** None at all. She actually thought they could back off in a couple of cases, in terms of their approaches.

**LLB:** Rigor, right.

**DC:** Whereas some other labs did have deficiencies, but we approached them in a positive way, saying, "When you're successful in an audit like this, it's something you can use to market yourself in the future." So one specific lab in Shanghai, they had 22 GLP deficiencies, but within six months they had fixed almost all of them. And they said to me, "We see you as our professor." And that's a good interaction, because they were motivated to make the changes.

**LLB:** And it speaks so highly of your influence, too, Dave, on wanting to do better and achieve a higher standard of quality control there. So that's very flattering for you.

**DC:** And then another thing. I know this is tough with the pandemic right now, but if you can go in person, there's great value in that. One, because you can see firsthand. But two, for the people who are there, who are in quality, who are in environmental controls, they want their clients to value what they do.

And I remember one ecotox laboratory we visited, we wanted to discuss their environmental controls, because we didn't want our test compounds going out into the environment. And they were very proud of their environmental treatment system. And that's what you want to see. If they're proud of their treatment system, you can have a good confidence that they're going to be careful with environmental discharges.

**LLB:** Absolutely. Well, I know many of our clients struggle to find consistently competent laboratories, whether it's for tox testing or ecotesting, and quite literally farm out their required testing to [contract research organization] CROs located throughout the world. With respect to U.S. companies undertaking testing pertinent to Chinese matters, my understanding is that a good deal of the testing needs to be done in China. How do you suggest to our listeners identifying the best laboratories to undertake work in China?

**DC:** When we did it, it was a little easier, because at that time the Ministry of Environmental Ecology identified a list of their approved laboratories, and there were, I think, ten or 12 laboratories. So we started from a defined list already, and we contacted them first by e-mail. And then some of them, we went out to look at in person, and then the ones who we felt were sufficient and adequate, that's the ones we actually did GLP audits.

One thing that's been done, too, is sometimes companies will collaborate in hiring a GLP auditor and then share the results between them, because there's no competitive issue here. You're all looking for a good laboratory. And then the other thing, too, is I don't think it's once and done. I think it's good to follow up on every number of years, whatever your company decides, three years, five years, to go back in and to make sure that things still are going well and to show the laboratory that you're interested, that you're aware. You keep track of the quality of the studies that are done.

**LLB:** Sure. And to your point earlier, it helps maintain that relationship, which, of course, is very important. At least it's important to the labs that we work with around the world.

Well, Professor, what's it like to teach at top universities in China? Let's rotate to that topic.

**DC:** Sure. I teach for Peking University and Beijing Normal University. And for me, it's a fascinating, dynamic experience. I like teaching in general. I used to teach at the University of the Sciences in the U.S., and I think it makes me much better professionally, because when you teach something, you have to know it. And also because I'm from industry, I feel like there's an extra level of credibility needed to show that what I'm teaching, what I'm training them about, is credible and well researched.

For me in China, I have a bit of an advantage in that I do a full introduction in Chinese, including my favorite mistake in Chinese. Everybody knows that Chinese -- or most people know -- Chinese is a tonal language. The tone you use can change. One time I was in Beijing on one of these big circular tables with a bunch of friends, and I wanted to tell them when my son goes to college, he wants to study chemistry. And at the time, *chemistry* was a new word for me. After I spoke, it triggered a vigorous debate between them, and I couldn't understand what they were saying. One finally looks at me and very diplomatically says, "We didn't know that skiing -- skiing down a hill -- could be a major in college." And I said, "Skiing? I meant chemistry." Well, the phonetics are exactly the same. I had my tones wrong, and apparently I had said skiing so well, none of them doubted that. They were just debating, "How can you be a skiing major in college?"

**LLB:** I could just imagine the animated conversation among your colleagues at that table.

**DC:** A mistake like that is good in introducing myself. Both, I use that with regulatory agencies and at the university, because it helps them relate to me, and it builds that connection. And I know for many people, they don't have time to learn Chinese, but even if you can learn a small amount, that can help you. English is the language of business and science. But because of that, an American who takes time to learn a little bit of Dutch, or a little bit of Japanese, or a little bit of Chinese stands out because it shows you made that effort.

**LLB:** Oh, absolutely. Absolutely. Are your teaching methods different? You had mentioned you teach as an adjunct at the University of the Sciences in Philadelphia. Do you teach Chinese students differently than you teach American students, for example?

**DC:** I teach somewhat differently. What I teach for Peking University is risk assessment related to drug quality. And then at Beijing Normal, it's environmental risk assessment. For both, though, a big piece of it is critical thinking. And my course at University of the Sciences was called Risk Assessment, Critical Thinking, and Health. And to teach critical thinking. I give questions that people get wrong, they get wrong, whether they're Ph.D. students, MBA students, when they're from the U.S. or from China. One difference of approach, though, is that in China, the students wouldn't want to lose face, so I'm more careful in terms of how I ask the questions, because I don't want them to be embarrassed in front of the whole class. And then, too, I use a lot of pauses when I speak in China, because I teach in English. My Chinese isn't good enough to teach in the language. And those pauses add a lot of ability for them to understand what I'm saying.

**LLB:** Sure. Just a little time to process some.

**DC:** Also, too, including a personal element is helpful as well for teaching. Last year, one of my main lectures for the graduate students and undergraduates was on extreme weather, worldwide energy shortages, and commitments to moving to electric vehicles. And when I was done, one of the graduate students got up, and he started by saying, "I know you respect

China,” and he said some nice things about me. But then he switched and said, “But how is it fair to ask poor Chinese people not to burn coal?” And I think that would have been a much more uncomfortable question if that personal connection hadn’t been established first.

**LLB:** Indeed. Let me ask you a different kind of question, recognizing that you are both a toxicologist working in a large multinational pharmaceutical company, and you bring a certain pragmatic, boots-on-the ground perspective. And you teach, which can be more along the lines of embedding academic content in your students. How do you juggle the need both to ensure students understand the content of what you are teaching, but also the way in which that information could be deployed with regard to product stewardship, and environmental protection, and some of the more intangible aspects that are very important in educating students today?

**DC:** One thing I emphasize to them is that the government can put forward regulations, and those are important, but it’s equally important for them to be part of the solution, whether they’re in the government or in companies, and look for ways to improve it. And it doesn’t always have to be based on what the law said. I give an example from one of our operating sites. It’s a vaccine site, and to make vaccines, you need really pure water. One of my colleagues took the initiative to go around the site and to look for steam escaping from stacks, because if steam was escaping, that meant the steam capture devices weren’t working.

And steam is very high quality water. It takes a lot of energy to take tap water or supply water and create the purity you need to make vaccines. By making sure the steam capture devices were working, he was reducing water use, he was reducing energy use, and that makes the company more profitable. And that didn’t require a government regulation. He was doing it because it was the right thing to do, and it was good for the company. And I like to instill in the students to think in that way.

**LLB:** Mm-hmm. How would you suggest? -- Well, if you were seated with your counterpart in a pharmaceutical company or industrial chemical company that was heading off to China and had never worked with a Chinese regulatory entity or lab worker of any sort? What are the four or five top points that you would share with that person in making their inaugural visit to China, in dealing with Chinese partners, maybe even just on the business side and/or regulatory agencies in China? Do you have a cheat sheet that you can share with our listeners?

**DC:** Well, one thing to recognize is that personal relationships matter much. And in the U.S., we can do business more easily with people because we have a legal system that we know will be fair and evaluate the situation in a way we can trust. In China, that’s not always the case. And so that personal rapport matters much, because they want to be able to trust you. You want to be able to trust them. So that’s the first thing.

Second, showing respect is always important. If someone knows you respect them and you respect China, you’ll have a much better connection. One thing I learned from living in England in high school was never to compare England and the U.S. unless I was saying something good about England. The same is true with China. Avoid comparing the countries, unless you’re saying something good about China. I know from high school I triggered a lot of accidental arguments with friends, just because -- I was just making an observation. But I found out that’s true really anywhere in the world. Be careful about how you compare.

And then, too, when you're working with partners, there's a Roman adage -- I mean, excuse me, Russian adage, "Trust but verify." And you want that as well. You want your partnership, but you also want opportunities to verify and to keep that partnership going in a way that's beneficial to both companies.

**LLB:** Our clients, historically and today, express pretty vigorous concern with their ability to protect confidential business information in China. In your experience, Dave, is that fear rooted in fact? And do you have any suggestions on how to address those concerns?

**DC:** It is rooted in fact. About ten years ago [actually 2007], *Genetic Engineering and Biotechnology News* had a really insightful article on intellectual property in China. The author, who's ethnically Chinese, pointed out that [intellectual property] IP is a Western concept. And it's introduced in China. And although there are legal requirements related to it, it's still a foreign concept. What he also pointed out, too, is that the IP issues are not just because it's between a Western company and a Chinese company. To illustrate with a number, he pointed out [that] out of 13,400 IP cases in Chinese courts, only 268 involve foreign companies. In other words, 98 percent were Chinese versus Chinese companies.

And I see that played out even on a personal level. Just last week, I was talking with a friend who works for a small Chinese biotech, and she was discussing with me how she's not allowed to share certain information with other people in the company, because the company was worried they'd take that information and leave. So they have that concern internally between -- even within a Chinese company.

Yet on the other side, the government wants to change that, because IP protection is crucial in innovation. If a new company has an innovation and it gets stolen, they don't get a chance to be successful. And companies generally want to start in their own country and be successful. And so IP is beneficial for Chinese companies as well. Intellectual property protection is beneficial as well.

**LLB:** Has the concern abated over the years, or is it pretty much as intense now or as real now as it was, say, ten years ago?

**DC:** I can just give a sense of that, and my sense of it is that the regulations and the enforcement of them are getting stronger. And certainly we see examples of this. I mean, Apple has wonderful IP, and they do a lot of their production in China, but they've been able to maintain that. So it *is* possible to be successful in China. I think, for a company making that decision, I think they want to get together, brainstorm, and say, "Okay, what is our key IP? How do we protect it? And how do we make it so our partner in China protects it because it's in our own best interest?"

**LLB:** Mm-hmm. One thing I've been musing about over the weekend in preparing for this conversation, Dave, is just recognizing that with the Chinese economy, rate of growth kind of slowing, some would say considerably, and just change generally of the state of the Chinese place in the world, economically and otherwise, are you seeing any meaningful differences in doing business there, now versus the past? Or do you see any that you would expect to be more present down the road?

**DC:** What I would say, what I see is more on the macro level from reading articles and the headlines in that the slowing economy there impacts the world, just like when the U.S. economy slows down. And both countries are also developing regulations that make trade between the countries more difficult. I think China will continue to want foreign



investments to help the economy grow. On the other hand, political tensions and regulations on both sides can limit this. So I think it is going to affect the worldwide economy, the fact that China's economy is growing more slowly.

**LLB:** David, another important question that often comes up is how do you ensure that the ambiguities in the roles and responsibilities and the complexity of the regulatory system in China are minded appropriately? For example, I know a number of years back, there were some regulatory changes in China that probably made it exponentially more challenging to appreciate who's doing what. And how are you mindful of addressing the right questions to the right regulators and ensuring that *they* are appropriately swimming in their lane, as it were?

**DC:** I think to answer that question, the key is to understand the difference. In the U.S., we have an idiom, "where the buck stops," but that's really not just an idiom. That's the way we think the world should be. We always want to know who's responsible, and that's important to us. In other countries of the world, that's not always the case. And just to give some specific examples from China. For example, back in 2013, four agencies in China issued a notice on Good Manufacturing Practices certification, GMP certification. In the U.S., it's FDA, it's only FDA, that's all. However, it's different in China. Or in 2008, when China went on the Globally Harmonized System for safety data sheets, 12 national agencies were involved. So again, there's that complexity. If we move it out to the equivalent of FDA, there is a Central National Medical Products Administration, but each of China's 32 provinces have their own National Medical Products Administration. So in answering your question, what I'll say is there are ambiguities in China, and they'll always be there. We're not going to change that. The key is to find individuals in China who can help you understand for this specific issue, which is the best agency to work with or which are the best agencies to work with, because we're not going to change China. China may change itself, but we're not going to change China.

**LLB:** And it underscores the need to have a very clear line of sight on what your commercial or business goal is and to have a pretty sophisticated understanding of the regulatory infrastructure in China, which probably changes with some degree of regularity, Dave?

**DC:** It does, although what we have seen with both the equivalent of China's FDA and EPA is they were raised to ministry status a number of years ago. Ministry status means that puts them at a much higher decision-making ability within China. And that was done because they want stronger control over food and drug quality. They want stronger control over environmental quality.

**LLB:** But I'm guessing having said that, at the ministry level, that probably makes the businessperson's job a lot tougher, to be dealing with the higher echelons of the government. Is that a fair assumption?

**DC:** Well, yes and no, because in China, you often have to deal with multiple levels. For example, the central government might agree with you, but if the local agency doesn't, then you can't go forward. So it's a question of for each particular issue, do you need to get both central and the provincial government or provincial agencies' agreement on your approach on what you want to do?

**LLB:** Mm hmm. Sounds like if you fail at the provincial level, you don't get a shot at the central level.

**DC:** It could go either way. Yes, it could go either way.

**LLB:** Got it. Excellent. Well, thank you for responding to that. Those are important subtleties that, again, for people that are not familiar with working in China, those subtle ambiguities are probably very important to achieve your transactional goals, and not being fully aware of them can compromise the success of your initiatives.

**DC:** Yes.

**LLB:** One last question, and that is, Dave, given your significant experience, your boots-on-the-ground approach to both doing business in China and teaching, it'd be great if you did some sort of how-to for the American businessperson traveling to China to conduct business: a video or the ten things a businessperson needs to know. Have you ever thought about doing something like that and making it available to the people in the world that need it most?

**DC:** I like giving talks. I'm not that much of a performer, but it *is* an interesting idea.

**LLB:** Yes, I think you should consider it. And one final point before I let you go, and that is circling back to your Distinguished Toastmaster status. There's a wedding in my future, not my own, but one of my children, and I'm going to be giving a toast. Anything I should bear in mind as I start thinking about my remarks?

**DC:** Well, I think you're a wonderful communicator, Lynn. And I would -- and your voice has a great sound to it. I would just focus on being concise and fun. That's what people want in a toast, and in most talks.

**LLB:** Brevity and entertainment. Got it. I can do that.

Those were great thoughts, and a great conversation speaking with you, Dave. Really, really enjoyed learning a little bit more about your background, your distinguished background, and your excellent pearls of wisdom for people doing business in China. It's a difficult space for some folks that have never been there and important points to be aware of, and you provided a great deal of guidance, and we're very grateful. Thank you so much.

**DC:** Thanks, Lynn.

**LLB:** My thanks again to Dave Cragin for speaking with me today about living and working in China and successfully navigating the cultural, scientific, and language differences that can make working together both fascinating and challenging.

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