

- John Noble: You want to get that product out there because this effectively cures people who have Factor IX deficiency, they never have to take medicine again if this works.
- Speaker 2: Wow, yeah right.
- John Noble: And number two, our client wants to be the first to market with that product. And they came to us and said, "Look, we'd like to find a way to get this job done in half the time, because we need to get to market quickly. And we believe this drug's going to be an absolute life saver for people."
- Steven Ludwig: Welcome to Inflection Points, a podcast series from Jacobs. I'm your host, Steven Ludwig. That was John Noble, Vice President General Manager of Life Sciences. Advances in Medicine over the past 30 years have extended and improved the quality of life for people around the world. John talks about the Life Sciences industry; companies that make drugs, and how integrated project management helps firms get their facilities done on time. All that makes a huge difference for people that need access to new medical treatments. Inflection Points is where we meet the people from Jacobs that help create solutions that deliver a more connected sustainable world. Just a quick note, we recorded today's episode at a conference so you may hear some background noise. With that out of the way it's on with the podcast.
- Speaker 2: John, what's your background?
- John Noble: So I guess I'll start at the beginning. I was born in Ashington. It's a little mining village in the Northeast of England near halfway between Newcastle and Edinburgh. It's famous because that's where the Charlton brothers came from. They're two of England's most famous footballing sons.
- Speaker 2: Oh, that's a big deal in the UK. Yeah.
- John Noble: Very big deal. I'm the son of two doctors and therefore I was-
- Speaker 2: So you're a disappointment is what you're saying?
- John Noble: No. I was very focused on not being a doctor. My dad's name was John Noble and the last thing I wanted to be was the other John Noble, the doctor in Ashington. So, yeah. I went to college in London, studied chemical engineering, did a PhD. And then-
- Speaker 2: So you are doctor John?
- John Noble: I am. Yes.
- Speaker 2: Yes.

John Noble: But a real doctor. So I studied in Imperial College in London, did seven years there. And then when I left, I started working in the contracting industry. I was really caught up in the whole environmental side of the business. This was in the late eighties and environmental permitting and pollution control was getting very high profile. And then one day a proposal came into the company where I was working and they wanted someone to do some purification for some therapeutic proteins; interferon in this case, which was a new blockbuster drug. I was the only guy in the office who could spell protein. And that was that. We won the job and I never looked back. I've been dedicated to life sciences ever since that day.

Speaker 2: Why is that a passion for you?

John Noble: I don't know. There are some subjects at school that just click and somehow that this whole natural biological cell base stuff and all the chemistry inside it, it just happened in my brain. I could see a picture of how it worked. And then as I became a chemical engineer, it translated into having a vision of all the stuff we needed to do. All the pots and pans and tanks and pumps and things. It all just clicked. And I loved it. I started off as a process designer, went through being a project manager, then I did various corporate roles in Jacobs and now I ended up running the business and it's fantastic.

Speaker 2: That's very interesting. Now you're an expert on Integrated Project Delivery. What does that mean?

John Noble: So expert is probably too strong a word, right? I know a lot about it because it's a very current trend and it's changing the industry. In classic project delivery, someone does the engineering, someone does the construction management, someone does the procurement, the contractors build the project being managed by the construction manager. And then probably one of those parties will commission and start up the facility. In Integrated Project Delivery what you're trying to do is divide the work amongst the same players, but in a way that gives the best value to the client. So what will provide the most optimal schedule, the most optimal cost and the optimal quality.

And it's trying to break down the paradigms of the silos and saying, "Listen, guys, there's a point in the transition of this job where for example, one of the contractors may be better at saying what the construction documents should look like rather than the engineer and vice versa." If you think about taking every step of the job from specifying, what say a door needs to be to installing the door, pick the best person or the best company for that task to do that task, don't just stick to the classic silos. And in doing that, you end up with a more optimum leaner, most important thing is a leaner solution, which helps you to make cost and schedule savings.

Speaker 2: So that instead of having these five separate parties, there's someone helping, like a conductor with an orchestra?

John Noble: Exactly. And it's much more collaborative. Now, the collaboration can take many forms. It can be completely ad hoc where you just get in a room and meet and form a team, or it can go all the way to what they call an integrated form of agreement, where everybody's on the same commercial paper and tied together by the same commercial incentives. But the key thing is driving out waste by getting the best party to do the tasks that they are best suited to do.

Speaker 2: So does it also increase efficiency? So you said scheduling. It helps deliver the project on time?

John Noble: Yes. When it works, it works really well because you remove the silos and you get a much more collaborative environment. You shift from a place where people are taskforced by company to working in an environment where people are taskforced across the whole project, which it's commonly called the big room nowadays; where people come together to collaborate. And at every point in the process, this group, instead of one person making the decision, you'll have a representative of all of the partners on the job, trying to make the optimum decision and trying to solve the problems. Because trust me, none of these jobs ever go right from day one. It's always about being able to adjust. And some of the theory is that with this collaborative agreement you can adjust better and quicker.

Speaker 2: It sounds like Integrated Project Delivery just makes a lot of sense. Why are not more people doing it? Is there an upfront cost that people just don't want to do?

John Noble: So I think if we went out and canvased a bunch of people in Jacobs or [floorods] and the main contracts is we'd say, "No, no, no, this is what we call EPCM." However-

Speaker 2: Engineering, procurement, construction management.

John Noble: Construction management, where we-

Speaker 2: That's where you design it, you buy all the stuff for it, and then you manage the building, correct?

John Noble: Yes.

Speaker 2: Okay.

John Noble: And we provide that umbrella. I think if you look at it from the outside, there are a lot of elements of that that deliver the same results as IPD. But there is a school of thought, and I think it's yet to be proven because we have to move through doing more and more complicated, larger projects with this strategy. But there is a school of thought that says by bringing people together in a

common environment, by really driving collaboration and giving everyone more of a say, you get a better a result.

Speaker 2: Interesting. Now, one of the areas that you've worked on, you mentioned life sciences and I've been doing some reading and I'm just acknowledging my ignorance here, because it sounds familiar. What's the difference between biotechnology, life sciences and pharmaceuticals?

John Noble: So life sciences is the subject area. And essentially what we use life sciences in Jacobs is the manufacturer of therapeutics, right? So that could be for humans or for animals, but it's the manufacturer of medicines, right? The medicines fall into two categories. One is traditional pharma, which goes everything from over the counter medicines to small molecules like the blood pressure medicine or something like that, where it's made by chemical synthesis in a reactor, okay? And traditionally that is the majority of the life sciences business. But today the biggest selling drugs in the world, things like Humira and Keytruda are made by cell culture. So by growing mammalian cells, which express this highly complicated protein molecule, and then you purify the protein. And so the cures for cancer, the cures for rheumatoid arthritis, all of these things are these very complicated biological molecules. And so bio tech or bio-pharmaceuticals are these molecules produced by fermentation or cell culture and the most complicated and the ones that are the most, I say in demand today, are those coming from mammalian cell culture.

Speaker 2: So basically, pharmaceuticals is traditional chemical work.

John Noble: Yes.

Speaker 2: And then the... what's the other category?

John Noble: Biotechnology or bio pharma.

Speaker 2: Biotech is dealing with cells and biological based cells.

John Noble: Yes.

Speaker 2: Oh, that's very helpful. Now both seem to be growing rapidly. These areas seem to be expanding.

John Noble: Yes.

Speaker 2: There's a lot of aging populations around the world and the demand. What are some issues that companies need to take into account when they're building one of these facilities? I'm sure there's plenty, but what are some of the major ones that you're seeing?

- John Noble: Well, I think the biggest shift in the industry in the last five years has been the need for stewardship of the cost of goods. So if you imagine the first few facilities that were made to make these drugs, so think about Enbrel when it first came out.
- Speaker 2: What does that treat?
- John Noble: I think rheumatoid arthritis.
- Speaker 2: Okay.
- John Noble: And I think why it's on that now owned by Pfizer. The day it launched that product was going to be a billion dollar product. And so every day that you can get it to market quicker, is a day that you can start returning on your investment and start beating the patent bust, which is coming up at some time in the future. And so the first wave of investment, really big wave came in the late nineties, early two thousands. And the focus there was, let's get this stuff built and let's start producing. Nowadays you're seeing much greater competition. And so having an efficient delivery strategy, so you can delay... So a lot of these drugs don't make it, right?
- Speaker 2: Yeah.
- John Noble: So they go through phase one, phase two phase three clinical trials. But think about it. If you want to get that jump on the market, you've got to be ready when it gets approved. So you've got to pre-invest in order to be ready for the day that it gets launched so that you have the product available. And these facilities aren't cheap, you're talking 500 million to maybe a billion for a very large scale cell culture, but certainly a 200 million, even for an intermediate scale single-use facility. So you've got to decide when you're going to say, "Let's go for it." And then of course, there's just a focus on what the cost of goods is at the end of the day. I think anybody who's listened to some of the discussions in Washington over the last two years will know the people are interested in the cost of life sciences drugs. Particularly these highly expensive [inaudible]
- Speaker 2: Everybody is. Yeah.
- John Noble: So there is this focus on how late can I delay the investment decision and how can I get the best use of my capital.
- Speaker 2: That's a very hard business calculation to make I would assume. Do you help clients figure that out?
- John Noble: Yeah, we do. And so that's one of the reasons people are very interested in Integrated Project Delivery. Because in theory, that might allow you to delay your investment decision to a later point and also get more value for every dollar that you put into the job. And that's what drives those kind of discussions.

Speaker 2: So those are some of the concerns for first to market.

John Noble: Yes.

Speaker 2: So you mentioned the patents expiring, and so they expire after a number of years and that's known by everybody. And then the generics come in. Do you work with generic manufacturers and do they have different considerations when they're putting together a facility?

John Noble: Yeah, we do. And they do. One of the interesting things that's happened in the industry recently is that it used to be very straightforward. So there are three or four companies that can do this work. The clients would come to them and ask them to bid. Now, we find the generic manufacturers are on the bid list because they'll come in, they'll stand up a facility and they'll build and operate that facility for the client. However, these are complicated things.

Speaker 2: I can only imagine.

John Noble: There's kind of an anecdote there that says you get the temperature right, you get the pressure right, you get all the conditions right, and then the cell goes off and does what it wants to do. So all of the clients that we have are very focused on, there's no point in saving a bit of money here or saving a bit of time here, if it doesn't work. And so the generic manufacturers are doing well, but there's still caution that I sense, but we are seeing more and more of the major companies leveraging the generic manufacturers to get that jump. Maybe it's for phase one of launch. And then they'll bring phase two of launch in house. So the industry is evolving in that way.

Speaker 2: That's very interesting. Now, how are the needs of a life sciences facility, either biotech or pharmaceuticals different than a traditional, I know it's going to be significant, but how are they different than a traditional light manufacturing plant or a food processing facility?

John Noble: Yeah. So the biggest thing about life sciences is it's highly regulated because anything that's going to go into a patient at the end of the day has to be very closely controlled. And so with food stuffs, we have thousands, if not tens of thousands of years of history of what happens when you eat stuff. Right? So there's a lot of evidence built up to say what's good and what's bad in the food chain.

Speaker 2: If I eat too many Oreos, it's clear how that's going to turn out.

John Noble: Exactly. Yeah. And so the FDA, the Food and Drug Administration in the US and it has its sister organizations all over the world, they regulate this industry. Everything has to have a trail of documentation that says that what you said you were going to do at the start, which matches how you produce this during your clinical trials flows through the whole project to the final commissioned and

operating plant. It's very highly regulated, probably less highly regulated than nuclear, but heading in that direction. And you have to understand how to ensure that the quality is built into the plant. And so it's a key thing around safety, and it's a key thing around the efficacy of the product. So safety and efficacy are the two really big differentiators.

Speaker 2: So as someone that builds these, how does Integrated Project Delivery help with this incredibly significant amount of compliance that you have to have? I assume that the building process gets a lot of checks and balances as well for regulators. Yeah.

John Noble: Yeah. So where IPD or Integrated Project Delivery comes in there is that you only get in the room with every one of those five companies is steeped in the history and the knowledge of life sciences. This isn't the kind of thing that you show up at and work it out as you go along.

Speaker 2: So Fred's Contracting is not going to be one of your partners.

John Noble: They're not going to get to the table.

Speaker 2: Yeah.

John Noble: It's a prerequisite. So on all our work, safety and previous performance on life sciences jobs are the prerequisites for engagement.

Speaker 2: So in addition to this regulatory thing, the timing issues, what are some of the other issues that companies are facing when trying to build and then maintain these types of facilities? They sound very sophisticated.

John Noble: Well, the war on talent is a big deal. So the hotspots for life sciences tend to move around the world, right? So when I was growing up, I remember there was a Glaxo and there was a Beecham right? And they were investing heavily in the UK. The UK market is completely flat. Ireland has been booming on and off since the early nineties and continues to be a hotbed for-

Speaker 2: Where?

John Noble: In Dublin Island and in Cork Island. People wanting to invest there because of they're a new European Union, they're getting good tax breaks, and there's a massive labor pool there. However, even that labor pool can be stretched if everybody's building there. So we're starting to see people coming in Switzerland, we're starting to see a reemergence in Singapore, but essentially the biggest challenge is finding the people who can run the plants I think. We design and source globally. Because we have to be prepared for the fact that the project is never going to be where the people are. And so we've adapted to meet that need.

Speaker 2: How is that... How. I'm sorry. I'm interrupting, but let's say you built a facility in the middle of nowhere, because it makes a lot of business sense, but without people to run it, as you say, how are organizations adapting to that?

John Noble: Well, they just wouldn't do it.

Speaker 2: Right. Oh, okay.

John Noble: So, what you see is the... Right now I would say Dublin is one of the hottest markets, Dublin Island. And you see a lot of people moving from the first generation settle, if you like, into the newcomers. And then eventually the market gets too hot or more people are coming in from Europe to staff these facilities. And then it'll move somewhere else where there is more labor supply. And it's quite simple. When we do master planning for clients, we help them decide where they want to put this in the world. We collaborate with the number of the groups in Jacobs who do this kind of advanced planning. And-

Speaker 2: That sounds like a critical thing to provide. If you put the plan here, we've done the research, the workforce is available.

John Noble: Yes. So we help with all of that stuff. And then they'll look at four, five options and make a decision.

Speaker 2: Now, you mentioned safety a few times. I know that's critical for these plants, but how big of a concern is safety? And then I'm sure security is not from just a bad actor point of view, but also from industrial espionage. So how important are those two things when designing these types of facilities?

John Noble: So, look, the main intellectual property here in life sciences comes from the chemistry or the biochemistry, and that remains the domain of the client largely. We can get involved. We understand. So the expression of the therapeutic protein from the cell, the genetic manipulation that was made to that cell is very easy for the client to keep to themselves. And the way they purify it, the specifics of the operating parameters, et cetera. That information is at the interface of ourselves and the client team. And so we treat that with the highest degree of confidentiality, but when someone buys a tank or a pump or a chromatography column, they're buying the same one that all their competitors are buying, it's the way they use it with their specific operating practices that makes the difference.

Speaker 2: Are there special safety features built into one of these facilities that you have to pay attention to?

John Noble: Yeah. So as time goes on, some of the regulations are relaxing, but certainly when you have a genetically modified organism, you're going to have containment to prevent that get into the environment. But I hasten to say this isn't super bugs or anything like this.

- Speaker 2: Right.
- John Noble: These mammalian cells aren't going to spend any time partying outside the cell culture vessel. They're pretty fragile things. You've got to coax them into life and stroke them every day to make sure they stay there.
- Speaker 2: If it was easy you wouldn't need such sophisticated facilities.
- John Noble: Exactly. Yeah.
- Speaker 2: What are some of the common mistakes people make when building a life science facility?
- John Noble: Yeah. Look, I don't want to say their mistakes. I think it's just so because you are pre-investing and the product is evolving, change is the biggest challenge we have. So critical change that can happen at a step of. You might have eight or nine steps in the purification process and the production process. And then suddenly you find that you have to make a tweak to, let's call it the recipe, okay? And then you have to make a change to the facility. You need a bigger tank or a smaller tank, and not play planning for the future can be a challenge. And so I'm not saying that anybody's cracked this, but making as few changes as possible and being really disciplined around change is the biggest single, if you like catalyst, to a smooth project.
- Speaker 2: So the change slows you down? Costs more? Can really throw the schedule off?
- John Noble: All of the above.
- Speaker 2: Oh, okay.
- John Noble: It depends where you catch it, right? The later you get in the job, the harder it is to implement change and the greater the impact of that change is. And so you can imagine if you're very early on, you're just changing one or two documents, but by the time you get into detailed design, one change could affect a thousand documents. Stuff could already be in fabrication. Stuff could already be built. So you're having to cut it out and replace it. And so change is the biggest challenge we face on these jobs. And interestingly, when I talk to other people who do your previous question about other manufacturing projects or even heavy industry, they know what these processes are. I'm just building another one of these. A lot of those, my colleagues in those days found it really hard to understand, well, "Why can't you just tell them not to change it?" I'd say, "You don't change it, it ain't going to work."
- Speaker 2: Yeah.
- John Noble: So you have to find a way to live with it.

Speaker 2: And then how do you build? There has to be some flexibility in the process, but I understand earlier is better. How do you work with clients or people to think that through?

John Noble: So there's two things, two sides to that. First, we have some really smart people as do the clients, our subject matter experts and their subject matter experts. And they work very hard to Futureproof the process, to make sure that... And we have experience of having done these things for multiple people. So we will bring that experience to bear, to make sure we come up with an operating window that'll meet their needs. And more often, 20 years ago, we would design one plant for one product, back to the argument about cost of goods, you can't do that anymore. Because what if that product fails, clients have a platform of eight or 10 molecules they're working on and you design a plant to match that platform. And that gives the flexibility to avoid the challenges of change. And-

Speaker 2: So to use a crude analogy. So I'm building four cars on the same platform. Right?

John Noble: Yes.

Speaker 2: That's a very crude analogy.

John Noble: Yes.

Speaker 2: Yeah. Is that what we're talking about?

John Noble: Yeah. And you can put them all through the same production line, even though the cars themselves can be very different.

Speaker 2: Right. Okay.

John Noble: And the other side of it is strategies for coping with this. It's another part of why IPD, Integrate Project Delivery, is important because it's the combined knowledge of those five parties working together to manage the impact of change. And for me that's one of the biggest elements of it. The group of five always comes up with a better answer than the one silo.

Speaker 2: So why is Integrated Project Delivery and life sciences so important for Jacobs?

John Noble: So look, there are moments in every industry, probably every five or 10 years, something that has a chance to change the industry. We have become extremely adept if you like at being on those trains. Or those buses. Catching that bus, delivering the facility of the future. And then moving on to work on the next facility of the future. We did a project last year, confidential project, that I was closely involved in. It's a cure. It works on Factor IX. So for hemophiliacs. And it's a gene therapy. And so number one, you want to get that product out there because this effectively cures people who have a Factor IX deficiency, they

never have to take medicine again when this works. And number two, our client wants to be the first to market with that product.

And they came to us and said, "Look, we'd like to find a way to get this job done in half the time, because we need to get to market quickly. And we believe this drug's going to be an absolute life saver for people." And so you're looking and saying, "Is Integrated Project Delivery a way for me to deliver that?" And I think the answer comes and it comes back yeah. It seems to be a strategy and we're using it on larger and larger projects that can help us get our clients the best value for money, get their products to market with the right safety and efficacy at the soonest time. It's not a panacea because it depends on the capabilities of everybody. So you have to look at each opportunity individually and some will be conventional and some will be fully IPD and some will be somewhere in the middle, but it definitely has to be part of the toolbox because it generates results and with the right teams it can generate incredible results.

Speaker 2: John, this has been fascinating conversation. Did I forget to ask anything that you wanted to address?

John Noble: I don't think so.

Speaker 2: Oh, great. Where can people find out more information about Integrated Project Delivery and life sciences?

John Noble: Yes. I think if they go to the Jacobs website, www.jacobs.com and there's a life sciences page there, you can see some of the profiles of the projects we've done. And it's interesting reading.

Speaker 2: Great. Thank you so much for being here.

John Noble: No, thank you.

Steven Ludwig: Thank you for listening to Inflection Points, a podcast series from Jacobs to find out more, please visit jacobs.com. Jacobs. Challenging today. Reinventing tomorrow.