An MDR Update That Might Actually Cheer You Up!

Presented by Bassil Akra, AliveCor
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Bassil Akra: The cost of regulatory compliance is actually a very important cost that you should not delay because if you delay, your revenue will disappear suddenly – and your whole company as well.

And I had that situation with a lot of manufacturers reaching out to me and said to me, "Bassil! What happened?!"

– It's, like, why?

"The Notified Body pulled our certificate away!"

I said, "Are you surprised?"

"Yes! They were auditing us and they were very strict!"

I said, "This is their job. The same as FDA or other country regulators. This is their job to make sure that the products that are getting on the market are compliant. And then they pulled back your certification – it has the reason – they didn't do it just for fun. And the reason was that you forgot regulatory compliance."

And they said, "Can you tell us what we did wrong?"

And as I started talking to the company, and they were working, that's where I went and audited them by myself. I said that when you started the company, like we heard today about innovators creating companies, starting a company, I said when you started the company, you had a big investment and regulatory

and quality. It was a small company but after one year, you had 12 people working on regulatory and quality.

When I got to audit you, how many people were there? One person and 12 marketing.

I said, “Well, where are the regulatory and compliance people?”

“Oh, this is, like, an unnecessary cost, we tried to reduce the cost.”

They cut costs in the wrong place. And they got actually in that problem. And this is important. We spoke about innovation today.

It’s important to recognize the regulatory obligations you have to meet. And this is important also for innovative performance of the company because if you are not looking to continuously improve your devices, this is one of the obligations.

You will kill your company by yourself.

> **Note:** The following was auto-transcribed by **otter.ai** and got probably 80+ percent correct without edits. Interpret accordingly.

Joe Hage: Bassil, please tell us about MDR.

Bassil Akra: Thank you, Joe, for inviting me to speak here about MDR. So regulatory is always boring, I was listening to everyone talking about innovation investments or getting a company established. And looking to that from a regulatory point of view, everyone talk about investment money, getting the money back, getting big revenue, growing as a company and they forget always market access. And this is a big point, which is also related to European legislation. I deal every day since many years with manufacturer.

In the past, I was working for notified bodies, the biggest notified body in Europe, I established for them, the MDR got it implemented. And then at the end, I said to them, guys, no, I built everything, every single is ready to run, I will go and help the other side. And that will help the manufacturers understanding how they have to fulfill the requirements.

When I get to the other side, people getting to me, manufacturers told me, “You know, now we’re going to tell you the right story. All the time, we’re telling you how good we are, how big we are, how strong we are. And honestly, we don’t have any single bats. And therefore, we need you to get us to help us to get out there to get the MDR implementation.”

A lot of you who are not dealing with regulatory are not perhaps knowledgeable about what is MDR. MDR is the medical device regulation in Europe, which was published in 2017. And it was under discussion since 2012. Why I’m telling you the history because…

We heard about innovation. Every company is like looking, “How can I get my market to the market?”

“How can I make sure that I keep my product on the market.”

But everyone with regard to regulatory aspect, wait till the last minute to react. Because a change means cost. Cost means something I push back. But the cost of regulatory compliance is actually a very important concept. You should not delay because if you delay, your revenue will disappear suddenly, and your whole company as well.

And I had that situation with a lot of manufacturers reaching out to me and said to me, “Bassil! What happened?!”

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And this is what happened. Historically, you know that a lot of us, we carry, Samsung, iPhone in hands, who was actually the market leader?

NOKIA, and Ericsson, they forgot actually improvement and continuous improvement. They are still there, but you don't hear about them anymore in the cellphone technology, because they don't deal with that anymore, same way like Apple and Samsung. So, talking about regulation and talking about European legislation, just to give you an update, I will try to keep it simple for everyone that everyone who's not regulatory background, understand what's happening here.

European system is changing. And it is already changed. We have in the past directives and that those directive change to new regulation. We had in the past in 2012, 82, notified bodies 83 notified bodies who are notified bodies today. In the US, you have FDA, this is how you get your product approved. In Europe, European systems said we don't want to do it as centralized authority.

We did centralize with give it to independent parties conformity assessment bodies, and we allow them through designation that they are allowed to act on our behalf. So, they are like the FDA, but they are in private hands.

Now we have 83 notified bodies, now with the the MDR, we just have 28. Why?

Because the process of getting a notified body is not anymore that simple like in the past 56 applied, 28 are there.

How did they take to get that? Two years, every notified bodies taking two years from application to designation, every notified body and last one of I was working for one of the biggest players there. And I got this second designation in Europe at that time.

Everyone was increasing resources, but you do the calculation very easily, you have 83 notified bodies serving the markets globally, you get reduction to 28. Even if you increase resources over a period of five years, you will not be able to digest everything immediately. Because capacity, competent people are limited. You can't find them all around, you can't get all these people running and able to deliver services. The second point which is important in the service provider part is that actually you need to train the people. It's not like a machine, you develop it, you verify and validate it, you bring it to the market. You need to get people trained, educated, and FDA is dealing with such a limitation. Also, European system is dealing in such a limitation.

Years ago, I told every one of us, "If you don't have capacity, start training your kids, because their future is in regulatory, is in quality, we gonna more and more of them."

A lot of people didn't listen, they waited, now the kids have to go to university, you have to pay as well. So you don't have actually the trained qualified people. So we have 28 notified bodies, they have to deal with all of this problem with the MDR. They have to implement MDR, they have to support everything.

The problem that we have in Europe, we are not getting, let's say a possibility to get all devices still ongoing under the old system. Every device even if it has been since 50 years on the market in Europe has to undergo a recertification. So, there is no possibility to deviate from this. Every manufacturer, if it's

Medtronic, or Stryker, or it's a no name company, everyone has to start from scratch.

The European market is rebuilding everything. If we look into system in Europe, we have nearly 10,000 certification of medical devices getting from all of Europe, as well as from European market as European market. So, they need to get the CE mark and all of these companies need to get certified again, so notified bodies.

In the past you could see them and conference like that, so Joe invited me at that time with my notified body responsibility to speak on 10x. Nowadays, if you look to conferences, you'll see some notified bodies presenting those are the big players, the other one, they are hiding because they don't have time to be there. They can't spend, send resources to spend time on conferences. They can't do that. Because they need every single capacity to digest the work and also they don't care anymore. Their sales strategy wasn't the best thing, they were fighting to get customers. We were doing road shows as notified bodies to get more customers now, so you sit there and customers are waiting, and they can say we have enough, go away, go away.

And this is what is happening and what is also happening, the process is getting very lengthy. So if you've got the certification application now for the European system in the past, you could do it like, you could do expedite it three months, six months, get your certificate. Now you can apply for expedite and if you get it, it's really a success story, if there is one notified body who would offer it for you, but they will not deliver it in three months or six months, you will need long time, typical time to get the product recertified is between 18 months and two years. And even a product which was approved in the European market, and what matters, how much clinical evidence do you have? What matters? Did you do your job accordingly in the past, and this is what's leading to a lot of trouble. You see, I told you 10,000 certificates, how many of those do you believe are already, MDR now ready? Guess, give me number.

Delegates: ZERO,,,400..

Bassil Akra: Actually, less than 10% of these 10,000 are even big manufacturers. So, which were telling me at the beginning, we already we got to submit we got to get everything on time.

They call me and say Bassil, “What’s happening, we don’t hold even one certificate from the European market.”

Now, this point is interesting, because it is an additional burden, the time the countdown is going down and down and down because we are ending was that transitional provision period in May 2024. So we still have two year’s time, and if you consider that a lot of manufacturers are not certified yet, and 28 notified bodies are not even allowed to start the process. So you recognize that the European system is still in its implementation phase, and a lot of manufacturers will not be able to make that market. So we spoke before about which kind of influence there was an example of Russia, leading to an influence on your business, did you consider also the influence of not being able to sell in Europe or not to sell in other countries, which depend on the European CE marking because a lot of manufacturers, they rely on CE marking for a lot of Asian market or Middle East. And if you don’t have it, you lost your business as well. And this is where a lot of people do not recognize that and do not care about that as well.

So what is the reason for all of this, the reason for all of this not readiness, no preparation of manufacturer, a lot of people didn’t start, we had the COVID situation, which led to additional burden because people couldn’t travel to do all the thing, to do, let’s say the initial steps. But the biggest burden also is related to manufacturers who didn’t prepare themselves who didn’t take it seriously.

In 2012, when the regulation was under preparation, I went out I was telling people, “Guys, you need to start collecting clinical data.”

I was at RAPS, big conferences all over the globe, telling everyone trying to educate on MDR. And I think I trained thousands of people on MDR.

And then everyone was telling me, “Bassil, come on, this will never happen. The European legislator will never implement such high requirements for Europe this will be higher than US FDA, they would never do it.”

What happened, in reality? It’s implemented. What happened? Nobody prepared himself. So a lot of manufacturers did not take it seriously. And now, surprise, surprise, manufacturer get their product rejected.

Then these comes to me like, “Oh! We invested about 500,000 to get our product certified on the end, our end result was reject, we have to pay for as reject.”

“It’s like yes, this is reality. Because you didn’t comply to this new legislation. It’s not fun. It’s actually a requirement which you have to fulfill in Europe. This is what is actually currently happening with European medical device regulation here.”

“What is the problem?”

I don’t know if people cannot read what is written, or they don’t want to read. I know it’s boring, but I kept saying, you can read the MDR with a glass of wine, and it will end with multiple bottles. And as soon as you start feeling the pain, then you got it because when you’re feeling the pain, you are getting the message and the wine will help you because you will get a bit of relief out of it. So read, what you have to comply to. Don’t just read your numbers because your numbers will be having a minus in front of them. If you didn’t actually read the obligation that you need to fulfill to be able to place device on the market.

Joe Hage: You make regulatory pain, very entertaining. I have to ask with, so few companies compared. what the reality it’s not as though you’re just going to say sorry, 90% of medical devices are no longer available. So…

Bassil Akra: it’s a good point. Joe, I think the legislator today they tell you, we told you about that years ago. So they will not give advantages potentially for all manufacturers, the manufacturer who are perhaps in the application process and they want to actually influence by the fact they try but they are not able because of delays and so on that they will get the benefit, but the manufacturer was still, probably like 8% of the industry is still saying, let’s wait, perhaps next year we gonna apply.

Joe Hage: Okay, let’s take that example that let’s say 30%, say, I don’t believe you, I’m not doing it, you don’t really think that half the products are going off the market,

Bassil Akra: They gonna look to medical need, they gonna look to source device manufacturer, and they’re gonna create different routes. So will that not get rid of every device and kill the healthcare system? They will not do it.

But they will apply the rules of authorities where they say, Okay, we're gonna prioritize, we're gonna decide, do we need 10 cultivators, or we take the one who was actually prepared to get this devices market.

Joe Hage: I know collusion is not really legal. And I didn't suggest it, but everyone and say what competing said we're not gonna do it, I'm not gonna do it.

Bassil Akra: And then yeah, I mean, we will see what will happen was such a situation that could come, we could come to such a situation that everyone would say, I will not do it.

But then you could have also regulators of saying, "Okay, we don't approve device by device, or we give you a big penalty, that you have to do it and you have a short time to deliver, if you would not do it, then we create our own solutions or whatever."

Because you know, regulators are, sometimes they create, like deviation from the old rules, but they don't want actually to blame themselves. They create rules, if you blame them, they will say, "Hey, guys, this is not the way that you want to have it."

Joe Hage: So, you're saying don't call their bluff, Joe?

Bassil Akra: Yeah.

Larry Stevens: I think I'm going to contact the European regulators and have a great suggestion; it's called an emergency use authorization.

Bassil Akra: I mean, they have that. And in Europe, we have 27 Member States, you can do that. But then you need to go with your device for every single member state and get approval, and you need to justify why you didn't do your job accordingly. And then you can get into I mean, there's always someone who did it. But as someone who prepared themselves.

Mike Belongie: And I'm talking about what I just talked about, it's called people not getting therapy and dying, because devices are not available, the government cannot ignore that.

Bassil Akra: Agree, agree, and they will, will take care of that they will take care of such a situation. But they will not allow manufacturers to play the role of saying we would not do it. Because this, this will mean that the rules are not followed for that country, which they would not enable doing.

Duane Mancini: Just to comment on that like the strategics, they will comply with the MDR, they are all doing it. They're all hiring heads of, of MDR transition plans, we did a lot of their CERCP, work and they're going to do this, the only thing that this is really changing is where start what startups do in Europe, instead of commercializing in their own country, they come to the US first.

Bassil Akra: This is a major change. So a shift in the way how manufacturers are planning that product introduction. They are designed with different market now. But we need to consider also that the fact that nobody is taking that that seriously what is happening in the EU, and this is what's going to punish a lot of manufacturing. And like you said the big ones they are doing that they are planning they are doing they are not succeeding yet. Because they believe based on their power, they can succeed faster, they are not. So they are recognizing we have to do the job in the right way.

Now, the small players, some of them are perfect, because they said we can't afford it. We need to get compliance. Some others they say, oh, let's give it a try. So I have one manufacturer, he said to me, you know, I just sent them the same documentation, which I was sending in the past the same evidence. I said, "Let's give it a try."

And they I replied from them that they do that in an expedited way. So I had to pay like four time the price, and that they got back to me, I said,"File is rejected, why?"

I just changed the name, because the rules are different. And you need to read the rules, what they are telling you, you have to do, and this is this is wrong, and those manufacturers will disappear. Because such an investment, we're worried about like 1 million revenue, 2 million revenue, 10 million revenue, if you invest like 500,000, just for an approval, and you got to reject, when do you get this money back. So you need to get that to recover as well.

Joe Hage: I asked Maurizio, I asked Daniel, you must have more companies coming at you than you could possibly support.

Bassil Akra: I agree this and this is…

Joe Hage: How do you choose who you will help?

Bassil Akra: I mean, what we do is like we have the selection of companies who we gonna help, or we will not help. I do not help companies that are not willing to be compliant, they are not willing to listen. Companies that say, "I want you to help us to get into compliant strategy," I help them.

But I get a lot of requests from companies saying to me, "Tell me how I can avoid the compliance and they say no, I can't do that because you can't avoid it. I can build for you a strategy which is lean, I can get you like a prioritization to get your submission done. But I can't get you non-compliant product on the market because I can't sleep at night when I know that that product is not compliance."

This is what we need to keep in mind as well.

Karandeep Singh Badwal: So currently, as a quality regulatory consultant, which areas should I be focusing on? auditing a client? What are the common mistakes that you see in terms of companies losing bases.

Bassil Akra: I will show you that in some minutes. So this is what I'm planning to share with you as well. The MDR, there's nothing actually, which is I was surprised that people are telling me like the MDR is not a complex, a lot of things are like overdoing. There's a lot of exceptional documentation, which you should have as the manufacturer.

And every time when you do something in a regulated field, you should document why you're putting that decision. I think, Rob, Michelle, told you a bit about that when we were speaking about FDA, so nothing unrealistic, unrealistic expectations. The biggest problem, sorry, it's like jumping.

The big problem is like people start with the first point was saying the European legislation is saying you need to know how you are getting a board like this market, your supply chain, you need to know how they communicate with you. People forget, for example, to have contractual agreement to them. They don't know who are the distributors.

Today. in the morning, before coming to the conference, a manufacturer was telling me, “You always sell millions of devices like, how do you sell them to the European market?”

Or we all know, “Is like, you have to have a first point of selling, how does it work, where who is distributing your product?”

Yeah, we have someone who’s one distributor, but he’s not distributing instead of giving that to further distributors like you need to build like clarity about your supply chain, because you need to make sure that you mitigate risk, there is something going wrong, the need to know what is happening. They don’t know that, so that the first important thing is like economic operators, who is part of my supply chain, as a non-European manufacturer, you will need an authorized representative, you will need an importer, you need distributors as well, you need to build contractual agreement with them, you need to understand what they are doing. You need to set obligation, duties and responsibilities. And guess what it is also a new ask the same thing. It’s the same thing that you need to do an ethic quality management system, but people do not recognize it. And suddenly they say oh, we have to have that you will not even order something without the contractual agreement.

Whatever it is consumer, you do contract as well. But they forgot that, the other point, which is important, and I just get on a high level to share with you some important information, which are not new, a quality management system, which includes every single question I was mentioning during her presentation, and Rob, is minimal. Guess what?

A lot of companies suddenly now they are like saying, “Oh, we didn’t have the data? What? Why, you didn’t have it? Yeah. nobody asked us for this.”

It’s like, do you have documentation for your device design? No, we lost some because we move multiple places, and we don’t know where they are now. And those are, US companies, Asian companies, European companies, and sometimes with a big name.

You know, it’s like, how could it be that you lose documentation?

“Yeah, we did a lot of acquisition and suddenly, we just forgot that we need to have us do computation with our acquisition.”

So we do actually the partial financial part of the product, but we forgot actually the remaining point, which is critical. The other importance is saying which is actually critical. What do you see a lot of gaps mis-managed, how was responsible done from the beginning and never stop it. This is where actually you shouldn't be with MDR. But this is what they are identifying gaps. The biggest gap, which you can see clinical, everyone was comparing apples with oranges, and saying the apple is an orange. But the orange doesn't have enough evidence.

And they were like trying to get those products on the market. Now, the mentality of equivalency in the US differ from the European equivalency approach, they are not the same, you can't apply the same mentality. And especially for US manufacturer, this was actually the strategies that we were pushing for, like 510k process, it doesn't work for you, you need to do it in a different way. And this is where a lot of people are getting now into trouble, because they recognized we need to do something in a different way.

The other big part, which I want to share with you is actually the post market, post market surveillance obligation or actually obligation which you have to do throughout the entire lifetime of advice. And this is where most of the manufacturers are not doing that. And they see this as a big investment. And they see this as just an investment. They don't see the add value of post market surveillance. I said regulatory as not actually a burden for a company regulatory is actually an add value for a company for continuous improvement.

And why should you sell it stand when you have just one year data?

Why don't you think about how can I make clinical studies to collect more data or establish urgency to collect more data to use them for my marketing strategy as well, not just for my regulatory compliance?

How can I use them to impress to show add value to show why you should buy my device. And this is where people forget it. They see it always we are just doing this.

I remember in the past, some CEOs came to me when I was at the notified body. They said, "Dr. Akra, we are doing all of this just for you."

"Oh, thank you, I say this is big. I am so impressed."

So thanks for that. They don't get the point that actually, this is actually for their own risk mitigation, business risk mitigation as well design continuous improvement and sales strategy. So you do that not just for making the regulator happy. You do that to show compliance and to make sure that are protecting yourself in case something happen.

Also the issue, which is leading to a lot of trouble is actually the fact that manufacturer were doing private labeling of other devices. So there was an original equipment manufacturer. And they were like using that device and putting that label on it and say they aren't the leading manufacturer. And they had no access to any information. And this kind of devices, they will disappear. And I was hoping legislation because the legislation is saying, if you want to do that, you need to have full access to the full documentation of your predecessor device. And if you don't do that, then you will not be able to get as much this is what is becoming now burdensome for a lot of money.

Now, the important part, which is critical, you asked me what will happen and all that you have got to get to a manufacturer, you got to see you got to ask them, "what is your regulatory strategy?"

So I think some of you spoke about pathway or pathway, the strategy of manufacturing that device in the market, no manufacturer has it, no, MDR requires every manufacturer to have a revenue strategy for the device. They expect them to develop a clinical strategy as well to document that. Everyone say we wanna have something for the future, but they don't document they don't have evidence, qualification of personnel involved and regulatory.

Not everyone can be ready to professional, most of the companies, they are hiring from university, which is great. I'm supportive for junior newcomers, but you need to handle some senior leadership in your company, you can't just get someone from the university would never have any idea about regulatory and give them the data. So you don't know the full qualified person. You need to select the right persons. You can't have an automatic surgeon, evaluating the clinical data of hardcourt even if he's a physician. He's not qualified. He can't do that. It's not like by definition, because I'm a physician, I can do everything.

Other things which are leading to another problem is actually capacity resources, hiring, we're hiring people, where are those people? How much time are they spending for that work? And a lot of people forget all that they, they also involve supplier, and they say we don't want to do the task internally, we

got the BRC personal responsibility compliance, we'll take an external one. But that external one is serving 20 manufacturer, and this is one single person doesn't make sense. No, it doesn't.

So they aren't getting nonconformity, it doesn't work, you can't get one person serving hundreds of manufacturers for getting a notification of the regulation. So there's a lot of things I don't want to go into the details. But I just want to tell you, if you want to succeed, and it is doable. So to get your point balance, that's something which is like, I know, FDA does the same thing, the requirement or a new ask, they are named differently, perhaps they are referring to different legislations, but you have the same requirement. And I'm surprised that everyone has seen that as a big burden. Because if you could prepare early, you could avoid a lot of costs. No manufacturer comes to me as like our certificate is ending in six months, can you rescue us?

It's like, what did you do? Nothing yet? Then you got MSA? How many devices? Do you have? Oh, we have like 25 devices? And we have five manufacturing facilities? Okay, can you do something on the quality management system? We have in some facilities, a good quality management system.

So we have certification, but we then look to gap so and you're so you start with this. And then you recognize actually, you need a lot of people to start doing the 25 technical documentations to get that all of them ready, and up to date.

Some of that they will ask me, "Would it be possible just to send them and say like, let's get a waiver and say it's fine?"

No, you will not do it because the cost of correction is higher than the cost of actually doing this in the right way. If you do it from the beginning, right, you will cost you $1. But if you correct afterwards, it costs you millions because you need to go back and back and back and you got to lose time. And time is long and a lot of people don't get that point.

Standards. We would like talking about a lot of standards and how US has standards and other regions have standards and guidance. And I was smiling when Michelle and Rob were presenting saying people to try to negotiate with them about user choice standards and guidance and whether those are like binding.

Now the European legislature, I remember when we got the regulation published, I was invited to the European Commission meeting in Brussels, the Commission presented about the MDR. And they were like presenting and impressed by the new legislation to say this is a good new document finally published which was a good step finally, and they had to present from my side and it's like I presented the legislation I said those are 175 pages which are meant in effect small, tiny size. If you read some information one time, you will understand nothing. If you read it multiple time you will recognize it's actually unclear at all, and you will need a lot of guidance. The commission was saying at the beginning, we wrote the relation in a very lengthy way because we wanted to avoid guidance. We want to be clear and be very specific. How many times do we have to now for the European medical device regulation? The regulation itself if you printed at a normal pace, and was a normal size or font size you will get 500 pages.

Since its publication, we got nearly 80 Guidance document and every guidance is between 10 and 30 pages, explaining what is written and five sentence in the revisions, every five sentence are leading now to 20 pages of explanation. Now the good sentence of guidance has actually gotten a bit more clarity but the bad thing is like you know, every legislator when they are trying to explain to you what they meant was three surfaces. They include the new requirements, which makes your life not easy industry, we want to have more clients more products, we can start because we don't have eyes because the eyes and everyone is crying as "Oh God! the guidance are expecting from us to do more at the moment. So this is problematic."

Joe Hage : Often, then I am asked or give unsolicited advice to speakers, you know, some come up and they say, let me tell you about my company and this and that I say no, just go up. Show them that you know what you're talking about. They're like, Oh! I know a guy. You haven't done that in spades and very entertaining had solo press.

From Germany, for which I'm very grateful. I would close by asking you to tell the camera for those watching later. If you've not gotten started question I'd say get started right away. But is there something specific like where do I start because calling you is a nice choice, but it's impractical for 80% of the companies to call you What do we need to do now?

Bassil Akra: Start with your gap assessment. This is what you have to start and don't do your capacity resources if you have enough resources, if you don't have, hire them or involve consultants to support you on that.

Joe Hage: Bassil Akra is my friend, ladies and gentlemen, Bassil Akra.