

# QSVs & The War of the Roses

With Prof. Dr. Christian Johner

## Transcript

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Medical Device Insights.

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A podcast by the IONE Institute for medical device manufacturers, authorities and notified bodies.

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Quality assurance agreements are contracts between companies, e.g.

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medical device manufacturers and their suppliers, their subcontractors.

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These quality assurance agreements are also required by regulation.

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However, they should not only help to comply with the regulations, but also create clarity between these companies and their suppliers.

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But sometimes the opposite succeeds and they are the cause of a War of the Roses between the two.

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We discuss how to write a good quality assurance agreement, what content it should contain and what exactly can save you these Wars of the Roses

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in today's podcast.

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My name is Christian Johner, head of the Johner Institute.

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As I just said, a Q.S.V., as it is sometimes abbreviated, a quality assurance agreement, is a contract in

which 2 parties want to determine the obligations regarding the quality of the products and services supplied.

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An example would be a medical device manufacturer who commissioned an engineering firm to design certain components or products.

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Another example would be an engineering service provider that develops software on behalf of a medical device manufacturer and where this medical device manufacturer wants to conclude a contract with the service provider for the quality of the processes and the delivered product.

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We also act as a service provider, for example by testing the usability of medical devices, or

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monitor these products in the market afterwards, i.e. take over post-market surveillance.

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And that's why we sign this quality assurance agreement with our respective clients on request.

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Such a quality assurance agreement should first regulate the general part, for example, what goals both parties are pursuing with it.

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Then what is the scope of this QSV, so that refers to all products or only to

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specific products or services, it refers to specific processes.

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It often also regulates secrecy.

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You regulate a validity period and deal with things, such as licenses or exploitation rights, which the client usually wants to reserve.

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Another point that you could or probably should regulate in your QSVs are the communication channels,

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that both sides want to communicate with each other.

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So, for example, it takes place by e-mail, by telephone, if you want an acknowledgement of receipt, what

do you do if a certain person is on vacation, so there are substitutions and the response times would also be examples of points that a quality assurance agreement can regulate.

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Often, however, it has very specific

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Things that a QA regulates, for example on the subject of handling documentation, the permission for the client to carry out unannounced audits.

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Things are regulated as to whether the supplier himself may subcontract again.

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Often, the client also wants information about

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If something changes in the customer's system, for example if their Q.

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system would change or perhaps in the worst case would lose the certification if there were new locations, these are also things that can be regulated in the quality assurance agreement, so especially if there are changes to it.

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Another point that is often the subject of quality assurance agreements is everything that has to do with resources or methods, with infrastructure.

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So, for example, you can stipulate that certain employees, i.e. very specific people, or at least very specific competences, are made available, that certain substances are used, for example, if it is a production process, and that these substances may only be changed if the client has given permission.

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Some have certain wishes regarding the methods or tools.

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so here is also an example, if someone commissions a software development, it may be that someone says, yes, we would like you to use certain test methods, for example black box test methods, that you achieve certain degrees of coverage with them or there are also limit values that have to be adhered to, for example, in the area of biocompatibility, so now another example.

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So here it is now about acceptance criteria, sometimes also with limit values or with tolerances and also

the client,

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he may have to take on certain obligations.

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This includes, for example, that he really checks the products and services promptly and then complains about it if this is not the case in time.

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There are obligations to provide information, such as tools, certain materials, which the contractor then also needs, and also information in the form of specifications, for example, which the client must provide.

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So these are examples of

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Contents of a quality assurance agreement.

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I'll summarize them very briefly.

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These were general aspects such as objectives, scope of application, secrecy, validity period, then everything that has to do with it in terms of communication, i.e. the communication channels and response times, then the concrete requirements for the

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process and to the supplier's organization.

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There were things like Q.

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system or permission to do unannounced audits.

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And the last thing was concrete requirements for the resources, the methodology, and the supplier's infrastructure.

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Now I had already said that there are regular Wars of the Roses and in fact we are called when a client and a contractor are at odds and cannot quite agree.

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And often you try to deal with it on the back of the regulations, but usually it is not the regulations that are the decisive factor or trigger of the problem, but it often has something to do with fairness.

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I would like to share with you a few thoughts on what fairness means, from both sides.

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Firstly, how does a fair client behave and how does a fair contractor behave?

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A client would be particularly fair if it is a large client in particular,

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that he does not poach any persons from the contractor.

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Unfortunately, we see this a lot.

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The big ones also have the slightly larger purse and they then occasionally subtract central people from the contractor, from the supplier and then really put him in unpleasant situations.

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The big ones also sometimes tend to gag the smaller ones as their suppliers, for example with unrealistic timelines.

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about which the clients actually know better than the contractors.

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Sometimes they put a tough price war on it and then lure it with long-term cooperation, without saying exactly what will really come out of it.

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And where it gets particularly unpleasant is when service contracts are then extended in the direction of work contracts without the other side really noticing.

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In other words, that she suddenly owes a result

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And no longer, as originally thought, a certain activity, activity, time, i.e. a service.

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Where I also see problems that perhaps extend into the area of fairness is when the company that com-

missions this, the service or the product, for example, makes the contractor responsible for the functioning of the overall system afterwards.

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But that can't be, because he can only ever take responsibility for the part for which he was commissioned.

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For example, for a certain component of the overall system or for a certain document that the person creates in turn.

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An example of this, perhaps, we regularly experience that clients commission a component and then say: 'Yes, please do the risk management for it as well.' And that's one thing that will only work to a very limited extent because of the risk.

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in the sense of the definition of the term, i.e. the combination of severity and probability of damage, cannot be assessed by the contractor, but can really only be done by the client, who knows the complete context in which the product will be used afterwards.

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But you can't say that it's just the clients, especially the big clients, who are sometimes not entirely fair to their smaller partners.

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We are also observing the opposite case.

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For example, suppliers who bring their clients into unsightly dependencies.

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We had cases where they had written proprietary software code, without which the other product would not work at all and which they had to pay very dearly.

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We have seen that they did not provide their test infrastructure at all.

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So the client ultimately then

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the delivered artifact, in this case it was now also software or programmable electrical subsystems, as the 60601 calls it, could not be checked at all or could not even rebuild the software.

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What some people did, and I found that particularly unfair, was that they used their own proprietary

component libraries in this software code and said afterwards, yes, that wasn't part of the job at all.

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But without these libraries, the entire software could not be used at all

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and then the client had to pay further license fees, which he originally did not expect.

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Even in the area of good developers, there are things that I wouldn't put in the category of fairness now.

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On the one hand, I said that the big ones shouldn't poach developers from the small suppliers.

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However, we have often seen the case that some development service provider and the super developer then

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went to the client, so to speak, and he thought, yes, there is a huge competence.

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De facto, it was one person and he was used mainly when it came to promoting the projects or getting them.

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But in the actual project, these stars were no longer there.

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I would also not see it as particularly fair from the point of view of the contractors if they do not inform about difficulties in time, in particular about the time delay.

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or, so to speak, the classic that we often observe, that although they are very inexpensive in their offer at the beginning, every little change or subsequent development can be paid for disproportionately expensively.

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Yes, those were the possibilities of unfairness that the two sides have, so to speak.

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So for you it would actually be more of a mandate, see that the reverse is regulated,

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in their quality assurance agreement, for example, that you don't poach developers or that developers who are present at these interviews, i.e. at the sales event, are really the people who work in the project afterwards, that you might be in Q.

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also regulates in the long term how expensive a further development will be.

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In the end, it is always a matter of staying in balance,

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do not conclude contracts that are only fair if you have somehow realized a long-term cooperation.

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It would be good if give and take are in this balance after each step.

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To make sure that it works well, perhaps one last thought, when you commission things, whether it is the development of a component or the production of a product, that you have very clear interfaces between yourself as the client and your contractor,

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Of course, the reverse is also true.

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And these interfaces here should now be precisely specified, what should the product or artifact to be developed or produced really be able to do afterwards.

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These are then also the acceptance criteria and only for this part, for this component or for this element that is developed or produced, the contractor assumes responsibility for that and not for the entire system afterwards.

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a good other best practice would be, don't make sure that you only talk about whether it worked at the end of this assignment, so to speak, but let us show you interim results.

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In other words, a kind of scrum-like thanksgiving model, apply scrum-like best practice, where you can find problems early on, react early and a partnership approach is also cultivated.

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Yes, those would be my tips, maybe one last one,

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if you want to know more about Q.S.V.s, then go to our website.

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There we have a contribution to the topic of quality assurance agreements.

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We also have something to download, namely a chapter structure that we would recommend to you.

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And if there is somehow a problem, if there is a marital crisis, a war of the roses that you want to resolve, if you want a review, we are neutral moderators, get in touch, we would then help and also

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Observe compliance with the regulations.

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That's it today on the subject of quality assurance agreements.

