

# A Certification Carol

By Ronald Boumans



While slipping into his coat, Mr Pip threw a last glimpse at Jane, his head of quality, regulatory and clinical affairs, main contact point for PMS and vigilance, and PRRC. As usual, she was very busy, trying to finish some final details before the long Christmas weekend. Her narrow room in the basement, with a small north-facing window that even in summer didn't allow much light in, was getting even darker as the evening fell. Jane was just Jane, sitting in silence, focused on her small screen. He thought it might be a good idea to invest in a larger screen, maybe even two, next year. He made a mental note to add this thought process to next year's to-do list.

Without looking up, Jane said: 'Did you sign and send those application forms for the notified body?'

'I saw this, thank you. I think engaging with a notified body is something serious. I will consider this over the coming days and I will come back on this in the next year.' This was something he had managed to postpone for a long time, he was sure he could drag this on a bit longer. CanKick Medical was doing well and he was certain it would remain doing well for much longer, despite all the warnings Jane had given.

'Enjoy Christmas, and don't make it too late today.' As he walked out, he had the feeling Jane was piercing his back with her sharp eyes...

He always enjoyed the Christmas drinks at his local bank. He could meet his peers from other companies in the area and they served good food and lots of free booze.

'Hey Pip! Still soldering on?' Mr Greenheavens handed him a glass of champagne. 'How is my company doing?'

Mr Pip took a sip and said: 'We are doing well, selling our devices all over Europe. Since I bought it from you in April 2017, CanKick has doubled in size.'

Mr Greenfields nodded. 'As expected, as expected. But have you managed MDR certification by now?'

'No, it is bloody expensive and I have until 2028 to arrange that.'

Mr Greenfields emptied his glass and started to move towards a waiter. He stopped and turned around. 'Can you wish Jane a Merry Christmas on my behalf? She was my best employee. I hope you treat her well. And for today: I hope you can sleep well because things are about to change for you...'

Mr Pip was not impressed by that warning. Mr Greenfields had been grumbling about the MDR almost from the moment he had sold the company and all that time CanKick had managed to do well. Other companies were leaving the European market or went out of business entirely. The large corporations were busy acquiring smaller ones. But CanKick Medical remained independent and increasingly profitable thanks to this decrease in competition. Obviously, those profits would have been much less if he had hired consultants and engaged with notified bodies. For now, that was not necessary – he had Jane – and he could keep his prices lower than his competitors. With a bit too much to drink, he went home and went to bed early.

After a few hours of restless sleep, he woke up. Mr Greenfields was in his room. How did he get there? He wondered if he was dreaming and then remembered a psychologist saying that there is one thing you cannot do while dreaming: realizing you are dreaming. He got to an upright position. 'Mr Pip, I come to warn you about your certification strategy. Let me first show you your Certification Past.'

The room vanished and he found himself in his office. Jane was worried about a device in a wrong risk class and there was a report about an injured patient. He could see that this was in December 2017, he was still in his first year as CEO of CanKick Medical. 'If I remember correctly what you said last week, all Essential Requirements are the same for all risk classes. Is that right?' Jane nodded, she knew where this was going. 'So, the risk class doesn't matter and we should not worry. And that injured patient, are you sure our device caused that?' Jane shook her head, she knew where this was going. 'Unless there is confirmation this is about our device, we do nothing. Don't start an investigation, and certainly don't report on it. Is that clear?'

He could see Jane wanted to say something else. He raised his eyebrows. 'When do you want to discuss the MDR certification strategy?' But before he replied, she knew what he was going to say. 'The MDR applies in May 2020, only then do we need to get that certificate. For now, we can take our time.'

Next, he was back in his bedroom. Mr Greenfields was still there. 'You thought you had all the time in the world, didn't you.' 'How else do you call an MDR that is postponed until the first of January 2029?' Mr Pip still did not feel he had done anything wrong. 'Well, let me show you your Certification Present.'

Again the room vanished and he was back in his office as he left it earlier that day. He could see himself leave and Jane kept working. While he was having a good time, she was still finishing documents. The street outside her office was dark and quiet, it was late. Then the phone rang. Jane listened for a few moments and then replied. 'No sorry, we are still certified under the MDD. I cannot convince Mr Pip he will lose his legacy status if he does not get his application filed with a notified body. He seems to think this can be done in six days instead of six months...' The person on the other side said something. Jane sounded surprised: 'Did it take you seven months...? We have just five months left now...' To the surprise of Mr Pip, she smiled. 'I don't think that matters. Our notified body wants to suspend our certificate and when I told him this was only for three months, he wasn't alarmed.'

Again he was back in his room. 'Did you hear what Jane said? Your legacy status is about to end. You have five months left and that is a very short time for all the things you still need to do. And that may not even be your only or most urgent problem. This is going to be tough, even with the help of Jane.' Mr Pip didn't say anything. He got the feeling there was something not going very well. 'I will now show you your Certification Future.'

This time he found himself standing outside in the sunshine. There was a sign announcing an auction of a company going bankrupt and he saw people leaving the building with furniture, tools, machinery, and other things you can get at such auctions. He wondered which company this was. Then he saw Jane leaving the building. She was carrying a picture. He knew that picture well. It had all the staff of CanKick Medical in front of the office at the 25th anniversary a few years ago. He could see she had been crying. He saw her put it in the back of a Volvo SUV. He remembered she had a small hatchback. This couldn't be hers. Just before she got behind the wheel, a man greeted Jane. 'Is that your new car, Jane?' 'Yes, Mr Vinci. All paid from your bonus, and there is still something left.' 'Well Jane, you deserve it. Without you, we wouldn't have access to the largest Single Market in the world and we would not be able to buy this plot here from your previous employer. Now we can expand.' Suddenly Mr Pip

realized he was standing in front of his own company. He also recognized who Jane was speaking with; the CEO of BRC, another medical devices manufacturer.

The rest of the night he slept well but when he woke up, he had the feeling there was something wrong. It was Christmas, so he prepared a proper breakfast. However, the unrest remained. He realized Jane had been supporting him all those years and maybe he should have recognized that earlier. He took a good bottle of wine from his cellar and went to Jane.

'Jane, I want to apologize. You have worked so hard all this time and I haven't appreciated that. I now realize I should have listened better to you. Please accept a small gift.'

Jane looked at the beautiful old burgundy, Romanee-Conti from 2004. He realized this was a very expensive bottle.

'Thank you, I appreciate that.' She put to bottle on the table, next to an open bottle of cheap rosé. Mr Pip felt his stomach cramp up.

'Now you are here, I have something to tell you. This is something I wanted to say on Friday, but you appeared to be in a hurry when you left.'

He hardly listened to her as he saw her mother approach the bottle with a very cheap corkscrew, one that ruins corks...

'I have decided to leave the company and with the normal notice time, all the overtime and unused vacation days, I will not come back. So this is it, goodbye.' She put out her hand.

Mr Pip took his eyes from the bottle under torture, he realized Jane had said something important. 'Ehrmm, sorry... can you repeat that?' He realized that for the first time, he was doing his best to listen to what his head of quality, regulatory and clinical affairs, main contact point for PMS and vigilance, and PRRC had to say.

'I quit... Now.' She said.

'But you can't do that! I need you.'

'I think I just did, and I finished all the work you asked me to do. The application form is still on your desk and all you have to do is to update the technical documentation to the MDR. And there is a message from the notified body that you have to reply to. Good luck. You can always hire a consultant if you need help. While you take care of all that, I will be doing training paid by my new employer, Mr Vinci from BRC, to become a Super PRRC. I already got the T-shirt...!' And indeed, she was proudly wearing a great T-shirt.

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