

Example Reflection
**“Crisis Management Simulation:
Before and After Educational
Supervisor Feedback”**



Version control

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Below are the reflections of a Trainee whom you supervise – she has experience in pharmacovigilance at a CRO and has recently joined your company as a safety physician within the central pharmacovigilance group. She is responsible for FEELFAB®. She wants to place this reflective commentary in her e-portfolio (under DSS 7 – ‘...capability to understand an issue and establish a crisis management team...’) and has asked for your feedback. What will you say to her?

1. What?

Describe a recent Learning Experience in your professional life.

Last Friday I got involved in a crisis management simulation run by an external company on behalf of the UK operating company. The scenario was that a group of four teenagers were supposed to have been taken to hospital after having shared a pack of one of their parent's FEELFAB® antidepressant tablets with a bottle of vodka. One of them had been admitted to ITU. There were a number of calls put through to medical information from people pretending to be journalists and MHRA staff and people rang me up for advice about five times during the day.

2. Why?

Analyse & interpret the events.

I think the UK Medical Director has organised the event to see if we were all prepared for something like this. The Medical Affairs Manager kept asking me about any interactions and previous reports of these events but there wasn't anything in the safety database so I wasn't much help. She obviously needed the information in a hurry. The Medical Director also sent me some press releases to review; it is obviously important to make sure that the company informs the media.

3. So What?

Consider overall meaning & application.

I've learnt that in a crisis it is difficult to understand what is going on; it was all a bit hectic and difficult to get any sense from anyone. I didn't know if the UK team had access to all the information sources and I did try to help them with that. It was all very unexpected and really got in the way of the work I was trying to get done so I missed the debrief at the end.

4. What next?

Implications for action.

If the UK company are organising something like this in the future, I think it would be a good idea to alert people in the other bits of the organisation so that they can plan better for it.



*As a result of your input, your trainee has revised her reflective commentary.
What feedback will you give her now?*

1. What?

Describe a recent Learning Experience in your professional life.

Last Friday I got involved in a crisis management simulation run by an external company on behalf of the UK operating company. The scenario was that a group of four teenagers were supposed to have been taken to hospital after having shared a pack of one of their parent's FEELFAB® antidepressant tablets with a bottle of vodka. One of them had been admitted to ITU. There were a number of calls put through to medical information from people pretending to be journalists and MHRA staff and people rang me up for advice about five times during the day.

2. Why?

Analyse & interpret the events.

I had a busy day arranged with several meetings to discuss the FEELFAB® PSUR which needed to be submitted on Monday so it was difficult to manage the extra workload resulting from the enquiries. I did manage to respond to all of the calls promptly – Carrie (our PV Administrator) picked up early on that something was going on and came to get me out of meetings which was really helpful. Neelam, the Medical Affairs Manager, rang several times to ask about interactions, particularly with alcohol and whether we had any previous reports of these events. She seemed to be under a lot of pressure from her Medical Director and rather flustered about what we should be reporting, so I did suggest that we should all refer to the relevant SOPs for guidance. There were no reports in the safety database but we were able to come up with a statement based on the pharmacological principles and one of the phase II studies which I found. I was managing to get the events processed in record time before the Medical Director rang me to tell me that it was a simulation and that we did not need to enter them in the database. I felt a bit let down by this because we had worked very hard. However he seemed pleased with the information I had come up with and sent me some press releases to review which was very interesting and not something I usually get to do. He invited me to the debrief at the end but I had to get the PSUR finished – I had to stay late but I got it done.

3. So What?

Consider overall meaning & application.

This was an unusual situation for me in a lot of ways. I am normally able to plan my days which I like and these events disrupted my plans, which I found I initially resented, although once I understood what was needed I quite enjoyed interacting on such an important matter with my colleagues in the operating company, and I think my input was

useful. I've read the report issued from the external company and have had another look at the central and local SOPs so I have a much better appreciation of what was happening and how the company's responses measured up. In fact we all did quite well and the ready availability of central PV staff was noted. The event has made me much better prepared for any future safety crisis, and I think I appreciate the difficulties and importance of prioritisation. I also now have some evidence to help satisfy curriculum Item DSS 7.

4. What next?

Implications for action.

As a result of this experience I hope I will be better able to deal with unexpected events in future. I intend to manage my diary so that I don't leave things to the last minute – if I had planned the meetings about the PSUR for earlier in the week I would not have been so stressed. I have also made some excellent contacts in the UK company – I have discovered that Neelam is planning to do the DPM next year too and we intend to do some revision together.