

How much reality is enough for students to learn?

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Introduction

Every pharmaceutical industry has to deliver an effective and safe drug product. Therefore, there are strict requirements for drug manufacturing with a quality control at its each stage. It means that all process operations during drug production are well-controlled and protocolled according to new norms that are frequently updated. In addition, there is quite often a rule that each subsequent operation during drug manufacturing cannot be initiated without approval the previous step by the selected authority. When pharmaceutical industry people hire new employees, they would like to get persons, who are at certain level familiar with new norms and requirements for drug manufacturing and who are able to easily implement that in practice.

However, a part of the current teaching material (drug production protocols) in the 2015 fall course ‘Drug production’ (‘Lægemiddelfremstilling’) (Bachelor level course, total amount of students is 190, duration of the course is 1 semester) has not been updated to the existing norms and requirements at the pharmaceutical industry nowadays.

The objective of the project was to find out how much reality in the teaching documents is enough for students to learn the subject. The aim was focused on clarifying the extent of the connection needed between the teaching material and the real life in order to assist in student becoming well-educated and at the same time career market-attractive. The overall goal was to prepare an updated version of the drug production protocol that could be used as a new teaching material in the future.

Implementation of the project

People at the pharmaceutical industries had been contacted to get help with the adaptation of educational documents before the implementation of the project. A part of the teaching material such as good manufacturing practice (GMP) documents for preparation of suppositories was rewritten in accordance with the suggestion from the industry experts. Two new versions were prepared: one was done in a way to be as close as possible to the real life (later on *fully-industrial* version) and another one (later on *semi-industrial* version) was an intermediate product between fully industrial version and existing one (later on old version). Two versions (the old one was part of the teaching material) were given to the students randomly in the middle of the course. However, students did not know which version they got. Three groups of the students per each version (in total 9 groups of 2 people) were selected. Six groups out of nine were asked to follow new instructions within their laboratory practice. The last three groups acted as control and used the old version during their lab work. At the end of the day, the feedback forms were given to the students to be filled out right away (one form for each student). The questionnaire covered the following two themes: (1) students' compliance with the document and (2) students' performance evaluation by themselves. Particularly, the students' opinion about the length, structure, relevance and understandability of the educational material was questioned. In addition, students were asked about their feeling & attitude if other course-mates had to evaluate their performance and, vice versa, if they had to assess work of other students. For instance, students could act as quality assurance personal by approving other students' work. All drug production protocols were written in Danish and students filled them in Danish. The feedback forms were constructed in English and students replied mostly in English. The feedback forms together with the filled drug production protocols were collected and analyzed.

Results

Compliance with the document

The students were most satisfied with the length, structure and details of the *semi-industrial* document. They liked the layout and the colors. The majority of the students found *fully-industrial* version too long and too structured.

The students pointed out that some questions/details could be omitted, because they are of minor importance. The pupils mentioned that the layout of the first page of the drug production protocol in both new versions is different from what they used that caused some confusion to them and would take for them some time to get used to. Some students replied that they would like to see more details and structure in the old version, whereas others were fine with the length and details of the existing document. One student mentioned that the teacher was very helpful when students were following the old version. In all three versions, there was missing the correct information about the cleaning of the production apparatus, because all versions of the drug production protocol refer to the standard operating procedure (SOP) that is out of date. Most students found it useful to write down all process parameters and have double check over them, because it prevented them from making any mistakes. In addition, it helped students to remember what to do and when to do. Although, students found it weird to have double check over some procedures such as 'Freitag skåle med afvetjet API og hjælpestoffer' and 'Noter støbetemperatur når udtapning' that *semi-industrial* and *fully-industrial* versions contain. Most of the students reported that it took around 10 minutes to fill in the old version. They filled the forms while doing the preparation of the suppositories. It took much longer time for students to complete the *fully-industrial* version. Most students, who used the *old* and *fully-industrial* versions, replied that they do not know if the drug production protocols are similar to the one used in the pharmaceutical industry, because they have never seen them. However, they pointed out that it would be misleading if the versions are not similar. The students, who filled in the *semi-industrial* version, were more positive about its similarity to the industrial. However, one student marked that it cannot be alike, because it is too simple and different.

Performance evaluation

All students had very positive attitude about other students evaluating their work (accepting or declining the drug production document), because they felt more secure about their work when other students had checked that. In addition, they found it as a good opportunity to discuss some unclear points before the final evaluation that will be performed by the responsible teacher. They found it useful to talk with each other, because both sides learn something by doing that. However, the pupils pointed out that they are absolutely fine when their course-mates check them as long as they know what they

are doing. In spite of that, some students replied that they would learn more if the teaching staff in the lab would check their drug production protocol, because the teachers are more professional and have more experience, so it is more comfortable when they do the job. In addition, the students pointed out that the teaching staff usually has more focus on their document. The rest students did not feel any difference, who accepts their work. One student stated that it will be time-consuming if the students would search/wait for the teacher to get the work approved. However, the scholars mentioned that students from both sides have to be kind to each other. In addition, the teaching staff has to be available if the students cannot find the solution. Most of the students said that they learn and understand more when they have to 'teach' others, because the students who act as teachers have to know exactly what they are doing. However, the students do not like to be the 'bad guys' by pointing out other students mistakes, because it creates discomfort situations.

By evaluating the new documents, filled by students, there were three types of mistakes present. The first one was related to the absent of the approving signature from the 'teaching' student that can be related to the fact that the students did not have to sign anything in the old document. The second mistake was due to students' carelessness and/or misunderstanding. Particularly, two groups mixed up the place, where to put the batch number for the used ingredients. However, forgetting the batch number is quite a common mistake regardless the type of the version. The last type of mistake was related to the protocolled parameters that were outside the established limits. For instance, the measured temperature was outside the allowed range. However, the students continued drug production, because they did not have instructions what to do if that happens. Definitely, this type of information has to be added to the new updated version.

Discussion

Nowadays group work is a common university teaching method. However, students' learning outcome greatly depends on the interpersonal group dynamics (Christensen, 2015). If people within a group are able to collaborate and communicate with each other, then the group work is a very positive, progressive pedagogical working method. When the communication within the students in the group does not work or they cannot divide their work efficiently, then it is difficult to overcome difficulties together and delivery

the work of good quality in the defined time frame. In this project, most negative answers about the compliance with the teaching material (any version) came in general from the students, which groups did not function very well. It was seen the most with the groups, who had to fill in the long *fully-industrial* version, which differ most from the existing one. The lack in communication could be due to the fact that groups were formed from the students that were being excluded or ended up in unfortunate position (Christensen, 2015). However, disability to allocate tasks between the group members could happened in the groups formed from friends, where all people have usually the same interests and are good in one thing and try to avoid the tasks outside their 'comfort zone'.

University education aims at delivering well-educated, independent and confident students, who are able for critical thinking. However, the *old* document requires the presence of teaching staff to be able to complete the task correctly. In that sense, updated versions allow students to work by themselves, because the documents are more structured and detailed.

The students were not familiar with the new versions beforehand. It took time for students (both who had to fill in and who had to check) to get used to them. This could be one of the reasons, why students would prefer teaching staff over other course-mates to check their work (especially, the *fully-industrial* version). Giving the new versions to the students before the lab might decrease students' discomfort. In addition, exchanging completely the existing materials for all labs with the new versions could easily have an effect on the students' opinion about their preferences (teacher or course-mate) for checking their documents.

Conclusions

Semi-industrial version was accepted most by the students, whereas the old version lacks some essential information and the full-industrial version seems to be too long and too detailed. The majority of students feel fine when they have to evaluate and 'teach' other students, because they learn and understand more by interacting with each other. The revised semi-industrial version was prepared that can be used as a future teaching material.

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